### **Patient details** Patient agreement to Patient's surname/family name: systemic anti-cancer therapy (SACT) Patient's first name(s): AIDA (All-transretinoic acid and Idarubicin) Date of birth: NHS number: (or other identifier) **Hospital/NHS Trust/NHS Board:** Special requirements: (eg other language/other communication method) Responsible consultant: Name: Job title: \_\_\_\_\_ Name of proposed course of treatment (include brief explanation if medical term not clear) AIDA - ATRA (All-transretinoic acid) or Tretinoin and Idarubicin chemotherapy for the treatment of acute promyelocytic leukaemia (APML). INDUCTION: ATRA taken orally on day 1 until haematologic complete response or for a maximum of 60 days. Idarubicin given intravenously on days 1,3, 5 & 7. 1st CONSOLIDATION: ATRA orally days 1-15. Idarubicin intravenously days 1-4. 2nd CONSOLIDATION: ATRA orally days 1-15. Mitoxantrone intravenously days 1-5. ☐ 3rd CONSOLIDATION: ATRA orally days 1-15. Idarubicin intravenously only day 1. Where will I have treatment? ☐ Outpatient ☐ Day unit/case Inpatient Other: Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy) ✓ Tick all relevant boxes ☐ I confirm the patient has capacity to give consent. ☐ I have explained the course of treatment and intended benefit to the patient. **The intended benefits** (there are no guarantees about outcome) Prolong survival. Control symptoms, reduce transfusion needs and improve quality of life. Induction – therapy given in the acute state of the disease, aiming to shrink the tumour. Curative – to give you the best possible chance of being cured.

Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control

Disease control / Palliative – the aim is not to cure but to control the disease and reduce the

symptoms. The aim is to improve both quality and quantity of life.

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Prepared by Pharmacist: Alia Nizam
Checked by Pharmacist: Elizabeth Davies
Checked by Consultant: Eleni Tholouli

the symptoms.

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Patient identifier/label

| You may have one or more of the side effect                                     | ts listed  |
|---|--|
| Common side effects:  | Occasional side effects continued:   |
| Affecting more than 10 in every 100 (>10%) people                               | temperature, shortness of breath, rapid  |
| ☐ An increased risk of getting an infection from a                              | breathing, build up of fluid with weight gain. You   |
| drop in white blood cells – this makes it harder                                | may be treated with steroids and tretinoin   |
| to fight infections and you can become very ill.                                | withheld or discontinued.  |
| If you have a severe infection this can be                                      | Other ricker   |
| life-threatening. Contact your doctor or  | Other risks:   |
| hospital straight away if:  | Idarubicin may leak out of the vein while it is  |
| your temperature goes over 37.5°C or  | being given (extravasation) and can damage   |
| over 38°C, depending on the advice given  | the tissue around the vein. Tell the nurse straight away if you have any stinging, pain,                                 |
| by your chemotherapy team   | redness or swelling around the vein. It's  |
| you suddenly feel unwell (even with a     normal temporature)                   | uncommon but important to deal with quickly.   |
| normal temperature)  Thinning of the hair or hair loss, nausea (feeling         | Increased risk of tumour lysis syndrome in some  |
| sick), vomiting (being sick), dry nose, dry                                     | patients (when treatment destroys cancer cells   |
| mouth, reduced appetite, sore mouth and   | too quickly for the kidneys to cope and leads to   |
| ulcers, abdominal (tummy pain), diarrhoea,                                      | changes in blood tests). Rarely, dialysis may be   |
| constipation, feeling tired and weak (fatigue).                                 | needed. You may be prescribed medicines for  |
| ☐ Vision and hearing problems including hearing                                 | prevention/ treatment.   |
| loss, headaches, dizziness, rash, itching, pins                                 | ☐ Before treatment you may have blood tests to   |
| and needles in hands and feet, chills, red colour                               | check for viruses (Hepatitis B or C, HIV, or   |
| urine (resolves 1-2 days after).  | unusual infections). Treatment may weaken  |
| Fast heart rate, breathlessness or breathing                                    | your natural defence (immune) system so  |
| changes, pain (chest, bone), increased  | infections like this may worsen or become  |
| sweating, flushing, mood changes, feeling                                       | active if you've had them before. You may have   |
| anxious, sad and confused, difficulty sleeping                                  | medicines to prevent or treat infection.  Growth factors (GCSF) will be prescribed to                                    |
| (insomnia), weight loss.  | maintain number of white cells to prevent  |
| Anaemia (low red blood cells), bruising or                                      | infection. You may experience bone pain,   |
| bleeding (low platelets); this may be prolonged and you may need a transfusion. | headaches, red and itchy skin around the   |
| Raised cholesterol and fat (triglycerides) levels,                              | injection site.  |
| changes in liver, kidney function (monitored),                                  | Late effects include a rare chance of a second   |
| inflammation of lips, pancreas.   | cancer (years later) and problems with your  |
| ☐ Tretinoin (ATRA) can cause increase pressure                                  | heart (months later).  |
| in the head. Symptoms may include double or                                     | ☐ Side effects of anti-sickness medication include   |
| loss of vision, feeling or being sick, dizziness,                               | diarrhoea, constipation, headaches.  |
| headaches, ringing in your ears and altered                                     | Changes in your memory, concentration or   |
| consciousness. Please contact your doctor or                                    | ability to think clearly. There can be many  |
| nurse.  | causes including your treatment, diagnosis or  |
| Occasional side effects:  | both.  |
| Affecting between 1-10 in every 100 (1-10%) people                              | <ul> <li>Cancer and its treatment can increase your risk<br/>of developing a blood clot (thrombosis), causing</li> </ul> |
| Heart problems (changes in the way the heart                                    | pain, redness and swelling in an arm or leg,   |
| works with fluid build-up, shortness of breath,                                 | breathlessness, chest pain. Tell your doctor   |
| risk of a heart attack), changes in heart rates                                 | straight away if you have any symptoms.  |
| (low or high). You may need an ECG  | Some anti-cancer medicines can damage  |
| (electrocardiogram).  | ovaries and sperm. This may lead to infertility  |
| Pain, redness, inflammation at the site of                                      | and/or early menopause (hot flushes, vaginal   |
| injection.  | dryness).  |
| Bleeding from the gut.  |  |
| Tretinoin (ATRA) can cause differentiation                                      | O continuo de di   |
| syndrome in the first month of treatment which                                  | Continue on to the next page   |
| can be life-threatening. Symptoms include:                                      |  |

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Patient identifier/label

### Other risks continued:

Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for up to 7 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse.

Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

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| Any other risks and information:   |  |
|--|--|
|  |  |
| ☐ I have discussed the intended benefit and risks available alternative treatments (including no treatments)   | <del>-</del>   |
| ☐ I have discussed the side effects of the recomm straight away or in the future, and that there may be rare or have not yet been reported. Each patient may           | e some side effects not listed because they are          |
| ☐ I have discussed what the treatment is likely to i timing of the treatment, blood and any additional test  | ,  |
| ☐ I have explained to the patient, that they have the should contact the responsible consultant or team if   | ·  |
| ☐ I have discussed concerns of particular importar   | nce to the patient in regard to treatment                |
| (please write details here):   |  |
| The following written information has been provided:  Information leaflet for Tretinoin (ATRA), Idarubicin and Mitoxantrone  24 hour alert card or SACT advice service | Health professional details: Signed: Date: Name (PRINT): |
| contact details  |  |
| SACT treatment record (cruk.org/treatment-record)  | Job title:   |
| Other, please state:   |  |
|  |  |
| Statement of interpreter (where a Interpreter booking reference (if applicable): I have interpreted the information above to the patient believe they can understand.  |  |
| Signed:  | Date:  |
| Name (PRINT):  | Job title:   |

### Statement of patient

Patient identifier/label

| your own copy of the form which describes the be   | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form.  |
|--|---|
| ☐ I have had enough time to consider my optio  | ns and make a decision about treatment.   |
| ☐ I agree to the course of treatment described   | on this form.   |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo   | ole to sign but has indicated their consent. A person with bung people under the age of 16 years.   |
| Patient's signature:   |   |
| Name (PRINT):  | Date:   |
| Person with parental responsibility/witness' signa   | ature:  |
| Name (PRINT):  | Date:   |
| (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)  On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of | patients Contact details (if patient wishes to discuss options later):  Contact your hospital team if you have any  |
| treatment/procedures to go ahead. Signed:  | questions about cancer and its treatment.   |
| Date:  | Cancer Research UK can also help answer your questions about cancer and treatment. If you   |
| Name (PRINT):  | want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to   |
| Job title:   | Friday, 9am to 5pm. Alternatively visit cruk.org for  |
| Important notes: (tick if applicable)  See also advance decision to refuse treatment  Patient has withdrawn consent (ask patient to sign and date here)  | more information.  These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.  The project is supported by |
| Signed: Date:  | Cancer Research UK.  This does not mean you are taking part in a clinical trial.  |

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### **Guidance for health professionals**

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

#### What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

#### The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

### Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

### When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- · retain that information in their mind
- use or weigh this information as a part of their decision making process, or

 communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

#### Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

### **NHS Scotland**

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

#### References

- 1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
- Cancer Research UK: cruk.org/aboutcancer/treatment/drugs
- Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

| Patient agreement to systemic anti-cancer therapy (SACT)   | Patient details Patient's surname/family name:  Patient's first name(s):  |
|--|---|
| ATRA (All-transretinoic acid)  | Date of birth:  |
|  | NHS number: (or other identifier)   |
| Hospital/NHS Trust/NHS Board:  | Special requirements: (eg other language/other communication method)  |
| Responsible consultant: Name:  |   |
| Job title:   |   |
| promyelocytic leukaemia (APML).  Tretinoin (ATRA) is taken orally twice each day for the continue of the conti | ation with chemotherapy for the treatment of acute or up to 1 week until diagnosis of APML is confirmed. with ATRA and add in chemotherapy. complete response or for a maximum of 60 days. A py.  |
| Statement of health professio  (to be filled in by health professional with appropriate the hospital/Trust/NHS board's consent policy)  Tick all relevant boxes  I confirm the patient has capacity to give consent  I have explained the course of treatment and interest to the intended benefits (there are no guarantees Prolong survival.  Control symptoms, reduce transfusion needs and Induction – therapy given in the acute state of the   | e knowledge of proposed procedure, as specified in a specified in |
| <ul><li>Curative – to give you the best possible chance of</li><li>Maintenance – therapy given on continuing basis the symptoms</li></ul>  | of being cured.  is, aiming to prevent disease flaring up and to control  |

Disease control / Palliative – the aim is not to cure but to control the disease and reduce the

symptoms. The aim is to improve both quality and quantity of life.

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Patient identifier/label

## You may have one or more of the side effects listed Common side effects:

| Affecting more than 10 in every 100 (>10%) people  An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.                                      | Other risks:  Increased risk of tumour lysis syndrome in some patients (when treatment destroys cancer cells too quickly for the kidneys to cope and leads to   |
|--|---|
| If you have a severe infection this can be<br>life- threatening. Contact your doctor or<br>hospital straight away if:  | changes in blood tests). Rarely, dialysis may be needed. You may be prescribed medicines for prevention/ treatment.   |
| <ul> <li>your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team</li> <li>you suddenly feel unwell (even with a normal temperature)</li> </ul>   | Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have                            |
| Thinning of the hair or hair loss, nausea (feeling sick), vomiting (being sick), dry nose, dry mouth, reduced appetite, abdominal (tummy pain), diarrhoea, constipation, feeling tired and weak (fatigue).                                 | <ul> <li>medicines to prevent or treat infection.</li> <li>Side effects of anti-sickness medication include diarrhoea, constipation, headaches.</li> <li>Changes in your memory, concentration or</li> </ul>  |
| <ul> <li>Vision and hearing problems including hearing loss, headaches, dizziness, rash, itching, pins and needles in hands and feet.</li> </ul>   | ability to think clearly. There can be many causes including your treatment, diagnosis, or both.  |
| Fast heart rate, breathlessness or breathing changes, pain (chest, bone), increased sweating, flushing, mood changes, feeling anxious, sad, confused, difficulty sleeping (insomnia).  | Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.  |
| Raised cholesterol and fat (triglycerides) levels, changes in liver and kidney function (monitored), inflammation of lips, inflammation of the pancreas.   | Some anti-cancer medicines can damage<br>ovaries and sperm. This may lead to infertility<br>and/or early menopause (hot flushes, vaginal<br>dryness).   |
| Tretinoin (ATRA) can cause increase pressure in the head. Symptoms may include double or loss of vision, feeling or being sick, dizziness, headaches, ringing in your ears and altered consciousness. Please contact your doctor or nurse. | Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for at least 1 month after Tretinoin. May be longer depending on the chemotherapy.                                       |
| Occasional side effects:   | Women of child bearing age will be tested for   |
| Affecting between 1-10 in every 100 (1-10%) people  Tretinoin (ATRA) can cause differentiation syndrome in the first month of treatment which  | pregnancy before and during treatment. Use effective contraception throughout. You can talk to your doctor or nurse about this.   |
| can be life-threatening. Symptoms include temperature, shortness of breath, rapid breathing, build up of fluid with weight gain. You may be treated with steroids and tretinoin withheld or discontinued.                                  | Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening. |

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| the recommended treatment, and of any nt).  |
|---|
| ded treatment, which could affect the patient ome side effects not listed because they are experience side effects differently. |
| olve (including inpatient/outpatient treatment, follow-up appointments etc) and location.                                       |
| right to stop this treatment at any time and ey wish to do so.  |
| e to the patient in regard to treatment   |
| bliant (please tick):<br>document reason here:  |
| Health professional details: Signed: Date:  |
| Name (PRINT):   |
| Job title:  |
|   |
| propriate)  |
| o the best of my ability and in a way in which l  |
| to the best of my ability and in a way in which l   |
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### Statement of patient

Patient identifier/label

| your own copy of the form which describes the be   | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form.  |
|--|---|
| ☐ I have had enough time to consider my optio  | ns and make a decision about treatment.   |
| ☐ I agree to the course of treatment described   | on this form.   |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo   | ole to sign but has indicated their consent. A person with bung people under the age of 16 years.   |
| Patient's signature:   |   |
| Name (PRINT):  | Date:   |
| Person with parental responsibility/witness' signa   | ature:  |
| Name (PRINT):  | Date:   |
| (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)  On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of | patients Contact details (if patient wishes to discuss options later):  Contact your hospital team if you have any  |
| treatment/procedures to go ahead. Signed:  | questions about cancer and its treatment.   |
| Date:  | Cancer Research UK can also help answer your questions about cancer and treatment. If you   |
| Name (PRINT):  | want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to   |
| Job title:   | Friday, 9am to 5pm. Alternatively visit cruk.org for  |
| Important notes: (tick if applicable)  See also advance decision to refuse treatment  Patient has withdrawn consent (ask patient to sign and date here)  | more information.  These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.  The project is supported by |
| Signed: Date:  | The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.   |

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### **Guidance for health professionals**

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

#### What a consent form is for

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- retain that information in their mind
- use or weigh this information as a part of their decision making process, or

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#### References

- Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
- Cancer Research UK: cruk.org/aboutcancer/treatment/drugs
- Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

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ATRA (All-transretinoic acid)

| Patient agreement to systemic anti-cancer therapy   | Patient details Patient's surname/family name: Patient's first name(s):  |  |
|---|--|--|
| (SACT)  ATRA (All-transretinoic   |  |  |
| acid) - ATO (Arsenic<br>trioxide)   | Date of birth:   |  |
|   | NHS number:(or other identifier)   |  |
| Hospital/NHS Trust/NHS Board:   | Special requirements: (eg other language/other communication method)   |  |
| Responsible consultant: Name:   |  |  |
| Job title:  |  |  |
| week only (usually Mondays and Thursdays) for 1 cy CONSOLIDATION (with ATRA): Weeks 1 and 2: treatment. Repeat every 28 days for 7 cycles. This is CONSOLIDATION (with ATO): Week 1: ATO intr   | n days 1 to 5. Weeks 2 - 8: ATO intravenously twice a vcle.  ATRA orally twice each day. Week 3 & 4: No s given together with ATO (see below). |  |
| Statement of health profession (to be filled in by health professional with appropriate the hospital/Trust/NHS board's consent policy)  ☑ Tick all relevant boxes ☐ I confirm the patient has capacity to give consent  | e knowledge of proposed procedure, as specified in   |  |
| ☐ I have explained the course of treatment and into <b>The intended benefits</b> (there are no guarantees   | ended benefit to the patient.  |  |
| <ul> <li>□ Prolong survival.</li> <li>□ Control symptoms, reduce transfusion needs an</li> <li>□ Induction – therapy given in the acute state of th</li> <li>□ Curative – to give you the best possible chance</li> <li>□ Maintenance – therapy given on continuing basis the symptoms.</li> <li>□ Disease control / Palliative – the aim is not to cu</li> </ul> | ne disease, aiming to shrink the tumour of being cured. s, aiming to prevent disease flaring up and to control                                 |  |

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symptoms. The aim is to improve both quality and quantity of life

Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version ATRA (All-transretinoic acid) - ATO (Arsenic trioxide)

Patient identifier/label

| You may have one or more of the side effect  | ts listed   |
|--|---|
| Common side effects:   | Occasional side effects:  |
| Affecting more than 10 in every 100 (>10%) people  An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.  If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:  • your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team  • you suddenly feel unwell (even with a normal temperature)  | Affecting between 1-10 in every 100 (1-10%) people  Low blood pressure, anaemia (low red blood cells) and bruising or bleeding (low platelets). This can be prolonged and you may need a transfusion.  Build-up of fluid between the heart and lungs, seizures, swelling in the face, blurry vision.  Inflammation of the blood vessels (vasculitis). This can affect different parts of the body causing weight loss, temperature, muscle and joint pains, feeling tired and general illness.  |
| <ul> <li>□ Thinning of the hair or hair loss, nausea (feeling sick), vomiting (being sick), dry nose, dry mouth, reduced appetite, abdominal (tummy pain), diarrhoea, constipation, feeling tired and weak (fatigue).</li> <li>□ Vision and hearing changes including hearing loss, headaches, dizziness, rash, itching, pins and needles in hands and feet.</li> <li>□ Fast heart rate, breathlessness or breathing changes, shortness of breath, pain (muscle, chest, bone), increased sweating, flushing, mood changes, feeling anxious, sad, confused, difficulty sleeping (insomnia).</li> <li>□ Raised cholesterol and fat (triglycerides) levels, low potassium, low magnesium, changes in liver, kidney function (monitored), inflammation of lips, inflammation of the pancreas.</li> <li>□ Arsenic can raise your blood sugar. This usually goes back to normal after treatment. If you have diabetes, it may lead to higher blood sugar levels. Please ask your doctor/nurse/GP if concerned.</li> <li>□ Tretinoin (ATRA) can cause increase pressure in the head. Symptoms may include double or loss of vision, feeling or being sick, dizziness, headaches, ringing in your ears and altered consciousness. Please contact your doctor or nurse.</li> <li>□ This treatment can cause differentiation syndrome in the first month which can be lifethreatening. Symptoms include temperature, shortness of breath, rapid breathing, build up of fluid with weight gain. You may be treated with steroids and treatment withheld or discontinued.</li> </ul> | Other risks:  Arsenic may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly.  Increased risk of tumour lysis syndrome in some patients (when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests). Rarely, dialysis may be needed. You may be prescribed medicines for prevention/ treatment.  Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.  Side effects of anti-sickness medication include diarrhoea, constipation, headaches.  Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.  Late effects include a rare chance of a second cancer (years later) and problems with your heart.  Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site. |
|  | Continue to the next page   |

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Lisa Yuen Checked by Consultant: Eleni Tholouli Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version ATRA (All-transretinoic acid) - ATO (Arsenic trioxide)

Patient identifier/label

# Statement of health professional

### Other risks continued:

| Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.  |
|---|
| Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).  |
| Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for at least 6 months. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception. You can talk to your doctor or nurse about this |
| Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.   |

| Patient  | idon | tifior/ | lahal |
|----------|------|---------|-------|
| rallelli | luei | luner/  | labei |

| Any other risks and information:  |  |  |
|---|--|--|
|   |  |  |
| ☐ I have discussed the intended benefit and risks of available alternative treatments (including no treatments)   |  |  |
| ☐ I have discussed the side effects of the recomme straight away or in the future, and that there may be rare or have not yet been reported. Each patient may   | some side effects not listed because they are            |  |
| $\hfill \square$ I have discussed what the treatment is likely to in timing of the treatment, blood and any additional test   | ` • • • • • • • • • • • • • • • • • • •                  |  |
| ☐ I have explained to the patient, that they have the should contact the responsible consultant or team if t  | •  |  |
| ☐ I have discussed concerns of particular important   | ce to the patient in regard to treatment                 |  |
| (please write details here):  |  |  |
| Clinical management guideline/Protocol com  Yes No Not available If No please  The following written information has been provided: Information leaflet for ATRA (All-transretinoic acid) - ATO (Arsenic trioxide)  24 hour alert card or SACT advice service contact details | Health professional details: Signed: Date: Name (PRINT): |  |
| SACT treatment record (cruk.org/treatment-record)   | Job title:   |  |
| Other, please state:  |  |  |
| Statement of interpreter (where ap Interpreter booking reference (if applicable): I have interpreted the information above to the patient believe they can understand.  |  |  |
| Signed:   | Date:  |  |
|   | Date:  |  |

### Statement of patient

Patient identifier/label

| your own copy of the form which describes the be   | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form.               |
|--|--|
| ☐ I have had enough time to consider my optio  | ns and make a decision about treatment.  |
| ☐ I agree to the course of treatment described   | on this form.  |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo   | ole to sign but has indicated their consent. A person with bung people under the age of 16 years.  |
| Patient's signature:   |  |
| Name (PRINT):  | Date:  |
| Person with parental responsibility/witness' signa   | ature:   |
|  | Date:  |
| (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)  On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of | patients Contact details (if patient wishes to discuss options later):  Contact your hospital team if you have any   |
| treatment/procedures to go ahead. Signed:  | questions about cancer and its treatment.  Cancer Research UK can also help answer your questions about cancer and treatment. If you   |
| Date:  |  |
| Name (PRINT):  | want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to  |
| Job title:   | Friday, 9am to 5pm. Alternatively visit cruk.org for   |
| Important notes: (tick if applicable)  See also advance decision to refuse treatment  Patient has withdrawn consent (ask patient to sign and date here)  | more information.  These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT. |
| Signed: Date:  | The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.  |

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### **Guidance for health professionals**

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

#### What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

#### The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

### Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

### When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or

 communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

#### Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

### **NHS Scotland**

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

#### References

- Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
- Cancer Research UK: cruk.org/aboutcancer/treatment/drugs
- Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

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| Patient agreement to systemic anti-cancer therapy (SACT)   | Patient details Patient's surname/family name:  |
|--|---|
| Azacitidine  | Patient's first name(s):  |
|  | Date of birth:  |
|  | NHS number:(or other identifier)  |
| Hospital/NHS Trust/NHS Board:  | Special requirements: (eg other language/other communication method)                                    |
| Responsible consultant: Name:  |   |
| Job title:   |   |
| OR Chronic Myelomonocytic Leukaemia (CMML).  Azacitidine given subcutaneously on days 1 to 7* appropriate). OR  AML maintenance only: Azacitidine taken orally o rest period). If required, this may be extended to once period). Your doctor will tell you if this is the case.  Each treatment cycle lasts for 28 days. Treatment unacceptable side effects.  Where will I have treatment?  Outpatient Day unit/case Inpatient | nce each day on days 1 to 14 (followed by a 14 day e each day on days 1 to 21 (followed by a 7 day rest |
| Statement of health profession (to be filled in by health professional with appropriate the hospital/Trust/NHS board's consent policy)  Tick all relevant boxes  I confirm the patient has capacity to give consent  | knowledge of proposed procedure, as specified in  |
| I have explained the course of treatment and inte  The intended benefits (there are no guarantees a  | •   |
| <ul> <li>□ Prolong survival.</li> <li>□ Control symptoms, reduce transfusion needs and</li> <li>□ Induction – therapy given in the acute stage of the</li> <li>□ Curative – to give you the best possible chance o</li> <li>□ Maintenance – therapy on a continuous basis, to</li> <li>□ Disease control/palliative – aim is not to cure, but</li> </ul>   | e disease, aiming to shrink the tumour.<br>If being cured.  |

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and survival.

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Patient identifier/label

| You may have one or more of the side effects listed  |   |  |  |
|--|---|--|--|
| Common side effects:   | Other risks:  |  |  |
| Affecting more than 10 in every 100 (>10%) people  An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.      | There may be increased risk of tumour lysis syndrome in some patients. This occurs when the treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in the blood tests. Parely, dislusis may be peeded   |  |  |
| <ul> <li>If you have a severe infection this can be<br/>life-threatening. Contact your doctor or<br/>hospital straight away if:</li> </ul>   | the blood tests. Rarely, dialysis may be needed. High risk patients will be prescribed medicines for prevention.  Before treatment you may have blood tests to  |  |  |
| <ul> <li>your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team</li> <li>you suddenly feel unwell (even with a normal temperature)</li> </ul>             | check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have   |  |  |
| <ul><li>Nausea (feeling sick) and vomiting (being sick).</li><li>Abdominal (tummy) pain, diarrhoea or constipation.</li></ul>  | medicines to prevent or treat infection.  Late effects include problems with your heart (risk is higher in patients with a history of heart   |  |  |
| Appetite loss, weight loss.  | problems).  |  |  |
| Fatigue (feeling tired).   | Potential side effects with the anti-sickness   |  |  |
| If you are having Azacitidine by subcutaneous  | medication may include: constipation, diarrhoea, headaches.   |  |  |
| injection, you may notice pain, redness, itching, bruising and swelling where the injection is given.  | Cancer and treatment for cancer can increase your risk of developing a blood clot (thrombosis). A blood clot may cause pain,  |  |  |
| Anaemia (low number of red blood cells) and<br>bruising or bleeding caused by low number of<br>platelets. This can be prolonged and you may<br>need a transfusion.   | redness and swelling in a leg or arm, or breathlessness and chest pain. Tell your doctor straight away if you have these symptoms  You may notice changes in your memory,   |  |  |
| ☐ Shortness of breath, chest pain.   | concentration, or your ability to think clearly.  There can be many causes of this, including   |  |  |
| Difficulty sleeping (insomnia), headaches, dizziness.  | your treatment, diagnosis, or both.  Some anti-cancer medicines can damage  |  |  |
| ☐ Itching, rash.   | ovaries and sperm. This may lead to infertility   |  |  |
| Pain in the muscles and joints.  | and/or early menopause. Early menopause may cause symptoms of hot flushes and   |  |  |
| Occasional side effects:   | vaginal dryness.  |  |  |
| Affecting between 1-10 in every 100 (1-10%) people  Thinning of the hair or hair loss.  Feeling generally unwell.  Drowsiness.  Oral fungal infection (white coating inside your mouth).  Blood shot eyes. | Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for at least 6 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective |  |  |
| <ul> <li>Sore mouth and ulcers, bleeding gums.</li> <li>Indigestion.</li> <li>Blood in the urine.</li> <li>Changes in kidney function (picked up in blood tosts)</li> </ul>                                | contraception. You can talk to your doctor or nurse about this.  Complications of treatment can very occasionally be life-threatening and may result  |  |  |
| tests.  High blood pressure.   | in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.   |  |  |

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| Patient | identif | ier/la | hel |
|---------|---------|--------|-----|
| 1 aucit | IUCITUI | 101/10 |     |

| Any other risks and information:   | <u></u>   |
|--|---|
|  |   |
| ☐ I have discussed the intended benefit and risks of available alternative treatments (including no treatments)  |   |
| ☐ I have discussed the side effects of the recommendation of the straight away or in the future, and that there may be rare or have not yet been reported. Each patient may  | some side effects not listed because they are   |
| ☐ I have discussed what the treatment is likely to it timing of the treatment, blood and any additional test   | · • • • • • • • • • • • • • • • • • • •   |
| ☐ I have explained to the patient, that they have the should contact the responsible consultant or team if   | ·   |
| ☐ I have discussed concerns of particular importar   | nce to the patient in regard to treatment   |
| (please write details here):   |   |
| Clinical management guideline/Protocol cor  Yes No Not available If No pleas  The following written information has been provided:  Information leaflet for Azacitidine  24 hour alert card or SACT advice service | mpliant (please tick): se document reason here:  Health professional details: Signed: Date: Name (PRINT): |
| contact details  SACT treatment record (cruk.org/treatment-  |   |
| record)  | Job title:  |
| Other, please state:   |   |
| Statement of interpreter (where a Interpreter booking reference (if applicable): I have interpreted the information above to the patier believe they can understand.   | nt to the best of my ability and in a way in which I  |
| Signed:  | Date:   |
| Name (PRINT):  | Job title:  |

### Statement of patient

Patient identifier/label

| your own copy of the form which describes the be  | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form.               |
|---|--|
| ☐ I have had enough time to consider my optio   | ns and make a decision about treatment.  |
| ☐ I agree to the course of treatment described  | on this form.  |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo  | ole to sign but has indicated their consent. A person with bung people under the age of 16 years.  |
| Patient's signature:  |  |
| Name (PRINT):   | Date:  |
| Person with parental responsibility/witness' signa  | iture:   |
| Name (PRINT):   | Date:  |
| Confirmation of consent (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance) On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of | Further information for patients Contact details (if patient wishes to discuss options later):  Contact your hospital team if you have any   |
| treatment/procedures to go ahead.   | questions about cancer and its treatment.  |
| Signed: Date:   | Cancer Research UK can also help answer your questions about cancer and treatment. If you  |
| Name (PRINT):   | want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to  |
| Job title:  | Friday, 9am to 5pm. Alternatively visit cruk.org for   |
| Important notes: (tick if applicable)  ☐ See also advance decision to refuse treatment  ☐ Patient has withdrawn consent (ask patient to sign and date here)   | more information.  These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT. |
| Signed:  Date:  | The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.  |

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### **Guidance for health professionals**

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

#### What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

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### Who can give consent

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### When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- · retain that information in their mind
- use or weigh this information as a part of their decision making process, or

 communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

#### Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

### **NHS Scotland**

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

#### References

- Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
- Cancer Research UK: cruk.org/aboutcancer/treatment/drugs
- Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

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| Patient agreement to systemic anti-cancer therapy (SACT)  | Patient details Patient's surname/family name:  |
|---|---|
| Azacitidine + Venetoclax  | Patient's first name(s):  |
|   | Date of birth:  |
|   | NHS number: (or other identifier)   |
| Hospital/NHS Trust/NHS Board:   | Special requirements: (eg other language/other communication method)  |
| Responsible consultant: Name: Job title:  |   |
| Name of proposed course of treatment (inclination   Azacitidine and venetoclax chemotherapy for the   Cycle 1: Azacitidine is given subcutaneously on dissubcutaneously on days 1 to 7 every 28 days* (*dele days 1-28.   Cycle 2: Azacitidine is given subcutaneously on dissubcutaneously on days 1 to 7 every 28 days* (*dele days 1-28. Your doctor will adjust the number of days   Treatment is continued until disease progression   Where will I have treatment?   Outpatient   Day unit/case   Inpatient | treatment of acute myeloid leukaemia (AML). days 1 to 5 and 8 and 9 every 28 days* OR given te as appropriate). Venetoclax is taken orally from days 1 to 5 and 8 and 9 every 28 days* OR given te as appropriate). Venetoclax is taken orally from s, depending on your blood results. |
| Statement of health profession (to be filled in by health professional with appropriate the hospital/Trust/NHS board's consent policy)  ✓ Tick all relevant boxes  ☐ I confirm the patient has capacity to give consent ☐ I have explained the course of treatment and inte  The intended benefits (there are no guarantees ☐ Prolong survival. ☐ Control symptoms, reduce transfusion needs and ☐ Induction – therapy given in the acute state of the ☐ Curative – to give you the best possible chance of       | t. ended benefit to the patient. about outcome) d improve quality of life. en disease, aiming to shrink the tumour.   |

Disease control / Palliative – the aim is not to cure but to control the disease and reduce the

symptoms. The aim is to improve both quality and quantity of life.

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Elizabeth Davies Checked by Consultant: Eleni Tholouli

the symptoms.

Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version **Azacitidine + Venetoclax** 

Patient identifier/label

| You may have one or more of the side effects listed   |  |  |  |
|---|--|--|--|
| Common side effects:  | Occasional side effects continued:   |  |  |
| Affecting more than 10 in every 100 (>10%) people  An increased risk of getting an infection from a   | Oral fungal infection (white coating inside your<br>mouth), bleeding gums.   |  |  |
| drop in white blood cells – this makes it harder to fight infections and you can become very ill.   | Other risks:   |  |  |
| <ul> <li>☐ If you have a severe infection this can be lifethreatening. Contact your doctor or hospital straight away if:         <ul> <li>your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team</li> <li>you suddenly feel unwell (even with a normal temperature)</li> </ul> </li> <li>☐ Nausea (feeling sick), vomiting (being sick), abdominal (tummy) pain, diarrhoea or constipation, lack of appetite, weight loss, sore mouth and ulcers,</li> <li>☐ Fatigue (feeling tired), difficulty sleeping (insomnia), headaches, dizziness, feeling drowsy.</li> <li>☐ Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets). This can be prolonged and you may need a transfusion.</li> <li>☐ Low potassium, changes in liver function (monitored).</li> <li>☐ Low blood pressure.</li> <li>☐ Itching, rash.</li> <li>☐ Shortness of breath, chest pain.</li> <li>☐ Pain in the muscle and joints.</li> <li>☐ If you are having Azacitidine by subcutaneous injection, you may notice pain, redness, itching, bruising and swelling where the injection is given.</li> </ul> | <ul> <li>□ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.</li> <li>□ Side effects of anti-sickness medication include diarrhoea, constipation, headaches.</li> <li>□ Late effects include problems with your heart (risk is higher in patients with a history of heart problems).</li> <li>□ Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.</li> <li>□ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.</li> <li>□ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.</li> <li>□ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal</li> </ul> |  |  |
|   | dryness).  |  |  |
| Occasional side effects:  Affecting between 1-10 in every 100 (1-10%) people  There may be increased risk of tumour lysis syndrome in some patients. This occurs when the treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in the blood tests. Rarely, dialysis may be needed. High risk patients will be prescribed medicines for prevention.  Thinning of the hair or hair loss, feeling generally unwell, blood shot eyes, indigestion, high blood pressure.  Changes in kidney function (monitored), development of gall stones, inflammation of the gall bladder, blood in the urine.  | <ul> <li>Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for at least 6 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception. You can talk to your doctor or nurse about this</li> <li>Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.</li> </ul>  |  |  |

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| Patient identifier/label |  |
|--------------------------|--|
|                          |  |
| Patient inentitier/lanel |  |

| Any other risks and information:   |  |  |
|--|--|--|
|  |  |  |
| ☐ I have discussed the intended benefit and risks of available alternative treatments (including no treatments)  | · · · · · · · · · · · · · · · · · · ·  |  |
| ☐ I have discussed the side effects of the recomme<br>straight away or in the future, and that there may be<br>rare or have not yet been reported. Each patient ma   | some side effects not listed because they are                                |  |
| ☐ I have discussed what the treatment is likely to in timing of the treatment, blood and any additional test   | , •  |  |
| ☐ I have explained to the patient, that they have th should contact the responsible consultant or team if  | •  |  |
| ☐ I have discussed concerns of particular importan   | ce to the patient in regard to treatment                                     |  |
| (please write details here):   |  |  |
| Clinical management guideline/Protocol cor  Yes No Not available If No pleas  The following written information has  | mpliant (please tick): e document reason here:  Health professional details: |  |
| been provided:   | Signed:  |  |
| ☐ Information leaflet for Azacitidine and Venetoclax   | Date:  |  |
| ☐ 24 hour alert card or SACT advice service contact details  | Name (PRINT):  |  |
| ☐ SACT treatment record (cruk.org/treatment-record)  | Job title:   |  |
| Other, please state:   |  |  |
| Statement of interpreter (where a Interpreter booking reference (if applicable): I have interpreted the information above to the patier believe they can understand. |  |  |
| Signed:  | Date:  |  |
| Name (PRINT):  | Job title:   |  |

### Statement of patient

Patient identifier/label

| your own copy of the form which describes the be   | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form. |
|--|--|
| ☐ I have had enough time to consider my optio  | ns and make a decision about treatment.  |
| ☐ I agree to the course of treatment described   | on this form.  |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo   | ole to sign but has indicated their consent. A person with bung people under the age of 16 years.  |
| Patient's signature:   |  |
| Name (PRINT):  | Date:  |
| Person with parental responsibility/witness' signa   | ature:   |
| Name (PRINT):  | Date:  |
| (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)  On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of | patients Contact details (if patient wishes to discuss options later):  Contact your hospital team if you have any   |
| treatment/procedures to go ahead. Signed:  | questions about cancer and its treatment.  |
| Date:  | Cancer Research UK can also help answer your<br>questions about cancer and treatment. If you   |
| Name (PRINT):  | want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to  |
| Job title:   | Friday, 9am to 5pm. Alternatively visit cruk.org for   |
| Important notes: (tick if applicable)  | more information.  |
| <ul><li>☐ See also advance decision to refuse treatment</li><li>☐ Patient has withdrawn consent (ask patient to sign and date here)</li></ul>  | These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.      |
| Signed: Date:  | The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.  |

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### **Guidance for health professionals**

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

#### What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

### The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

### Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

### When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or

 communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

#### Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

### **NHS Scotland**

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

#### References

- Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
- Cancer Research UK: cruk.org/aboutcancer/treatment/drugs
- Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

| Patient agreement to   | Patient details   |  |
|--|---|--|
| systemic anti-cancer therapy (SACT)  | Patient's surname/family name:  ———————————————————————————————————   |  |
| DA (Daunorubicin and   |   |  |
| Cytarabine)  | Date of birth:  |  |
|  | NHS number:   |  |
|  | (or other identifier)   |  |
| Hospital/NHS Trust/NHS Board:  | Special requirements:   |  |
|  | (eg other language/other communication method)  |  |
| Responsible consultant:  |   |  |
| Name:  |   |  |
| Job title:   |   |  |
|  |   |  |
| OR high risk myelodysplastic syndrome (MDS).  ☐ DA 3+10: Daunorubicin intravenously on days 1, on days 1 to 10. Usually followed by DA 3+8: Daunorubicin days 1 to 8 OR  ☐ DA 2+5: Daunorubicin intravenously on days 1 are 1 to 5 OR                                      | y for the treatment of acute myeloid leukaemia (AML)  3 and 5 and Cytarabine intravenously twice each day rubicin on days 1, 3 and 5 and Cytarabine twice a day and 3, Cytarabine intravenously twice each day on days and 5, Cytarabine intravenously over 24 hours on  Other: |  |
| Statement of health professio  (to be filled in by health professional with appropriate the hospital/Trust/NHS board's consent policy)  ☑ Tick all relevant boxes ☐ I confirm the patient has capacity to give consent ☐ I have explained the course of treatment and inte | e knowledge of proposed procedure, as specified in  |  |
| The intended benefits (there are no guarantees   | about outcome)  |  |
| <ul> <li>□ Prolong survival</li> <li>□ Control symptoms, reduce transfusion needs and</li> <li>□ Induction – therapy given in the acute state of the</li> <li>□ Curative – to give you the best possible chance of</li> </ul>  | e disease, aiming to shrink the tumour.   |  |

Disease control / Palliative – the aim is not to cure but to control the disease and reduce the

symptoms. The aim is to improve both quality and quantity of life.

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the symptoms.

Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version **DA (Daunorubicin and Cytarabine)** 

Patient identifier/label

| Affecting more than 10 in every 100 (>10%) people   | You may have one or more of the side effects listed |   |  |
|---|---|---|--|
| □ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very iii. □ If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:  • your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team  • you suddenly feel unwell (even with a normal temperature)  Nausea (feeling sick), vomiting (being sick), sore mouth and ulcers, difficulty swallowing, taste changes, loss of appetite, abdominal (tummy) pain, diarrhoea.  □ Thinning of the hair or hair loss, skin changes (itching, rash, darkening), change in nail colour. □ Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged requiring a transtrusion.  □ Changes in liver and kidney function (monitored), red colour urine for 1-2 days after treatment (due to Daunorubicin).  □ Cytarabine syndrome can occur 6 to 12 hours after receiving Cytarabine. Symptoms include a high temperature or chills, rash, pain in the eyes, bones, tummy and chest. Inform your doctor or nurse.  Occasional side effects:  Affecting between 1-10 in every 100 (1-10%) people   Skin changes (severe symptoms with redness, itching, blisters), changes in eye sight (reversible).  □ High uric acid levels, weight loss.  □ This treatment rarely causes other nervous system side effects, such as drowsiness, unsteadiness or mood changes.  □ This treatment rarely causes other nervous system side effects, such as drowsiness, unsteadiness or mood changes.  □ This treatment rarely causes other nervous system side effects, such as drowsiness, unsteadiness or mood changes.  □ This treatment rarely causes other nervous system side effects, such as drowsiness, unsteadiness or mood changes.  □ This treatment rarely causes other nervous destore of the body elastis. Thereliens side of tumour lysis syndrome can ceceded to cope and least to changes in the blood tests to changes in the blood tests of            | Common side effects:                                | Other risks continued:                          |  |
| □ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very iii. □ If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:  • your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team  • you suddenly feel unwell (even with a normal temperature)  □ Nausea (feeling sick), vomiting (being sick), sore mouth and ulcers, difficulty swallowing, taste changes, loss of appetite, abdominal (tummy) pain, diarrhoea.  □ Thinning of the hair or hair loss, skin changes (itching, rash, darkening), change in nail colour.  □ Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged requiring a transtrusion.  □ Changes in liver and kidney function (monitored), red colour urine for 1-2 days after treatment (due to Daunorubicin).  □ Cytarabine syndrome can occur 6 to 12 hours after receiving Cytarabine. Symptoms include a high temperature or chills, rash, pain in the eyes, bones, tummy and chest. Inform your doctor or nurse.  Occasional side effects:  Affecting between 1-10 in every 100 (1-10%) people   Skin changes (severe symptoms with redness, itching, blisters), changes in eye sight (reversible).  □ High uric acid levels, weight loss.  □ This treatment rarely causes other nervous system side effects, such as drowsiness, unsteadiness or mood changes.  □ This treatment rarely causes other nervous system side effects, such as drowsiness, unsteadiness or mood changes.  □ This treatment rarely causes other nervous system side effects, such as drowsiness, unsteadiness or mood changes.  □ This treatment rarely causes other nervous system side effects, such as drowsiness, unsteadiness or mood changes.  □ This treatment rarely causes other nervous destored files the such as frows malients (when the blood dests to changes in sk of tumour lysis syndrome leads to changes in the blood tests to changes in the            | Affecting more than 10 in every 100 (>10%) people   | side effect. Symptoms include headaches.        |  |
| drop in white blood cells — this makes it harder to fight infections and you can become very ill. If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:  • your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team  • you suddenly feel unwell (even with a normal temperature)    Nausea (feeling sick), vomiting (being sick), sore mouth and ulcers, difficulty swallowing, taste changes, loss of appetite, abdominal (turmny) pain, diarrhoea.   Thinning of the hair or hair loss, skin changes (itching, rash, darkening), change in nail colour.     Anaemia (due to low patelets); this can be prolonged requiring a transfusion.     Changes in liver and kidney function (monitored), red colour urine for 1-2 days after treatment (due to Daunorubicin).     Cytarabine syndrome can occur 6 to 12 hours after receiving Cytarabine. Symptoms include a high temperature or chills, rash, pain in the eyes, bones, tummy and chest. Inform your doctor or nurse.    Affecting between 1-10 in every 100 (1-10%) people     Skin changes (severe symptoms with redness, itching, bilsters), changes in eye sight (reversible).     High uric acid levels, weight loss.   Inflammation and ulcers at the opening end of the bowel (anus).     Heart problems with changes in the way your heart works including abnormal heart rhythms (fast heart rate) and risk of an heart attack.    Other risks:     This treatment may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. It's uncommon but important to deal with quickly.     Late effects include a rare chance of a second cancer (years later) and heart problems.  | - · · · · · · · · · · · · · · · · · · ·             |   |  |
| If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:  • your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team  • you suddenly feel unwell (even with a normal temperature)  □ Nausea (feeling sick), vomiting (being sick), sore mouth and ulcers, difficulty swallowing, taste changes, loss of appetite, abdominal (turnmy) pain, diarrhoea.  □ Thinning of the hair or hair loss, skin changes (tiching, rash, darkening), change in nail colour.  □ Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged requiring a transfusion.  □ Changes in liver and kidney function (monitored), red colour urine for 1-2 days after treatment (due to Daunorubicin).  □ Cytarabine syndrome can occur 6 to 12 hours after receiving Cytarabine. Symptoms include a high temperature or chills, rash, pain in the eyes, bones, tummy and chest. Inform your doctor or nurse.  Occasional side effects:  Affecting between 1-10 in every 100 (1-10%) people   Skin changes (severe symptoms with redness, itching, blisters), changes in eye sight (reversible).  □ High unic acid levels, weight loss. □ Infiammation and ulcers at the opening end of the bowel (anus). □ Heart problems with changes in the way your heart works including abnormal heart rhythms (fast heart rate) and risk of a heart attack.  Other risks: □ This treatment may leak out of the vein while it is being given (extravastion) and can damage warried the size around the vein. It's uncommon but important to deal with quickly. Late effects include a rare chance of a second cancer (years later) and heart problems.  |   | •         |  |
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| • your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team     • you suddenly feel unwell (even with a normal temperature)      □ Nausea (feeling sick), womiting (being sick), sore mouth and ulcers, difficulty swallowing, taste changes, loss of appetite, abdominal (tummy) pain, diarrhoea.      □ Thinning of the hair or hair loss, skin changes (itching, rash, darkening), change in nail colour.      □ Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged requiring a transfusion.      □ Changes in liver and kidney function (monitored), red colour urine for 1-2 days after treatment (due to Daunorubicin).      □ Cytarabine syndrome can occur 6 to 12 hours after receiving Cytarabine. Symptoms include a high temperature or chills, rash, pain in the eyes, bones, tummy and chest. Inform your doctor or nurse.  Cocasional side effects:  Affecting between 1-10 in every 100 (1-10%) people   Skin changes (severe symptoms with redness, itching, blisters), changes in eye sight (reversible).      □ High uric acid levels, weight loss.      □ This treatment may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly. Late effects include a rare chance of a second cancer (years later) and heart problems.  A control of the bowel (anus).   |   |   |  |
| destroys cancer cells too quickly for the kidneys to cope and leads to changes in the blood tests), vour chemotherapy team  you suddenly feel unwell (even with a normal temperature)  Nausea (feeling sick), vomiting (being sick), sore mouth and ulcers, difficulty swallowing, taste changes, loss of appetite, abdominal (tummy) pain, diarrhoea.  Thinning of the hair or hair loss, skin changes (itching, rash, darkening), change in nail colour.  Anaemia (due to low platelets); this can be prolonged requiring a transfusion.  Changes in liver and kidney function (monitored), red colour urine for 1-2 days after treatment (due to Daunorubicin).  Cytarabine syndrome can occur 6 to 12 hours after receiving Cytarabine. Symptoms include a high temperature or chills, rash, pain in the eyes, bones, tummy and chest. Inform your doctor or nurse.  Occasional side effects:  Affecting between 1-10 in every 100 (1-10%) people   Skin changes (severe symptoms with redness, itching, blisters), changes in eye sight (reversible).  Heart problems with changes in the way he prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.  Before treatment you may have blood tests to cope and leads to changes in the blood tests). Rarely, dialysis may be prescribed medicines for prevention or treatment.  Side effects of anti-sickness medication include diarrhoea, constipation, headaches, red and itchy skin around the injection site.  Before treatment you may have blood tests to cope and leads to changes in the tests). Rarely, dialysis may be prescribed medicines for prevention or treatment.  Side effects of anti-sickness medication include diarrhoea, constipation, headaches, red and itchy skin around the injection. Side effects of effects to prevent or treatment can empty our maintain number of white cells to prevent infection.  Changes in your memory, concentration or ability to think clearly.  Cancer and its treatment can increase your risk of developi          | •   |   |  |
| by your chemotherapy team you suddenly feel unwell (even with a normal temperature)  Nausea (feeling sick), vomiting (being sick), sore mouth and ulcers, difficulty swallowing, taste changes, loss of appetite, abdominal (tummy) pain, diarrhoea.  Thinning of the hair or hair loss, skin changes (itching, rash, darkening), change in nail colour.  Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged requiring a transfusion.  Changes in liver and kidney function (monitored), red colour urine for 1-2 days after treatment (due to Daunorubicin).  Cydarabine syndrome can occur 6 to 12 hours after receiving Cytarabine. Symptoms include a high temperature or chills, rash, pain in the eyes, bones, tummy and chest. Inform your doctor or nurse.  Occasional side effects:  Affecting between 1-10 in every 100 (1-10%) people   Skin changes (severe symptoms with redness, itching, blisters), changes in eye sight (reversible).  High uric acid levels, weight loss. Inflammation and ulcers at the opening end of the bowel (anus).  Heart problems with changes in the way your hamble of the bowel (anus).  Heart problems with changes in the way our hamble it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly. Late effects include a rare chance of a second cancer (years later) and heart problems.  Acception may be prescribed medicines for prevention or treatment.  Side effects of anti-sickness medication include diarrhoea, constipation, headaches.  Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infections. You may experience bone pain, headaches.  Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infections. You may experience bone pain, headaches.  Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infections. Yo           |   | · · · · · · · · · · · · · · · · · · ·           |  |
| <ul> <li>you suddenly feel unwell (even with a normal temperature)</li> <li>Nausea (feeling sick), vomiting (being sick), sore mouth and ulcers, difficulty swallowing, taste changes, loss of appetite, abdominal (tummy) pain, diarrhoea.</li> <li>□ Thinning of the hair or hair loss, skin changes (itching, rash, darkening), change in nail colour.</li> <li>□ Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged requiring a transfusion.</li> <li>□ Changes in liver and kidney function (monitored), red colour urine for 1-2 days after treatment (due to Daunorubicin).</li> <li>□ Cytarabine syndrome can occur 6 to 12 hours after receiving Cytarabine. Symptoms include a high temperature or chills, rash, pain in the eyes, bones, tummy and chest. Inform your doctor or nurse.</li> <li>Occasional side effects:</li> <li>Affecting between 1-10 in every 100 (1-10%) people   Skin changes (severe symptoms with redness, itching, blisters), changes in eye sight (reversible).</li> <li>□ Heart problems with changes in the way hour heart works including abnormal heart rhythms (fast heart rate) and risk of a heart attack.</li> <li>Other risks:</li> <li>□ This treatment may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly. Late effects include a rare chance of a second cancer (years later) and heart problems.</li> <li>A creative attent and the problems with changes in the way to the problems with changes in the way the prescribed to maintain number of white cells to prevent infections. Class of effects of anti-sickness medication include thandarhoea, constipation, headaches, (GCSF) may be prescribed to maintain number of white cells to prevent infections. Discretely interesting to an interesting to maintain number of white cells to revent in real treatment.</li> <li>□ Before treatment,</li></ul> |   |   |  |
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| encephalopathy syndrome (PRES) is a rare  | —   | be life-threatening.                            |  |

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Lisa Yuen Checked by Consultant: Eleni Tholouli Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version **DA (Daunorubicin and Cytarabine)** 

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| been provided:  Information leaflet for Daunorubicin and Cytarabine  24 hour alert card or SACT advice service contact details  SACT treatment record (cruk.org/treatment-record)  Other, please state:  Statement of interpreter (where appropriate)  Interpreter booking reference (if applicable):  I have interpreted the information above to the patient to the best of my ability and in a way in which believe they can understand.  Signed:  Date:  Date: Date: Date: Date: Date: Dat | Any other risks and information:   |   |
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| available alternative treatments (including no treatment).    Thave discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.    I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.    I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.    I have discussed concerns of particular importance to the patient in regard to treatment (please write details here):    Clinical management guideline/Protocol compliant (please tick):   Yes   |  |   |
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|  | Interpreter booking reference (if applicable):   |   |
|  | Signed:  | Date:   |
|  | Name (PRINT):  | Job title:                                    |

### Statement of patient

Patient identifier/label

| your own copy of the form which describes the be   | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form.               |
|--|--|
| ☐ I have had enough time to consider my optio  | ns and make a decision about treatment.  |
| ☐ I agree to the course of treatment described   | on this form.  |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo   | ole to sign but has indicated their consent. A person with bung people under the age of 16 years.  |
| Patient's signature:   |  |
| Name (PRINT):  | Date:  |
| Person with parental responsibility/witness' signa   | ature:   |
| Name (PRINT):  | Date:  |
| (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)  On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of | patients Contact details (if patient wishes to discuss options later):  Contact your hospital team if you have any   |
| treatment/procedures to go ahead. Signed:  | questions about cancer and its treatment.  |
| Date:  | Cancer Research UK can also help answer your questions about cancer and treatment. If you  |
| Name (PRINT):  | want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to  |
| Job title:   | Friday, 9am to 5pm. Alternatively visit cruk.org for   |
| Important notes: (tick if applicable)  See also advance decision to refuse treatment  Patient has withdrawn consent (ask patient to sign and date here)  | more information.  These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT. |
| Signed: Date:  | The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.  |

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Lisa Yuen Checked by Consultant: Eleni Tholouli Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version **DA (Daunorubicin and Cytarabine)** 

### **Guidance for health professionals**

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

#### What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

#### The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

### Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

### When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or

 communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

#### Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

### **NHS Scotland**

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

#### References

- 1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
- Cancer Research UK: cruk.org/aboutcancer/treatment/drugs
- Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

| Patient agreement to systemic anti-cancer therapy (SACT)   | Patient details Patient's surname/family name:  |  |
|--|---|--|
| Etoposide (Oral)   | Patient's first name(s):  |  |
|  | Date of birth:  |  |
|  | NHS number:(or other identifier)  |  |
| Hospital/NHS Trust/NHS Board:  | Special requirements: (eg other language/other communication method)  |  |
| Responsible consultant: Name:  |   |  |
| Job title:   |   |  |
|  | tment of acute myeloid leukaemia (AML).  a week* or on alternate days* (*delete as appropriate).  ed by your doctor depending on your blood results.  or unacceptable side effects. |  |
| Statement of health profession (to be filled in by health professional with appropriate the hospital/Trust/NHS board's consent policy)  ☑ Tick all relevant boxes ☐ I confirm the patient has capacity to give consent ☐ I have explained the course of treatment and inte   | knowledge of proposed procedure, as specified in .  nded benefit to the patient.  |  |
| The intended benefits (there are no guarantees a   | about outcome)  |  |
| <ul> <li>□ Prolong survival.</li> <li>□ Control symptoms, reduce transfusion needs and</li> <li>□ Induction – therapy given in the acute state of the</li> <li>□ Curative – to give you the best possible chance o</li> <li>□ Maintenance – therapy given on continuing basis the symptoms.</li> <li>□ Disease control / Palliative – the aim is not to cure symptoms. The aim is to improve both quality and quality</li> </ul> | e disease, aiming to shrink the tumour of being cured.  , aiming to prevent disease flaring up and to control the but to control the disease and reduce the                         |  |

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Elizabeth Davies Checked by Consultant: Eleni Tholouli Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version **Etoposide (Oral)** 

Patient identifier/label

| You may have one or more of the side effects listed  |   |  |
|--|---|--|
| Common side effects:   | Other risks:  |  |
| Affecting more than 10 in every 100 (>10%) people  An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.  If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:  • your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team  • you suddenly feel unwell (even with a normal temperature)  Feeling sick (nausea) and being sick (vomiting), abdominal (tummy) pain, weight loss, constipation.  Tiredness and feeling weak (fatigue).  Thinning of the hair or hair loss.  Change in skin colour.  Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged and you may need a transfusion. | <ul> <li>☐ Side effects of anti-sickness medication include diarrhoea, constipation, headaches.</li> <li>☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.</li> <li>☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.</li> <li>☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.</li> <li>☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).</li> <li>☐ Some anti-cancer medicines may damage the</li> </ul> |  |
| Changes in liver function tests (monitored).  Occasional side effects:  Affecting between 1-10 in every 100 (1-10%) people  Sore mouth and ulcers,  Diarrhoea, feeling dizzy.  Rash and/or itching of the skin.  Changes in heart rhythm, high blood pressure.  Etoposide can increase the risk of developing a second cancer (acute leukaemia), years after treatment.  | <ul> <li>Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for up to 6 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse.</li> <li>Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other, exceedingly rare side effects may also be life-threatening.</li> </ul>   |  |

| D - 4! 4 | identifier/ | /  _   _ |
|----------|-------------|----------|
| Patient  | ICANTITIAN  | /Ianai   |
|          |             |          |

| Any other risks and information:   |   |
|--|---|
|  |   |
| ☐ I have discussed the intended benefit and risks available alternative treatments (including no treatments)   | · · · · · · · · · · · · · · · · · · ·           |
| ☐ I have discussed the side effects of the recomm straight away or in the future, and that there may be rare or have not yet been reported. Each patient may                 | e some side effects not listed because they are |
| ☐ I have discussed what the treatment is likely to i timing of the treatment, blood and any additional test  | •         |
| ☐ I have explained to the patient, that they have the should contact the responsible consultant or team if   | ·   |
| ☐ I have discussed concerns of particular importar   | nce to the patient in regard to treatment       |
| (please write details here):   |   |
| Clinical management guideline/Protocol con  Yes No Not available If No pleas  The following written information has been provided:  Information leaflet for Etoposide (oral) | Health professional details:  Signed:           |
| 24 hour alert card or SACT advice service contact details  | Date:Name (PRINT):                              |
| SACT treatment record (cruk.org/treatment-record)  | Job title:                                      |
| Other, please state:   |   |
| Otatawa ant of intermedian   |   |
| Statement of interpreter (where a Interpreter booking reference (if applicable): I have interpreted the information above to the patient believe they can understand.        |   |
| •  | Data  |
| Signed:  | Date:   |
| Name (PRINT):  | Job title:                                      |

### Statement of patient

Patient identifier/label

| your own copy of the form which describes the be   | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form.  |
|--|---|
| ☐ I have had enough time to consider my optio  | ns and make a decision about treatment.   |
| ☐ I agree to the course of treatment described   | on this form.   |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo   | ole to sign but has indicated their consent. A person with bung people under the age of 16 years.   |
| Patient's signature:   |   |
| Name (PRINT):  | Date:   |
| Person with parental responsibility/witness' signa   | ature:  |
|  | Date:   |
| (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)  On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of | patients Contact details (if patient wishes to discuss options later):  Contact your hospital team if you have any  |
| treatment/procedures to go ahead. Signed:  | questions about cancer and its treatment.   |
| Date:  | Cancer Research UK can also help answer your questions about cancer and treatment. If you   |
| Name (PRINT):  | want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to   |
| Job title:   | Friday, 9am to 5pm. Alternatively visit cruk.org for  |
| Important notes: (tick if applicable)  See also advance decision to refuse treatment  Patient has withdrawn consent (ask patient to sign and date here)  Signed:   | more information.  These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.  The project is supported by |
| Date:  | Cancer Research UK.  This does not mean you are taking part in a clinical trial.  |

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Elizabeth Davies Checked by Consultant: Eleni Tholouli Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version **Etoposide (Oral)** 

### **Guidance for health professionals**

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

### What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

### The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

### Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

### When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- · retain that information in their mind
- use or weigh this information as a part of their decision making process, or

 communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

#### Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

### **NHS Scotland**

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

### References

- Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
- Cancer Research UK: cruk.org/aboutcancer/treatment/drugs
- Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Elizabeth Davies Checked by Consultant: Eleni Tholouli Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version **Etoposide (Oral)** 

| Patient agreement to  | Patient details   |
|---|---|
| systemic anti-cancer therapy (SACT)   | Patient's surname/family name:  |
| Gemtuzumab ozogamicin +   | Patient's first name(s):  |
| chemotherapy  | Date of birth:  |
|   | NHS number:(or other identifier)                                      |
| Hospital/NHS Trust/NHS Board:   | Special requirements:  (eg other language/other communication method) |
| Responsible consultant: Name:   |   |
| Job title:  |   |
|   |   |
| Name of proposed course of treatment (incl  | ude brief explanation if medical term not clear)                      |
| Gemtuzumab ozogamicin as part of chemotherap  | by for CD33 positive acute myeloid leukaemia (AML).                   |
| Gemtuzumab is given intravenously in combination consolidation.   | on with chemotherapy as part of induction and                         |
| ☐ A separate consent form must be completed for t   | he chemotherapy regimen.  |
| Where will I have treatment?  ☐ Outpatient ☐ Day unit/case ☐ Inpatient  | ☐ Other:  |
| Statement of health professio (to be filled in by health professional with appropriate the hospital/Trust/NHS board's consent policy)  Tick all relevant boxes  |   |
| ☐ I confirm the patient has capacity to give consent  | t.  |
| I have explained the course of treatment and interest   | ended benefit to the patient.   |
| The intended benefits (there are no guarantees  | about outcome)  |
| <ul> <li>□ Prolong survival.</li> <li>□ Control symptoms, reduce transfusion needs and</li> <li>□ Induction – therapy given in the acute state of the</li> <li>□ Curative – to give you the best possible chance of</li> <li>□ Maintenance – therapy given on continuing basis</li> </ul> | e disease, aiming to shrink the tumour.                               |

Disease control / Palliative – the aim is not to cure but to control the disease and reduce the

symptoms. The aim is to improve both quality and quantity of life.

the symptoms.

Patient identifier/label

| You may have one or more of the side effects listed   |  |  |
|---|--|--|
| Common side effects:  | Occasional side effects continued:   |  |
| Affecting more than 10 in every 100 (>10%) people   | prescribed medicines for prevention or   |  |
| ☐ An increased risk of getting an infection from a  | treatment.   |  |
| drop in white blood cells – this makes it harder  | ☐ Itching and redness of the skin.   |  |
| to fight infections and you can become very ill.  | One or more of your organs may not work  |  |
| ☐ If you have a severe infection this can be  | properly (this can be life-threatening).   |  |
| life-threatening. Contact your doctor or  |  |  |
| hospital straight away if:  | Other risks:   |  |
| <ul> <li>your temperature goes over 37.5°C or</li> </ul>  | Gemtuzumab ozogamicin may leak out of the  |  |
| over 38°C, depending on the advice given  | vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the |  |
| by your chemotherapy team   | nurse straight away if you have any stinging,  |  |
| you suddenly feel unwell (even with a parmet temperature)   | pain, redness or swelling around the vein. It's  |  |
| normal temperature)   | uncommon but important to deal with quickly.   |  |
| Nausea (feeling sick), vomiting (being sick), abdominal (tummy) pain, indigestion,                | Side effects with the anti-sickness medication   |  |
| constipation, diarrhoea.  | may include: constipation, diarrhoea,  |  |
| Sore mouth and ulcers, loss of appetite, feeling  | headaches.   |  |
| weak and tired (fatigue).   | ☐ Before treatment you may have blood tests to   |  |
| Anaemia (due to low red blood cells) and  | check for viruses (Hepatitis B or C, HIV, or   |  |
| bruising or bleeding (due to low platelets); this   | unusual infections). Treatment may weaken  |  |
| can be prolonged and you may need a   | your natural defence (immune) system so  |  |
| transfusion, changes in liver function  | infections like this may worsen or become  |  |
| (monitored).  | active if you've had them before. You may have   |  |
| You may have nose bleeds, bleeding gums, blood in the urine, stools or tiny red, brown or         | medicines to prevent or treat infection.   |  |
| purple spots that may look like a rash.   | Growth factors (GCSF) may be prescribed to   |  |
| Headache, fluid build-up in hands and feet,   | maintain number of white cells to prevent infection. You may experience bone pain,               |  |
| rash.   | headaches, red and itchy skin around the   |  |
| High or low blood pressure, high heart rate,  | injection site.  |  |
| shortness of breath, chills.  | Late effects include a very rare chance of a   |  |
| This treatment can raise your blood sugar. If   | second cancer (years later) and problems with  |  |
| you have diabetes, it may lead to higher blood sugar levels.                                      | your heart.  |  |
| Occasional side effects:  | ☐ Changes in your memory, concentration or   |  |
| Affecting between 1-10 in every 100 (1-10%) people  | ability to think clearly. There can be many  |  |
| Liver related side effects from minor through to  | causes including your treatment, diagnosis, or   |  |
| veno-occlusive disease which can be potentially   | both.  |  |
| life-threatening. Let your doctor or nurse know if  | Cancer and its treatment can increase your risk  |  |
| you experience rapid weight gain, pain in the   | of developing a blood clot (thrombosis), causing   |  |
| upper right side of your belly, jaundice (yellow  | pain, redness and swelling in an arm or leg,   |  |
| skin), build-up of fluid around your tummy.   | breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.             |  |
| Infusion related side effects may occur during or   | Some anti-cancer medicines can damage  |  |
| shortly after the infusion. Symptoms include fast heart rate, wheezing, face swelling, difficulty | ovaries and sperm. This may lead to infertility  |  |
| breathing, fluctuating blood pressure and rash.   | and/or early menopause (hot flushes, vaginal   |  |
| There may be an increased risk of tumour lysis  | dryness).  |  |
| syndrome in some patients (when treatment   | - ,  |  |
| destroys cancer cells too quickly for the kidneys   |  |  |
| to cope and leads to changes in blood tests.  | Continue on to the payt page   |  |
| Rarely, dialysis may be needed. You may be  | Continue on to the next page   |  |

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Lisa Yuen Checked by Consultant: Eleni Tholouli Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version **Gemtuzumab ozogamicin + chemotherapy** 

Patient identifier/label

# Statement of health professional

### Other risks continued

Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for up to 7 months following last dose of Gemtuzumab ozogamicin. Use effective contraception throughout. It is advisable to use 2 methods of effective contraception during treatment with Gemtuzumab ozogamicin. Women of child bearing age will be tested for pregnancy before and during treatment. Speak to your doctor or nurse.

□ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

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| Patient  | identifier/label   |  |
|----------|--------------------|--|
| i auciti | Idol Idillol/Idbol |  |

| Any other risks and information:   |  |  |
|--|--|--|
|  |  |  |
| ☐ I have discussed the intended benefit and risks of available alternative treatments (including no treatments)  | ·  |  |
| ☐ I have discussed the side effects of the recomme<br>straight away or in the future, and that there may be<br>rare or have not yet been reported. Each patient ma | some side effects not listed because they are  |  |
| ☐ I have discussed what the treatment is likely to in timing of the treatment, blood and any additional test   | ,  |  |
| ☐ I have explained to the patient, that they have the should contact the responsible consultant or team if   | •  |  |
| ☐ I have discussed concerns of particular importan   | ce to the patient in regard to treatment       |  |
| (please write details here):   |  |  |
|  |  |  |
| Clinical management guideline/Protocol cor  ☐ Yes ☐ No ☐ Not available If No pleas   | npliant (please tick): e document reason here: |  |
| The following written information has been provided:   | Health professional details: Signed:           |  |
| ☐ Information leaflets for Gemtuzumab ozogamicin and chemotherapy  | Date:  |  |
| ☐ 24 hour alert card or SACT advice service contact details  | Name (PRINT):                                  |  |
| SACT treatment record (cruk.org/treatment-record)  | Job title:                                     |  |
| Other, please state:   |  |  |
| Statement of interpretor .   |  |  |
| Statement of interpreter (where applicable): I have interpreted the information above to the patient believe they can understand.                                  |  |  |
| Signed:  | Date:  |  |
| Name (PRINT):  | Job title:                                     |  |

# Statement of patient

Patient identifier/label

| your own copy of the form which describes the be   | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form.               |
|--|--|
| ☐ I have had enough time to consider my optio  | ns and make a decision about treatment.  |
| ☐ I agree to the course of treatment described   | on this form.  |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo   | ble to sign but has indicated their consent. A person with bung people under the age of 16 years.  |
| Patient's signature:   |  |
| Name (PRINT):  | Date:  |
| Person with parental responsibility/witness' signa   | ature:   |
| Name (PRINT):  | Date:  |
| (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)  On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of | patients Contact details (if patient wishes to discuss options later):  Contact your hospital team if you have any   |
| treatment/procedures to go ahead. Signed:  | questions about cancer and its treatment.  |
| Date:  | Cancer Research UK can also help answer your questions about cancer and treatment. If you  |
| Name (PRINT):  | want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to  |
| Job title:   | Friday, 9am to 5pm. Alternatively visit cruk.org for   |
| Important notes: (tick if applicable)  See also advance decision to refuse treatment  Patient has withdrawn consent (ask patient to sign and date here)  | more information.  These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT. |
| Signed: Date:  | The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.  |

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### **Guidance for health professionals**

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

### What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

### The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

### Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

### When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- · retain that information in their mind
- use or weigh this information as a part of their decision making process, or

 communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

#### Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

### **NHS Scotland**

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

### References

- 1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
- Cancer Research UK: cruk.org/aboutcancer/treatment/drugs
- Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

| Patient agreement to systemic anti-cancer therapy (SACT)   | Patient details Patient's surname/family name: Patient's first name(s):   |  |
|--|---|--|
| Gemtuzumab ozogamicin with Daunorubicin and  |   |  |
|  | Date of birth:  |  |
| Cytarabine   | NHS number:   |  |
|  | (or other identifier)   |  |
| Hospital/NHS Trust/NHS Board:  | Special requirements:  (eg other language/other communication method)   |  |
| Responsible consultant:  Name:  Job title:   |   |  |
| (AML).   | bicin on day 1, Cytarabine on days 1 to 4.  |  |
| Statement of health professio  (to be filled in by health professional with appropriate the hospital/Trust/NHS board's consent policy)  Tick all relevant boxes  I confirm the patient has capacity to give consent I have explained the course of treatment and inte  The intended benefits (there are no guarantees  Prolong survival.  Control symptoms, reduce transfusion needs and Induction – therapy given in the acute state of the  Curative – to give you the best possible chance of | e knowledge of proposed procedure, as specified in ended benefit to the patient. about outcome)  d improve quality of life. e disease, aiming to shrink the tumour. |  |
|  | s, aiming to prevent disease flaring up and to control  |  |

Disease control / Palliative – the aim is not to cure but to control the disease and reduce the

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symptoms. The aim is to improve both quality and quantity of life

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| You may have one or more of the side effect  | ts listed  |
|--|--|
| Common side effects:   | Occasional side effects:   |
| Affecting more than 10 in every 100 (>10%) people                                      | Affecting between 1-10 in every 100 (1-10%) people   |
| An increased risk of getting an infection from a                                       | Liver related side effects from minor through to   |
| drop in white blood cells – this makes it harder                                       | veno-occlusive disease which can be potentially  |
| to fight infections and you can become very ill.                                       | life-threatening. Let your doctor or nurse know if   |
| If you have a severe infection this can be   | you experience rapid weight gain, pain in the  |
| life-threatening. Contact your doctor or   | upper right side of your belly, jaundice (yellow skin), build-up of fluid around your tummy. |
| hospital straight away if:   | Infusion related side effects may occur during or  |
| • your temperature goes over 37.5°C or   | shortly after the infusion. Symptoms include fast  |
| over 38°C, depending on the advice given   | heart rate, wheezing, face swelling, difficulty  |
| by your chemotherapy team  | breathing, fluctuating blood pressure and rash.  |
| <ul> <li>you suddenly feel unwell (even with a<br/>normal temperature)</li> </ul>      | Inflammation and ulcers at the opening end of  |
|  | the bowel (anus), which can be severe leading  |
| Nausea (feeling sick), vomiting (being sick), abdominal (tummy) pain, indigestion,     | to infections.   |
| constipation, diarrhoea.   | Heart problems with changes in the way your<br>heart works including abnormal heart rhythm   |
| Sore mouth and ulcers, loss of appetite,   | (fast heart rate) and risk of a heart attack.  |
| difficulty swallowing, taste changes, feeling  | Severe skin changes (redness, itching  |
| weak and tired (fatigue).  | sometimes blisters), acid reflux, weight loss.   |
| Thinning of the hair or hair loss, skin changes  | Eye sight changes (reversible), high uric acid   |
| (itching, rash, darkening), change in nail colour.                                     | levels.  |
| Anaemia (due to low red blood cells) and   | One or more of your organs may not work  |
| bruising or bleeding (due to low platelets); this can be prolonged and you may need a  | properly (this can be life-threatening).   |
| transfusion, changes in liver and kidney function                                      | High dose Cytarabine can cause temporary or<br>occasionally permanent changes to the nervous |
| (monitored).   | system. Symptoms include seizures (fits),  |
| You may have nose bleeds, bleeding gums,   | drowsiness, unsteadiness and mood changes.   |
| blood in the urine, stools or tiny red, brown or                                       | ☐ There may be an increased risk of tumour lysis   |
| purple spots that may look like a rash.  | syndrome in some patients (when treatment  |
| Red colour urine for 1-2 days after treatment  | destroys cancer cells too quickly for the kidneys  |
| (due to daunorubicin).  Headache, fluid build-up in hands and feet,                    | to cope and leads to changes in blood tests.   |
| rash, high or low blood pressure, high heart   | Rarely, dialysis may be needed. You may be   |
| rate, shortness of breath, chills.   | prescribed medicines for prevention or treatment.  |
| ☐ Inflammation of the lining of the eye lids   | Other risks:   |
| (conjunctiva) making eyes feel sore, red and   | All intravenous drugs may leak out of the vein   |
| itchy (this is temporary). Steroid eye drops   | while it is being given (extravasation) and can  |
| during and for 3 days after Cytarabine to  | damage the tissue around the vein. Tell the  |
| prevent this will be given.  | nurse straight away if you have any stinging,  |
| Gemtuzumab ozogamicin can raise your blood sugar. If you have diabetes, it may lead to | pain, redness or swelling around the vein. It's  |
| higher blood sugar levels.   | uncommon but important to deal with quickly.   |
| Cytarabine syndrome can occur 6 to 12 hours  | Also, rarely high dose Cytarabine can cause  |
| after receiving Cytarabine. Symptoms include a   | changes in the lungs with shortness of breath, wheeezing, cough or a fever. Please inform    |
| high temperature or chills, rash, pain in the  | your doctor or nurse if you notice these   |
| eyes, bones, tummy and chest. Inform your  | symptoms.  |
| doctor or nurse.   | ☐ Side effects with the anti-sickness medication   |
|  | may include: constipation, diarrhoea,  |
|  | headaches.   |
|  | Continue on to the next page   |

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# Statement of health professional

### Other risks continued:

| Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.  |
|--|
| Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.   |
| Late effects include a rare chance of a second cancer (years later) and problems with your heart.  |
| Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.  |
| Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.   |
| Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).   |
| Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for up to 7 months afterwards. It is advisable to use 2 methods of effective contraception during treatment with Gemtuzumab ozogamicin. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse. |
| Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.  |

| Patient  | identifi | ar/lahel |
|----------|----------|----------|
| I auciii | IUCITUII | 51/10DG1 |

| ☐ I have discussed the intended benefit and risks available alternative treatments (including no treatments)   | ment).   |
|--|--|
| ☐ I have discussed the side effects of the recomme straight away or in the future, and that there may be rare or have not yet been reported. Each patient m  | <u>.</u>   |
| ☐ I have discussed what the treatment is likely to timing of the treatment, blood and any additional te  | involve (including inpatient/outpatient treatment, ests, follow-up appointments etc) and location. |
| ☐ I have explained to the patient, that they have the should contact the responsible consultant or team in   | ·  |
| ☐ I have discussed concerns of particular importa  | ince to the patient in regard to treatment   |
| (please write details here):   |  |
| The following written information has  |  |
| _  |  |
| been provided:  Information leaflet for Gemtuzumab ozogamicin, Daunorubicin and Cytarabine  24 hour alert card or SACT advice service  | Signed:  |
| been provided:  Information leaflet for Gemtuzumab ozogamicin, Daunorubicin and Cytarabine   | Signed: Date: Name (PRINT): Job title:   |
| been provided:  Information leaflet for Gemtuzumab ozogamicin, Daunorubicin and Cytarabine  24 hour alert card or SACT advice service contact details  SACT treatment record (cruk.org/treatment-  | Signed:  Date:  Name (PRINT):  Job title:  |
| been provided:  Information leaflet for Gemtuzumab ozogamicin, Daunorubicin and Cytarabine  24 hour alert card or SACT advice service contact details  SACT treatment record (cruk.org/treatment-record)  Other, please state:  Statement of interpreter (where a Interpreter booking reference (if applicable): I have interpreted the information above to the patie | Signed:  Date:  Name (PRINT):  Job title:  appropriate)  |
| been provided:  Information leaflet for Gemtuzumab ozogamicin, Daunorubicin and Cytarabine  24 hour alert card or SACT advice service contact details  SACT treatment record (cruk.org/treatment-record)  Other, please state:  Statement of interpreter (where a Interpreter booking reference (if applicable):   | Signed:  Date:  Name (PRINT):  Job title:  appropriate)  |

# Statement of patient

Patient identifier/label

| your own copy of the form which describes the be  | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form.               |
|---|--|
| ☐ I have had enough time to consider my optio   | ns and make a decision about treatment.  |
| ☐ I agree to the course of treatment described  | on this form.  |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo  | ole to sign but has indicated their consent. A person with bung people under the age of 16 years.  |
| Patient's signature:  |  |
| Name (PRINT):   | Date:  |
| Person with parental responsibility/witness' signa  | iture:   |
| Name (PRINT):   | Date:  |
| Confirmation of consent (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance) On behalf of the team treating the patient, I | Further information for patients Contact details (if patient wishes to discuss options later):   |
| have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.   | Contact your hospital team if you have any questions about cancer and its treatment.   |
| Signed:   | Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information   |
| Job title:  | nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for  |
| Important notes: (tick if applicable)  See also advance decision to refuse treatment  Patient has withdrawn consent (ask patient to sign and date here)                                       | more information.  These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT. |
| Signed:  Date:  | The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial   |

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Gemtuzumab ozogamicin with Daunorubicin and Cytarabine
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### **Guidance for health professionals**

(to be read in conjunction with the hospital's consent policy)

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### What a consent form is for

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### When NOT to use this form

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- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or

communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

#### Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

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### References

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- Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

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| Patient agreement to systemic anti-cancer therapy (SACT)   | Patient details Patient's surname/family name:                       |  |
|--|--|--|
| FLAG   | Patient's first name(s):   |  |
|  | Date of birth:   |  |
|  | NHS number:  |  |
|  | (or other identifier)  |  |
| Hospital/NHS Trust/NHS Board:  | Special requirements: (eg other language/other communication method) |  |
|  |  |  |
| Responsible consultant: Name:  |  |  |
| Job title:   |  |  |
|  | 1  |  |
| Name of proposed course of treatment (inclu  | ude brief explanation if medical term not clear)                     |  |
| (AML).  G-CSF (granulocyte colony-stimulating factor) is good before chemotherapy for 7 days in total). Local policy   | llowed by Cytarabine. Cytarabine given intravenously                 |  |
| Where will I have treatment?   | g on blood counts.   |  |
| Outpatient Day unit/case Inpatient   | Other:   |  |
|  |  |  |
| Statement of health profession (to be filled in by health professional with appropriate the hospital/Trust/NHS board's consent policy)  ☑ Tick all relevant boxes ☐ I confirm the patient has capacity to give consent | knowledge of proposed procedure, as specified in                     |  |
| ☐ I have explained the course of treatment and inte  | nded benefit to the patient.   |  |
| The intended benefits (there are no guarantees   | about outcome)   |  |
| ☐ Prolong survival.  |  |  |
| Control symptoms, reduce transfusion needs and   | •  |  |
| Induction – therapy given in the acute state of the  | _  |  |
| Curative – to give you the best possible chance of   | _  |  |
| Maintenance – therapy given on continuing basis<br>the symptoms  | , aiming to prevent disease flaring up and to control                |  |

☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the

symptoms. The aim is to improve both quality and quantity of life.

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| You may have one or more of the side effect        | ts listed  |
|--|--|
| Common side effects:                               | Other risks:                                       |
| Affecting more than 10 in every 100 (>10%) people  | Cytarabine, Fludarabine may leak out of the        |
| An increased risk of getting an infection from a   | vein while it is being given (extravasation) and   |
| drop in white blood cells – this makes it harder   | can damage the tissue around the vein. Tell the    |
| to fight infections and you can become very ill.   | nurse straight away if you have any stinging,      |
| ☐ If you have a severe infection this can be       | pain, redness or swelling around the vein. It's    |
| life-threatening. Contact your doctor or           | uncommon but important to deal with quickly.       |
| hospital straight away if:                         | Growth factors (GCSF) will be prescribed to        |
|  | maintain number of white cells to prevent          |
| your temperature goes over 37.5°C or               | infection. You may experience bone pain,           |
| over 38°C, depending on the advice given           | headaches, red and itchy skin around the           |
| by your chemotherapy team                          | injection site.                                    |
| you suddenly feel unwell (even with a              | Late effects include a rare chance of a second     |
| normal temperature)                                | cancer (years later) and problems with your        |
| Nausea (feeling sick) and vomiting (being sick),   | heart.   |
| abdominal (tummy) pain, diarrhoea.                 | ☐ Fludarabine depletes a certain type of cell in   |
| Sore mouth and ulcers, weight loss, feeling tired  | your blood (T-cells) and therefore you will        |
| and weak (fatigue).                                | require irradiated blood products if transfused.   |
| Thinning of hair or hair loss, cough.              | Rarely, this treatment can cause changes in the    |
| Anaemia (due to low red blood cells) and           | lungs with shortness of breath, wheezing, cough    |
| bruising or bleeding (due to low platelets); this  | or a fever. Please inform your doctor or nurse if  |
| can be prolonged and you may need a                | you notice these symptoms.                         |
| transfusion.  Changes in liver and kidney function | There is an increased risk of tumour lysis         |
| (monitored).                                       | syndrome in some patients when treatment           |
| Cytarabine syndrome can occur 6 to 12 hours        | destroys cancer cells too quickly for the kidneys  |
| after receiving Cytarabine. Symptoms include       | to cope and leads to changes in blood tests.       |
| fever or chills, rash, pain in the eyes, bones,    | Rarely, dialysis may be needed. You may be         |
| tummy and chest.                                   | prescribed medicines for prevention or             |
| Inflammation of the lining of the eye lids         | treatment.   |
| (conjunctiva) making eyes feel sore, red and       | ☐ Before treatment you may have blood tests to     |
| itchy (this is temporary). Steroid eye drops       | check for viruses (Hepatitis B or C, HIV, or       |
| during and for 3 days after Cytarabine to          | unusual infections). Treatment may weaken          |
| prevent this will be given.                        | your natural defence (immune) system so            |
| Occasional side effects:                           | infections like this may worsen or become          |
| Affecting between 1-10 in every 100 (1-10%) people | active if you've had them before. You may have     |
| Inflammation and ulcers at the opening end of      | medicines to prevent or treat infection.           |
| the bowel (anus), sometimes can be severe          | ☐ Side effects of anti-sickness medication include |
| leading to infections.                             | diarrhoea, constipation, headaches.                |
| Numbness and tingling in hands and feet, skin      | Changes in your memory, concentration or           |
| changes (redness, itching, sometimes blisters).    | ability to think clearly. There can be many        |
| Eye sight changes (reversible), weight loss, high  | causes including your treatment, diagnosis, or     |
| uric acid levels.                                  | both.  |
| ☐ This treatment increases the risk of temporary   | Cancer and its treatment can increase your risk    |
| or occasionally permanent changes to the           | of developing a blood clot (thrombosis), causing   |
| nervous system. Symptoms include fits,             | pain, redness and swelling in an arm or leg,       |
| drowsiness, unsteadiness, irritability and mood    | breathlessness, chest pain. Tell your doctor       |
| changes. Inform your doctor or nurse.              | straight away if you have any symptoms.            |
| Blood pressure changes.                            | J , , , , , , , , , , , , , , , , , , ,            |
| Recovery of blood counts may be very slow and      |  |
| in rare cases recovery may be incomplete.          | <b>.</b>   |
|  | Continue on to the next page                       |

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Patient identifier/label

# Statement of health professional

### Other risks continued:

| Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).  |
|---|
| Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for up to 6 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse. |
| Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.   |

| Patient   | identifie | r/lahel  |
|-----------|-----------|----------|
| i aliciii | IUCITUIL  | ,1/10001 |

| Any other risks and information:   |   |
|--|---|
|  |   |
| ☐ I have discussed the intended benefit and risks of available alternative treatments (including no treatments)  |   |
| I have discussed the side effects of the recomme straight away or in the future, and that there may be rare or have not yet been reported. Each patient may  | some side effects not listed because they are |
| ☐ I have discussed what the treatment is likely to intiming of the treatment, blood and any additional test  | , , ,   |
| ☐ I have explained to the patient, that they have the should contact the responsible consultant or team if t   | •   |
| ☐ I have discussed concerns of particular important  | ce to the patient in regard to treatment      |
| (please write details here):   |   |
|  |   |
| been provided:   | Health professional details: Signed:          |
| been provided: Information leaflet for Fludarabine,  | Signed:                                       |
| been provided: Information leaflet for Fludarabine, Cytarabine and GCSF 24 hour alert card or SACT advice service  | Signed:                                       |
| been provided:  Information leaflet for Fludarabine, Cytarabine and GCSF  24 hour alert card or SACT advice service contact details  SACT treatment record (cruk.org/treatment-  | Signed:  Date:  Name (PRINT):  Job title:     |
| been provided:  Information leaflet for Fludarabine, Cytarabine and GCSF  24 hour alert card or SACT advice service contact details  SACT treatment record (cruk.org/treatment-  | Signed: Date: Name (PRINT):                   |
| Cytarabine and GCSF  24 hour alert card or SACT advice service contact details  SACT treatment record (cruk.org/treatment-record)  | Signed:  Date:  Name (PRINT):  Job title:     |
| Deen provided:  Information leaflet for Fludarabine, Cytarabine and GCSF  24 hour alert card or SACT advice service contact details  SACT treatment record (cruk.org/treatment-record)  Other, please state:   | Signed:  Date:  Name (PRINT):  Job title:     |
| Deen provided:  Information leaflet for Fludarabine, Cytarabine and GCSF  24 hour alert card or SACT advice service contact details  SACT treatment record (cruk.org/treatment-record)  Other, please state:  Statement of interpreter (where aponterpreter booking reference (if applicable): have interpreted the information above to the patient | Signed:  Date:  Name (PRINT):  Job title:     |
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# Statement of patient

Patient identifier/label

| your own copy of the form which describes the be  | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form. |
|---|--|
| ☐ I have had enough time to consider my option  | ns and make a decision about treatment.  |
| ☐ I agree to the course of treatment described  | on this form.  |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo  | ole to sign but has indicated their consent. A person with bung people under the age of 16 years.  |
| Patient's signature:  |  |
| Name (PRINT):   | Date:  |
| Person with parental responsibility/witness' signa  | iture:   |
| Name (PRINT):   | Date:  |
| Confirmation of consent (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance) On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of | Further information for patients Contact details (if patient wishes to discuss options later):  Contact your hospital team if you have any   |
| treatment/procedures to go ahead.   | questions about cancer and its treatment.  |
| Signed: Date:   | Cancer Research UK can also help answer your questions about cancer and treatment. If you  |
| Name (PRINT):   | want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to  |
| Job title:  | Friday, 9am to 5pm. Alternatively visit cruk.org for   |
| Important notes: (tick if applicable)   | more information.  |
| <ul><li>☐ See also advance decision to refuse treatment</li><li>☐ Patient has withdrawn consent (ask patient to sign and date here)</li></ul>   | These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.      |
| Signed:   | The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.  |

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### **Guidance for health professionals**

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

### What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

### The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

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Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

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If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- · retain that information in their mind
- use or weigh this information as a part of their decision making process, or

 communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

#### Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

### **NHS Scotland**

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

### References

- 1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
- Cancer Research UK: cruk.org/aboutcancer/treatment/drugs
- Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

### Patient agreement to **Patient details** systemic anti-cancer Patient's surname/family name: therapy (SACT) Patient's first name(s): FLAG + Idarubicin Date of birth: NHS number: (or other identifier) **Hospital/NHS Trust/NHS Board:** Special requirements: (eg other language/other communication method) Responsible consultant: Name: \_\_\_\_ Job title: \_\_\_\_\_ Name of proposed course of treatment (include brief explanation if medical term not clear) FLAG (Fludarabine, Cytarabine, GCSF) & Idarubicin chemotherapy for the treatment of acute myeloid leukaemia (AML) or high risk Myelodysplastic Syndrome (MDS). G-CSF (granulocyte colony-stimulating factor) given subcutaneously on days 1 to 7 (starting the day before chemotherapy for 7 days in total). Local policy may vary. Fludarabine given intravenously on days 2 to 6 followed by Cytarabine. Cytarabine given intravenously on days 2 to 6. Total of 5 doses. Idarubicin is given intravenously on days 4, 5 and 6. Total of 3 doses or less. This is guven for a maximum of 2 cycles depending on blood counts. Where will I have treatment? ☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy) ✓ Tick all relevant boxes ☐ I confirm the patient has capacity to give consent. I have explained the course of treatment and intended benefit to the patient. **The intended benefits** (there are no guarantees about outcome) Prolong survival. Control symptoms, reduce transfusion needs and improve quality of life. Induction – therapy given in the acute state of the disease, aiming to shrink the tumour. Curative – to give you the best possible chance of being cured. Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control

Disease control / Palliative – the aim is not to cure but to control the disease and reduce the

symptoms. The aim is to improve both quality and quantity of life.

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Lisa Yuen Checked by Consultant: Eleni Tholouli

the symptoms.

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Patient identifier/label

| You may have one or more of the side effect  | ts listed   |
|--|---|
| Common side effects:   | Occasional side effects continued:  |
| Affecting more than 10 in every 100 (>10%) people  An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.  If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:  | <ul> <li>☐ This treatment increases the risk of temporary or occasionally permanent changes to the nervous system. Symptoms include fits, drowsiness, unsteadiness and mood changes. Inform your doctor or nurse.</li> <li>☐ Pain, redness and inflammation at the site of injection.</li> <li>Other risks:</li> </ul>  |
| your temperature goes over 37.5°C or     over 38°C depending on the advise given   | Cytarabine, Fludarabine, Idarubicin may leak  |
| over 38°C, depending on the advice given by your chemotherapy team • you suddenly feel unwell (even with a normal temperature)  Nausea (feeling sick), vomiting (being sick), abdominal (tummy) pain, diarrhoea, weight loss.  Thinning of hair or hair loss, cough.  Sore mouth and ulcers, weight loss, feeling tired and weak (fatigue), headache, chills, red colour | out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly.  Growth factors (GCSF) will be prescribed to maintain number of white cells to prevent   |
| urine for 1-2 days following treatment with  | infection. You may experience bone pain, headaches, red and itchy skin around the   |
| Idarubicin.  Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged and you may need a transfusion.  Changes in liver and kidney fuction (monitored).  Cytarabine syndrome can occur 6 to 12 hours after receiving Cytarabine. Symptoms include fever or chills, rash, pain in the eyes, bones, tummy and chest.    | injection site.  Late effects include a rare chance of a second cancer (years later) and problems with your heart.  Fludarabine depletes a certain type of cell in your blood (T-cells) and therefore you will require irradiated blood products if transfused.  Rarely, this treatment can cause changes in the lungs with shortness of breath, wheezing, cough or a fever. Please inform your doctor or |
| ☐ Inflammation of the lining of the eye lids (conjunctiva) making eyes feel sore, red and itchy (this is temporary). Steroid eye drops during and for 3 days after Cytarabine to prevent this will be given.   | nurse if you notice these symptoms.  There is an increased risk of tumour lysis syndrome in some patients when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests.   |
| Occasional side effects:   | Rarely, dialysis may be needed. You may be  |
| Affecting between 1-10 in every 100 (1-10%) people  Inflammation and ulcers of the opening at the end of the bowel (anus), sometimes can cause bleeding leading to severe infections.  Numbness and tingling in hands and feet, skin   | prescribed medicines for prevention or treatment.  Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so  |
| <ul> <li>changes (redness, itching sometimes blisters).</li> <li>Changes in eye sight (reversible), high uric acid levels.</li> <li>Rapid changes in heart rates (high or low), changes in the way the heart works with fluid build-up, shortness of breath, fast heart beat.</li> <li>Such symptoms can occur early on or within 2-</li> </ul>                          | infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.  Side effects of anti-sickness medication include diarrhoea, constipation, headaches.   |
| <ul> <li>3 months after treatment.</li> <li>Recovery of blood counts may be very slow and in rare cases recovery may be incomplete.</li> </ul>   | Continue on to the next page  |

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Patient identifier/label

# Statement of health professional

### Other risks continued:

| Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.  |
|--|
| Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.   |
| Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).   |
| Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone elase pregnant during treatment and for up to 7 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse. |
| Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.  |

| Patient  | identifi | iar/lahal |
|----------|----------|-----------|
| rallelli | ıaenını  | er/laber  |

| been provided:  Information leaflet for Fludarabine, Cytarabine, GCSF and Idarubicin  24 hour alert card or SACT advice service contact details  SACT treatment record (cruk.org/treatment-record)  Other, please state:  Statement of interpreter (where appropriate) Interpreter booking reference (if applicable): I have interpreted the information above to the patient to the best of my ability and in a way in which believe they can understand.  Signed:  Date:  Date: Da | Any other risks and information:  |   |
|--|---|---|
| available alternative treatments (including no treatment).    I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.    I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.    I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.    I have discussed concerns of particular importance to the patient in regard to treatment (please write details here):    Clinical management guideline/Protocol compliant (please tick):   Yes   |   |   |
| straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.  I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.  I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.  I have discussed concerns of particular importance to the patient in regard to treatment (please write details here):  Clinical management guideline/Protocol compliant (please tick):  Yes No Not available If No please document reason here:  The following written information has been provided:  Information leaflet for Fludarabine, Cytarabine, GCSF and Idarubicin  24 hour alert card or SACT advice service contact details  SACT treatment record (cruk.org/treatment-record)  Other, please state:  Statement of interpreter (where appropriate)  Interpreter booking reference (if applicable):  I have interpreted the information above to the patient to the best of my ability and in a way in which believe they can understand.  Signed:  Date:  Date:  |   | · · · · · · · · · · · · · · · · · · ·         |
| timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.  I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.  I have discussed concerns of particular importance to the patient in regard to treatment (please write details here):  Clinical management guideline/Protocol compliant (please tick):  Yes No Not available If No please document reason here:  The following written information has been provided:  Information leaflet for Fludarabine, Cytarabine, GCSF and Idarubicin  24 hour alert card or SACT advice service contact details  SACT treatment record (cruk.org/treatment-record)  Other, please state:  Statement of interpreter (where appropriate)  Interpreter booking reference (if applicable):  I have interpreted the information above to the patient to the best of my ability and in a way in which believe they can understand.  Signed:  Date:  Date:  | straight away or in the future, and that there may be                             | some side effects not listed because they are |
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| The following written information has been provided:   | (please write details here):  |   |
| 24 hour alert card or SACT advice service contact details   Job title:   Job title:  | The following written information has been provided:                              | Health professional details: Signed: Date:    |
| Other, please state:  Statement of interpreter (where appropriate) Interpreter booking reference (if applicable): I have interpreted the information above to the patient to the best of my ability and in a way in which believe they can understand.  Signed: Date:  | <ul> <li>24 hour alert card or SACT advice service<br/>contact details</li> </ul> | Name (PRINT):                                 |
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|  | Interpreter booking reference (if applicable):                                    |   |
| Name (PRINT): Job title:   | Signed:   | Date:   |
|  | Name (PRINT):   | Job title:                                    |

# Statement of patient

Patient identifier/label

| your own copy of the form which describes the be  | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form.               |
|---|--|
| ☐ I have had enough time to consider my optio   | ns and make a decision about treatment.  |
| ☐ I agree to the course of treatment described  | on this form.  |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo  | ole to sign but has indicated their consent. A person with bung people under the age of 16 years.  |
| Patient's signature:  |  |
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| Name (PRINT):   | want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to  |
| Job title:  | Friday, 9am to 5pm. Alternatively visit cruk.org for   |
| Important notes: (tick if applicable)  See also advance decision to refuse treatment  Patient has withdrawn consent (ask patient to sign and date here)   | more information.  These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT. |
| Signed: Date:   | The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.  |

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### **Guidance for health professionals**

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

### What a consent form is for

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- · retain that information in their mind
- use or weigh this information as a part of their decision making process, or

 communicate their decision (by talking, using sign language or any other means)

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FLAG + Idarubicin

| Patient agreement to systemic anti-cancer therapy (SACT)   | Patient details Patient's surname/family name:  Patient's first name(s):  |
|--|---|
| Gilteritinib (single agent)  | attent's mist hame(s).  |
|  | Date of birth:  |
|  | NHS number:   |
|  | (or other identifier)   |
| Hospital/NHS Trust/NHS Board:  | Special requirements: (eg other language/other communication method)  |
| Responsible consultant: Name:  |   |
| Job title:   |   |
| Name of proposed course of treatment (included and included as a second course of treatment (included and included as a second course of treatment (included and included as a second course of treatment is continued until disease progression of the course of treatment is continued until disease progression of the course of treatment included and included as a second course of treatment included and include | tive relapsed/resistant acute myeloid leukaemia supplied every 28 days (one cycle). or unacceptable side effects. |
| Statement of health profession (to be filled in by health professional with appropriate the hospital/Trust/NHS board's consent policy)  ✓ Tick all relevant boxes  ☐ I confirm the patient has capacity to give consent.  ☐ I have explained the course of treatment and inter-  | knowledge of proposed procedure, as specified in  |
| The intended benefits (there are no guarantees a   | about outcome)  |
| Prolong survival.  |   |
| Control symptoms, reduce transfusion needs and   |   |
| ☐ Induction – therapy given in the acute state of the ☐ Curative – to give you the best possible chance or   | _   |
|  | , aiming to prevent disease flaring up and to control   |
| the symptoms.  | 3 .   |

Disease control / Palliative – the aim is not to cure but to control the disease and reduce the

symptoms. The aim is to improve both quality and quantity of life.

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Elizabeth Davies Checked by Consultant: Eleni Tholouli Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version **Gilteritinib (single agent)** 

Patient identifier/label

| You may have one or more of the side effect  | ts listed  |
|--|--|
| Common side effects:   | Occasional side effects continued:   |
| Affecting more than 10 in every 100 (>10%) people  An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.  If you have a severe infection this can be  | Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.   |
| life-threatening. Contact your doctor or hospital straight away if:  | ☐ There may be an increased risk of tumour lysis syndrome in some patients when treatment  |
| <ul> <li>your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team</li> <li>you suddenly feel unwell (even with a normal temperature)</li> </ul>   | destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests.  Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.   |
| <ul> <li>Nausea (feeling sick), diarrhoea and/or constipation, feeling weak and tired (fatigue).</li> <li>☐ Feeling dizzy, low blood pressure.</li> <li>☐ Shortness of breath and/or cough, pain in muscle and joints, pain and fluid build-up in</li> </ul>   | Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have       |
| hands and feet.  Changes in liver function tests (monitored).  High level of creatine kinase in the blood (a type of protein present in blood if abnormal muscle and heart function).  | medicines to prevent or treat infection.  Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.  |
| Occasional side effects:  Affecting between 1-10 in every 100 (1-10%) people  Generally feeling unwell, allergic reactions, muscle stiffness.  | Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor   |
| <ul> <li>Changes in kidney function causing less urine to pass, swelling in the legs.</li> <li>Changes in the way the heart works, abnormal heart rhythms (QT prolongation). Contact your doctor if you have changes in your heartbeat, or if you feel dizzy, lightheaded, or faint. You may need an ECG (electrocardiogram).</li> </ul> | straight away if you have any symptoms.  Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).  Some anti-cancer medicines may damage the development of a baby in the womb. It is  |
| Gilteritinib can cause a condition called differentiation syndrome, which can be lifethreatening. Symptoms include temperature, shortness of breath, rapid breathing, build-up of fluid. You may be treated with steroids.   | important not to become pregnant or make someone else pregnant during treatment and for up to 6 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor       |
| Other risks:   | or nurse.  |
| <ul> <li>☐ A condition called posterior reversible encephalopathy syndrome (PRES) is a rare side effect. Symptoms include headaches, feeling confused, vision problems (including blindness), fits. Contact your doctor or nurse.</li> <li>☐ Side effects with the anti-sickness medication</li> </ul>                                   | Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also |
| may include: constipation, diarrhoea, headaches.   | be life-threatening.   |

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| Patient  | identifie | er/lahel |
|----------|-----------|----------|
| I auciii | IUCITUIL  | JI/Iabci |

| Any other risks and information:   |  |  |
|--|--|--|
|  |  |  |
| ☐ I have discussed the intended benefit and risks of available alternative treatments (including no treatments)  | · · · · · · · · · · · · · · · · · · ·  |  |
| ☐ I have discussed the side effects of the recomme<br>straight away or in the future, and that there may be<br>rare or have not yet been reported. Each patient ma | some side effects not listed because they are  |  |
| ☐ I have discussed what the treatment is likely to in timing of the treatment, blood and any additional test   | ` • • • • • • • • • • • • • • • • • • •  |  |
| ☐ I have explained to the patient, that they have the should contact the responsible consultant or team if   | ·  |  |
| ☐ I have discussed concerns of particular importan   | ice to the patient in regard to treatment  |  |
| (please write details here):   |  |  |
| Clinical management guideline/Protocol cor  Yes No Not available If No pleas  The following written information has been provided:                                 | mpliant (please tick): e document reason here:  Health professional details: Signed: |  |
| Information leaflet for Gilteritinib   | Date:  |  |
| ☐ 24 hour alert card or SACT advice service contact details  | Name (PRINT):  |  |
| SACT treatment record (cruk.org/treatment-record)  | Job title:   |  |
| Other, please state:   |  |  |
|  |  |  |
| Statement of interpreter (where a  |  |  |
| Statement of interpreter (where applicable): I have interpreted the information above to the patient believe they can understand.                                  |  |  |
| Signed:  | Date:  |  |
| Name (PRINT):  | Job title:   |  |
|  |  |  |

# Statement of patient

Patient identifier/label

| your own copy of the form which describes the be   | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form.  |
|--|---|
| ☐ I have had enough time to consider my optio  | ns and make a decision about treatment.   |
| ☐ I agree to the course of treatment described   | on this form.   |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo   | ole to sign but has indicated their consent. A person with bung people under the age of 16 years.   |
| Patient's signature:   |   |
| Name (PRINT):  | Date:   |
| Person with parental responsibility/witness' signa   | ature:  |
|  | Date:   |
| (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)  On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of | patients Contact details (if patient wishes to discuss options later):  Contact your hospital team if you have any  |
| treatment/procedures to go ahead. Signed:  | questions about cancer and its treatment.   |
| Date:  | Cancer Research UK can also help answer your questions about cancer and treatment. If you   |
| Name (PRINT):  | want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to   |
| Job title:   | Friday, 9am to 5pm. Alternatively visit cruk.org for  |
| Important notes: (tick if applicable)  See also advance decision to refuse treatment  Patient has withdrawn consent (ask patient to sign and date here)  Signed:   | more information.  These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.  The project is supported by |
| Date:  | Cancer Research UK.  This does not mean you are taking part in a clinical trial.  |

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Elizabeth Davies Checked by Consultant: Eleni Tholouli Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version **Gilteritinib (single agent)** 

### **Guidance for health professionals**

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

### What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

### The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

### Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

### When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- · retain that information in their mind
- use or weigh this information as a part of their decision making process, or

communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

#### Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

### **NHS Scotland**

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

### References

- 1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
- Cancer Research UK: cruk.org/aboutcancer/treatment/drugs
- Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

| Patient details Patient's surname/family name:  Patient's first name(s):  |
|---|
| Date of birth:  |
| NHS number:(or other identifier)  |
| Special requirements: (eg other language/other communication method)  |
|   |
|   |
| de brief explanation if medical term not clear) e treatment of acute myeloid leukaemia (AML). n days 1, 3 and 5. blood counts. and patients with underlying conditions at the  Other: |
| knowledge of proposed procedure, as specified in ded benefit to the patient. cout outcome)  mprove quality of life. disease, aiming to shrink the tumour.                             |
|   |

Disease control / Palliative – the aim is not to cure but to control the disease and reduce the

symptoms. The aim is to improve both quality and quantity of life.

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Lisa Yuen Checked by Consultant: Eleni Tholouli Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version **High dose Cytarabine (Ara C)** 

Patient identifier/label

### You may have one or more of the side effects listed

| Common side effects:   | Other risks:  |
|--|---|
| Common side effects:  Affecting more than 10 in every 100 (>10%) people  An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.  If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:  • your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team  • you suddenly feel unwell (even with a normal temperature)  Nausea (feeling sick), vomiting (being sick), abdominal (tummy) pain, diarrhoea, sore mouth and ulcers, difficulty swallowing, thinning of hair or hair loss.  Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged and you may need a transfusion.  Cytarabine syndrome can occur 6 to 12 hours after receiving Cytarabine. Symptoms include a high temperature or chills, rash, pain in the eyes, bones, tummy and chest. Inform your doctor or nurse.  Inflammation of the lining of the eye lids (conjunctiva) making eyes feel sore, red and itchy (this is temporary). Steroid eye drops during and for 3 days after Cytarabine to prevent this will be given.  Occasional side effects:  Inflammation and ulcers at the opening of the bowel (anus), sometimes can be severe leading to infections, skin changes (redness, itching sometimes blisters).  Changes in liver, kidney function (monitored).  High dose Cytarabine can cause temporary or occasionally permanent changes to the nervous system. Symptoms include seizures (fits), drowsiness, unsteadiness, mood changes. Inform your doctor or nurse. | Other risks:  ☐ Cytarabine may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly.  ☐ Also, this treatment can cause changes in the lungs with shortness of breath, wheezing, cough or a fever. Please inform your doctor or nurse if you notice these symptoms.  ☐ There is a risk of tumour lysis syndrome in some patients when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests. Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.  ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.  ☐ Late effects include a very rare chance of a second cancer (years later) and problems with your heart.  ☐ Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.  ☐ Side effects of anti-sickness medication include diarrhoea, constipation, headache.  ☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.  ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.  ☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal |
|  | dryness).   |
|  | Continue on to the next page  |

Date of issue: Mar-25; Version 2; Review date: Mar-28 To be retained in patient notes Prepared by Pharmacist: Alia Nizam Approved by: Janine Mansi UK SACT Board

Check cruk.org/sact\_consent for latest version High dose Cytarabine (Ara C)

Patient identifier/label

# Statement of health professional

### Other risks continued:

Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant up to 12 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout.

Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Lisa Yuen Checked by Consultant: Eleni Tholouli Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version

High dose Cytarabine (Ara C)

| Patient | iden | tifier | /lahel |  |
|---------|------|--------|--------|--|
| rauciii | IUCI | ıuııcı | /lauci |  |

| Any other risks and information:  |  |
|---|--|
|   | _  |
| ☐ I have discussed the intended benefit and risks of available alternative treatments (including no treatments)   |  |
| ☐ I have discussed the side effects of the recomme<br>straight away or in the future, and that there may be<br>rare or have not yet been reported. Each patient may | some side effects not listed because they are  |
| ☐ I have discussed what the treatment is likely to in timing of the treatment, blood and any additional test  | ` • • • • • • • • • • • • • • • • • • •  |
| ☐ I have explained to the patient, that they have the should contact the responsible consultant or team if  | •  |
| ☐ I have discussed concerns of particular importan  | ce to the patient in regard to treatment   |
| (please write details here):  |  |
| The following written information has been provided:  | npliant (please tick): e document reason here:  Health professional details: Signed: |
| ☐ Information leaflet for high dose Cytarabine ☐ 24 hour alert card or SACT advice service contact details  | Date:  |
|   | Name (PRINT):  |
| SACT treatment record (cruk.org/treatment-record)   | Job title:   |
| Other, please state:  |  |
|   |  |
| Statement of interpreter (where applicable): I have interpreted the information above to the patien   |  |
| believe they can understand.  | and and way in which   |
| Signed:   | Date:  |
| Name (PRINT):   | Job title:   |
|   |  |

# Statement of patient

Patient identifier/label

| your own copy of the form which describes the be   | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form.               |
|--|--|
| ☐ I have had enough time to consider my optio  | ns and make a decision about treatment.  |
| ☐ I agree to the course of treatment described   | on this form.  |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo   | ole to sign but has indicated their consent. A person with bung people under the age of 16 years.  |
| Patient's signature:   |  |
| Name (PRINT):  | Date:  |
| Person with parental responsibility/witness' signa   | ature:   |
| Name (PRINT):  | Date:  |
| (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)  On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of | patients Contact details (if patient wishes to discuss options later):  Contact your hospital team if you have any   |
| treatment/procedures to go ahead. Signed:  | questions about cancer and its treatment.  |
| Date:  | Cancer Research UK can also help answer your questions about cancer and treatment. If you  |
| Name (PRINT):  | want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to  |
| Job title:   | Friday, 9am to 5pm. Alternatively visit cruk.org for   |
| Important notes: (tick if applicable)  See also advance decision to refuse treatment  Patient has withdrawn consent (ask patient to sign and date here)  | more information.  These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT. |
| Signed: Date:  | The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.  |

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Lisa Yuen Checked by Consultant: Eleni Tholouli Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version **High dose Cytarabine (Ara C)** 

### **Guidance for health professionals**

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

### What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

### The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

### Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

### When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or

 communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

#### Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

### **NHS Scotland**

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

### References

- Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
- Cancer Research UK: cruk.org/aboutcancer/treatment/drugs
- Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

| Patient agreement to  | Patient details   |
|---|---|
| systemic anti-cancer therapy (SACT)   | Patient's surname/family name:  |
| High dose Cytarabine  | Patient's first name(s):  |
| (Ara C) and Amsacrine   | Date of birth:  |
|   |   |
|   | NHS number:(or other identifier)                                      |
| Hospital/NHS Trust/NHS Board:   | Special requirements  |
|   | Special requirements:  (eg other language/other communication method) |
| Responsible consultant:   |   |
| Name:   |   |
| Job title:  |   |
| Name of proposed course of treatment (incl  High dose Cytarabine (Ara C) and Amsacrine che resistant acute myeloid leukaemia (AML). | emotherapy for salvage therapy in relapsed or                         |
| ☐ High dose Cytarabine (Ara C) is given intravenou intravenously on days 1 to 3.  | usly on days 1 to 5 and Amsacrine is given                            |
| ☐ A minimum of 1 course is given. Consideration for   | or subsequent courses requires a consultant decision                  |
| Where will I have treatment?  ☐ Outpatient ☐ Day unit/case ☐ Inpatient  | ☐ Other:  |
|   |   |
| Statement of health professio   | nal   |
| (to be filled in by health professional with appropriate the hospital/Trust/NHS board's consent policy)                             |   |
| ☑ Tick all relevant boxes   |   |
| ☐ I confirm the patient has capacity to give consent  | t.  |
| $\hfill \square$ I have explained the course of treatment and integral $\hfill$   | ended benefit to the patient.   |
| The intended benefits (there are no guarantees  | about outcome)  |
| Prolong survival.   |   |
| Control symptoms, reduce transfusion needs and  |   |
| Induction – therapy given in the acute state of the   | _   |
| <ul><li>Curative – to give you the best possible chance</li><li>Maintenance – therapy given on continuing basis</li></ul>           | _   |

☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the

symptoms. The aim is to improve both quality and quantity of life.

To be retained in patient notes
Prepared by Pharmacist: Alia Nizam
Checked by Pharmacist: Elizabeth Davies
Checked by Consultant: Eleni Tholouli

the symptoms.

Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version High dose Cytarabine (Ara C) and Amsacrine

Patient identifier/label

| You may have one or more of the side effects listed   |   |  |  |
|---|---|--|--|
| Common side effects:  Affecting more than 10 in every 100 (>10%) people  An increased risk of getting an infection (including COVID-19) from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.  If you have a severe infection this can be life- threatening. Contact your doctor or hospital straight away if:  • your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team  • you suddenly feel unwell (even with a normal temperature)  Nausea (feeling sick) and vomiting (being sick), abdominal (tummy) pain, diarrhoea, sore mouth and ulcers.  Thinning of the hair or hair loss, red or brown spots on the skin (purpura). | Ccasional side effects continued:  Sudden frequent mood swings, blood in the urine, low potassium levels, shortness of breath, weight loss.  High dose Cytarabine can cause temporary or occasionally permanent changes to the nervous system. Symptoms include seizures (fits), drowsiness, unsteadiness and mood changes. Inform your doctor or nurse.  Other risks:  All intravenous drugs may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly.  There may be an increased risk of tumour lysis syndrome in some patients (when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests). |  |  |
| <ul> <li>□ Low blood pressure.</li> <li>□ Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged and you may need a transfusion.</li> <li>□ Changes in liver and kidney function (monitored).</li> <li>□ Cytarabine syndrome can occur 6 to 12 hours after receiving Cytarabine. Symptoms include a high temperature or chills, rash, pain in the eyes, bones, tummy and chest. Inform your doctor or nurse.</li> <li>□ Inflammation of the lining of the eye lids (conjunctiva) making eyes feel sore, red and itchy (this is temporary). Steroid eye drops during and for 3 days after Cytarabine to prevent this will be given.</li> </ul>                                  | Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.  Rarely, high dose Cytarabine can cause changes in the lungs with shortness of breath, wheezing, cough or a fever. Please contact your doctor or nurse if you notice these symptoms.  Side effects of anti-sickness medication include diarrhoea, constipation, headache.  Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.   |  |  |
| Occasional side effects:  Affecting between 1-10 in every 100 (1-10%) people  Inflammation and ulcers of the opening at the end of the bowel (anus), which can be severe leading to infections.  Skin changes (redness, itching sometimes blisters).  Changes in eye sight (reversible).  Changes in the way the heart works with symptoms of fluid build-up and shortness of breath, abnormal heart rhythm (fast heart rate).  | <ul> <li>Late effects include a very rare chance of a second cancer (years later) and problems with your heart.</li> <li>Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.</li> <li>Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.</li> </ul>   |  |  |

Continue on to the next page

Patient identifier/label

# Statement of health professional

#### Other risks continued:

| Cancer and its treatment can increase your risk   |
|---|
| of developing a blood clot (thrombosis), causing<br>pain, redness and swelling in an arm or leg,<br>breathlessness, chest pain. Tell your doctor<br>straight away if you have any symptoms.   |
| Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).  |
| Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for up to 6 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse. |
| Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.   |

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| Patient | INENTITIE | r/Ianei |
|         |           |         |

| Any other risks and information:   |  |  |  |
|--|--|--|--|
|  |  |  |  |
| ☐ I have discussed the intended benefit and risks of available alternative treatments (including no treatments)  |  |  |  |
| ☐ I have discussed the side effects of the recomme<br>straight away or in the future, and that there may be<br>rare or have not yet been reported. Each patient ma | some side effects not listed because they are  |  |  |
| ☐ I have discussed what the treatment is likely to in timing of the treatment, blood and any additional test   |  |  |  |
| ☐ I have explained to the patient, that they have the should contact the responsible consultant or team if   | •  |  |  |
| ☐ I have discussed concerns of particular importan   | ce to the patient in regard to treatment       |  |  |
| (please write details here):   |  |  |  |
| Clinical management guideline/Protocol con  Yes No Not available If No please  | npliant (please tick): e document reason here: |  |  |
| The following written information has been provided:  Information leafet for high dose Cytarabine  | Health professional details: Signed: Date:     |  |  |
| and Amsacrine  24 hour alert card or SACT advice service contact details   | Name (PRINT):                                  |  |  |
| SACT treatment record (cruk.org/treatment-record)  | Job title:                                     |  |  |
| Other, please state:   |  |  |  |
|  | 1  |  |  |
| Statement of interpreter (where ap   | opropriate)                                    |  |  |
| Interpreter booking reference (if applicable): I have interpreted the information above to the patient believe they can understand.                                |  |  |  |
| Signed:  | Date:  |  |  |
| Name (PRINT):  | Job title:                                     |  |  |

# Statement of patient

Patient identifier/label

| your own copy of the form which describes the be   | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form. |
|--|--|
| ☐ I have had enough time to consider my optio  | ns and make a decision about treatment.  |
| ☐ I agree to the course of treatment described   | on this form.  |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo   | ole to sign but has indicated their consent. A person with bung people under the age of 16 years.  |
| Patient's signature:   |  |
| Name (PRINT):  | Date:  |
| Person with parental responsibility/witness' signa   | iture:   |
| Name (PRINT):  | Date:  |
| (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)  On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of | patients Contact details (if patient wishes to discuss options later):  Contact your hospital team if you have any   |
| treatment/procedures to go ahead.  | questions about cancer and its treatment.  |
| Signed: Date:  | Cancer Research UK can also help answer your questions about cancer and treatment. If you  |
| Name (PRINT):  | want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to  |
| Job title:   | Friday, 9am to 5pm. Alternatively visit cruk.org for   |
| Important notes: (tick if applicable)  | more information.  |
| <ul> <li>☐ See also advance decision to refuse treatment</li> <li>☐ Patient has withdrawn consent (ask patient to sign and date here)</li> </ul>   | These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.      |
| Signed:  | The project is supported by  |
| Date:  | Cancer Research UK.  This does not mean you are taking part in a clinical trial.   |

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Elizabeth Davies Checked by Consultant: Eleni Tholouli

Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version **High dose Cytarabine (Ara C) and Amsacrine** 

### **Guidance for health professionals**

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

#### What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

#### The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

#### Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

#### When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or

 communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

#### Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

#### **NHS Scotland**

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

#### References

- Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
- Cancer Research UK: cruk.org/aboutcancer/treatment/drugs
- Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

### Patient agreement to **Patient details** systemic anti-cancer Patient's surname/family name: therapy (SACT) Patient's first name(s): Hydroxycarbamide Date of birth: NHS number: (or other identifier) **Hospital/NHS Trust/NHS Board:** Special requirements: (eg other language/other communication method) Responsible consultant: Name: Job title: Name of proposed course of treatment (include brief explanation if medical term not clear) Hydroxycarbamide as palliative chemotherapy\* or cytoreduction\* (\*delete as appropriate) for the treatment of acute myeloid leukaemia (AML). Hydroxycarbamide is taken orally each day. Treatment is continued until disease progression or unacceptable side effects. Where will I have treatment? ☐ Outpatient ☐ Day unit/case ☐ Inpatient Other: Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy) ✓ Tick all relevant boxes ☐ I confirm the patient has capacity to give consent. ☐ I have explained the course of treatment and intended benefit to the patient. **The intended benefits** (there are no guarantees about outcome) Prolong survival. Control symptoms, reduce transfusion needs and improve quality of life. Induction – therapy given in the acute state of the disease, aiming to shrink the tumour. Curative – to give you the best possible chance of being cured. Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control

Disease control / Palliative – the aim is not to cure but to control the disease and reduce the

symptoms. The aim is to improve both quality and quantity of life.

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Lisa Yuen Checked by Consultant: Eleni Tholouli

the symptoms.

Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version **Hydroxycarbamide** 

Patient identifier/label

| You may have one or more of the side effects listed   |  |  |  |
|---|--|--|--|
| Common side effects:  | Other risks:   |  |  |
| Affecting more than 10 in every 100 (>10%) people  An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.  If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if: | Increased risk of skin cancers if taking Hydroxycarbamide long term. Protect your skin from sun exposure and check your skin for any changes in appearance, new growths, or lesions (that may look like a wart), or change in the size or colour of a mole. Inform your doctor or nurse if you are worried about any new/enlarging skin growths or lesions.  |  |  |
| <ul> <li>your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team</li> <li>you suddenly feel unwell (even with a normal temperature)</li> </ul>  | Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.  |  |  |
| <ul> <li>Nausea (feeling sick), vomiting (being sick), indigestion, abdominal (tummy) pain, diarrhoea, constipation, dark stools.</li> <li>Sore mouth and ulcers, weight loss, feeling</li> </ul>   | Cancer and its treatment can increase your risk<br>of developing a blood clot (thrombosis), causing<br>pain, redness and swelling in an arm or leg,<br>breathlessness, chest pain. Tell your doctor<br>straight away if you have any symptoms.   |  |  |
| tired and weak (fatigue).   | ☐ Growth factors (GCSF) may be prescribed to   |  |  |
| <ul><li>Thinning of the hair or hair loss.</li><li>Skin changes (redness, rash, darkening, peeling, raised patches), skin ulcers (this is usually on the lower legs and feet).</li></ul>  | maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.  |  |  |
| <ul> <li>Nail changes (change in colour, thicker, thinner or brittle).</li> <li>Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged and you may need a transfusion.</li> <li>Pain when passing urine, changes in kidney function (monitored).</li> </ul>      | <ul> <li>□ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.</li> <li>□ Hydroxycarbamide can damage ovaries and sperm. This may lead to infertility and/or early</li> </ul>  |  |  |
| Occasional side effects:  Affecting between 1-10 in every 100 (1-10%) people  Changes in lungs function causing shortness of breath, cough.  Hallucinations, feeing disoriented.  Feeling drowsy, dizziness, headache, fits.  Changes in liver function (monitored).  | menopause (hot flushes, vaginal dryness).  Hydroxycarbamide may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment or for several months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception during this time. You can talk to your doctor or nurse about this.  Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening. |  |  |

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Lisa Yuen Checked by Consultant: Eleni Tholouli Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version **Hydroxycarbamide** 

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| Any other risks and information:   |   |
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|  |   |
| ☐ I have discussed the intended benefit and risks of available alternative treatments (including no treatments)  |   |
| ☐ I have discussed the side effects of the recomme<br>straight away or in the future, and that there may be<br>rare or have not yet been reported. Each patient ma | some side effects not listed because they are |
| ☐ I have discussed what the treatment is likely to in timing of the treatment, blood and any additional test   | ` • • • • • • • • • • • • • • • • • • •       |
| ☐ I have explained to the patient, that they have the should contact the responsible consultant or team if   | ·   |
| ☐ I have discussed concerns of particular importan   | ice to the patient in regard to treatment     |
| (please write details here):   |   |
|  | e document reason here:                       |
| The following written information has been provided:  Information leaflet for Hydroxycarbamide   | Health professional details: Signed: Date:    |
| 24 hour alert card or SACT advice service contact details  | Name (PRINT):                                 |
| SACT treatment record (cruk.org/treatment-record)  | Job title:                                    |
| Other, please state:   |   |
|  |   |
| Statement of interpreter (where a  | opropriato)                                   |
| Interpreter booking reference (if applicable): I have interpreted the information above to the patier believe they can understand.                                 |   |
| Signed:  | Date:   |
| Name (PRINT):  | Job title:                                    |
|  |   |

# Statement of patient

Patient identifier/label

| your own copy of the form which describes the be  | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form. |
|---|--|
| ☐ I have had enough time to consider my optio   | ns and make a decision about treatment.  |
| ☐ I agree to the course of treatment described  | on this form.  |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo  | ole to sign but has indicated their consent. A person with bung people under the age of 16 years.  |
| Patient's signature:  |  |
| Name (PRINT):   | Date:  |
| Person with parental responsibility/witness' signa  | iture:   |
| Name (PRINT):   | Date:  |
| Confirmation of consent (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance) On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of | Further information for patients Contact details (if patient wishes to discuss options later):   |
| treatment/procedures to go ahead.   | Contact your hospital team if you have any questions about cancer and its treatment.   |
| Signed: Date:   | Cancer Research UK can also help answer your questions about cancer and treatment. If you  |
| Name (PRINT):   | want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to  |
| Job title:  | Friday, 9am to 5pm. Alternatively visit cruk.org for   |
| Important notes: (tick if applicable)   | more information.  |
| <ul> <li>☐ See also advance decision to refuse treatment</li> <li>☐ Patient has withdrawn consent (ask patient to sign and date here)</li> </ul>  | These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.      |
| Signed:  Date:  | The project is supported by Cancer Research UK.  This does not mean you are  CANCER RESEARCH   |
|   | taking part in a clinical trial.   |

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Lisa Yuen Checked by Consultant: Eleni Tholouli Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version **Hydroxycarbamide** 

### **Guidance for health professionals**

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

#### What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

#### The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

#### Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

#### When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- · retain that information in their mind
- use or weigh this information as a part of their decision making process, or

 communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

#### Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

#### **NHS Scotland**

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

#### References

- 1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
- Cancer Research UK: cruk.org/aboutcancer/treatment/drugs
- Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Lisa Yuen Checked by Consultant: Eleni Tholouli Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version **Hydroxycarbamide** 

### Patient agreement to **Patient details** Patient's surname/family name: systemic anti-cancer therapy (SACT) Patient's first name(s): Ivosidenib and Azacitidine Date of birth: NHS number: (or other identifier) **Hospital/NHS Trust/NHS Board:** Special requirements: (eg other language/other communication method) Responsible consultant: Name: \_\_\_\_\_ Job title: Name of proposed course of treatment (include brief explanation if medical term not clear) Ivosidenib and azacitidine chemotherapy for the treatment of acute myeloid leukaemia (AML). Ivosidenib is taken orally once a day for 28 days. Azacitidine is given subcutaneously once a day on days 1 -7. Each treatment cycle lasts for 28 days. Treatment is continued until disease progression or unacceptable side effects. Response may be assessed by regular blood counts and possibly a bone marrow aspirate and biopsy. Where will I have treatment? Inpatient ☐ Outpatient ☐ Day unit/case Other: Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy) ✓ Tick all relevant boxes I confirm the patient has capacity to give consent. ☐ I have explained the course of treatment and intended benefit to the patient. **The intended benefits** (there are no guarantees about outcome) Prolong survival. Control symptoms, reduce transfusion needs and improve quality of life. Induction – therapy given in the acute state of the disease, aiming to shrink the tumour. Curative – to give you the best possible chance of being cured. Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control

Disease control / Palliative – the aim is not to cure but to control the disease and reduce the

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Lisa Yuen/Elizabeth Davies Checked by Consultant: Eleni Tholouli

symptoms. The aim is to improve both quality and quantity of life.

the symptoms.

Patient identifier/label

| You may have one or more of the side effects listed  |   |  |  |
|--|---|--|--|
| Common side effects:   | Other risks:  |  |  |
| Affecting more than 10 in every 100 (>10%) people  An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.  If you have a severe infection this can be lifethreatening. Contact your doctor or hospital straight away if:  • your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team  • you suddenly feel unwell (even with a normal temperature) | <ul> <li>There may be an increased risk of tumour lysis syndrome in some patients when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests. Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.</li> <li>Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have</li> </ul> |  |  |
| ☐ Vomiting (being sick).   | medicines to prevent or treat infection.  Side effects of anti-sickness medication include  |  |  |
| Headache, dizziness.   | diarrhoea, constipation, headache.  |  |  |
| ☐ Difficulty sleeping (insomnia).  | Late effects include a very rare chance of a second cancer (years later) and problems with  |  |  |
| <ul><li>☐ Pain in hands and feet, muscles and joints and back.</li><li>☐ Anaemia (due to low red blood cells) and bruising or bleeding caused by low number of</li></ul>   | your heart.  Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor   |  |  |
| platelets. This can be prolonged and you may need a transfusion.  Ivosidenib can cause differentiation syndrome which can be life-threatening. Symptoms include temperature, shortness of breath, rapid  | straight away if you have any symptoms.  Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.  |  |  |
| breathing, build-up of fluid with weight gain. You may be treated with steroids and Ivodesinib withheld or discontinued.   | Some anti-cancer medicines can damage<br>ovaries and sperm. This may lead to infertility<br>and/or early menopause (hot flushes, vaginal<br>dryness).   |  |  |
| □ Ivodesinib can cause changes in heart rhythm.<br>Contact your doctor if you have a change in<br>your heart beat, feel dizzy, lighheaded or faint.  | Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and  |  |  |
| ☐ With Azacitidine injection, you may notice pain, redness, itching, bruising and swelling.  | for up to 1 month after Ivodesinib and 6 months after Azacitidine. Women of child bearing age will be tested for pregnancy before and during  |  |  |
| Occasional side effects:  Affecting between 1-10 in every 100 (1-10%) people  Numbness and tingling in hands and feet.  Pain in the throat, mouth area.  | treatment. Use effective contraception throughout. Speak to your doctor or nurse.  Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.  |  |  |

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| Patient   | identifier/la | ahel |
|-----------|---------------|------|
| i aliciii |               | IDGI |

| ☐ Information leaflet for Ivosidenib and Azacitidine Date:   | Any other risks and information:  |   |
|--|---|---|
| I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.   I have discussed concerns of particular importance to the patient in regard to treatment (please write details here):  | available alternative treatments (including no treatments)  I have discussed the side effects of the recommendations are or in the future, and that there may be rare or have not yet been reported. Each patient materials I have discussed what the treatment is likely to in | ent). ended treatment, which could affect the patient some side effects not listed because they are y experience side effects differently. envolve (including inpatient/outpatient treatment, |
| The following written information has been provided:  Information leaflet for Ivosidenib and Azacitidine  24 hour alert card or SACT advice service contact details  SACT treatment record (cruk.org/treatment-record)  Other, please state:  Statement of interpreter (where appropriate)  Interpreter booking reference (if applicable):  I have interpreted the information above to the patient to the best of my ability and in a way in which believe they can understand.  Signed:  Date:  Name (PRINT):  Job title:  Job title:  I have interpreted the information above to the patient to the best of my ability and in a way in which believe they can understand.  Signed:  Date:  Date: Date: Date: Date: Date: Date: Date: Date: Date: Date: Date: Date: Date: Date: Date: Date: Date: Date: Date: D | ☐ I have explained to the patient, that they have the should contact the responsible consultant or team if ☐ I have discussed concerns of particular important  | e right to stop this treatment at any time and they wish to do so.  ce to the patient in regard to treatment  |
| 24 hour alert card or SACT advice service contact details   SACT treatment record (cruk.org/treatment-record)   Job title:   Job title:   Statement of interpreter (where appropriate)   | Yes ☐ No ☐ Not available If No please The following written information has been provided: ☐ Information leaflet for Ivosidenib and   | Health professional details:  Signed:   |
| Statement of interpreter (where appropriate) Interpreter booking reference (if applicable): I have interpreted the information above to the patient to the best of my ability and in a way in which believe they can understand.  Signed: Date:  | ☐ 24 hour alert card or SACT advice service   | Name (PRINT):   |
| Statement of interpreter (where appropriate) Interpreter booking reference (if applicable): I have interpreted the information above to the patient to the best of my ability and in a way in which believe they can understand.  Signed: Date:  |   |   |
| Statement of interpreter (where appropriate) Interpreter booking reference (if applicable): I have interpreted the information above to the patient to the best of my ability and in a way in which believe they can understand.  Signed: Date:  |   |   |
|  | Statement of interpreter (where applicable): I have interpreted the information above to the patient  |   |
|  | Signed:   | Date:   |
|  | Name (PRINT):   | Job title:  |

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# Statement of patient

Patient identifier/label

| your own copy of the form which describes the be  | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form.      |
|---|---|
| ☐ I have had enough time to consider my option  | ns and make a decision about treatment.   |
| ☐ I agree to the course of treatment described  | on this form.   |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo  | ole to sign but has indicated their consent. A person with bung people under the age of 16 years.   |
| Patient's signature:  |   |
| Name (PRINT):   | Date:   |
| Person with parental responsibility/witness' signa  | ature:  |
| Name (PRINT):   | Date:   |
| Confirmation of consent (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance) On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of | Further information for patients Contact details (if patient wishes to discuss options later):  Contact your hospital team if you have any  |
| treatment/procedures to go ahead. Signed:   | questions about cancer and its treatment.   |
| Date:   | Cancer Research UK can also help answer your questions about cancer and treatment. If you   |
| Name (PRINT):   | want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to   |
| Job title:  | Friday, 9am to 5pm. Alternatively visit cruk.org for  |
| Important notes: (tick if applicable)  See also advance decision to refuse treatment  Patient has withdrawn consent   | more information.  These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting |
| (ask patient to sign and date here)   | to SACT.  |
| Signed: Date:   | The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.   |

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### **Guidance for health professionals**

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

#### What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

#### The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

#### Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

#### When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- · retain that information in their mind
- use or weigh this information as a part of their decision making process, or

 communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

#### Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

#### **NHS Scotland**

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

#### References

- Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
- Cancer Research UK: cruk.org/aboutcancer/treatment/drugs
- Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Elizabeth Davies Checked by Consultant: Eleni Tholouli Date of issue: Mar-25; Version 1; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact consent for latest version

Ivosidenib and Azacitidine

### Patient agreement to **Patient details** Patient's surname/family name: systemic anti-cancer therapy (SACT) Patient's first name(s): **Liposomal Daunorubicin** and Cytarabine (Vyxeos) Date of birth: NHS number: (or other identifier) **Hospital/NHS Trust/NHS Board:** Special requirements: (eg other language/other communication method) Responsible consultant: Name: \_\_\_\_ Job title: \_\_\_\_\_ Name of proposed course of treatment (include brief explanation if medical term not clear) Liposomal Daunorubicin and Cytarabine (Vyxeos) chemotherapy for the treatment of newly diagnosed acute myeloid leukaemia (AML). INDUCTION 1: Liposomal Daunorubicin and Cytarabine (Vyxeos) is given intravenously on days 1, 3 and 5. INDUCTION 2: Liposomal Daunorubicin and Cytarabine (Vyxeos) is given intravenously on days 1 and 3, if needed. CONSOLIDATION: Liposomal Daunorubicin and Cytarabine (Vyxeos) is given intravenously on days 1 and 3. Where will I have treatment? ☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy) ✓ Tick all relevant boxes ☐ I confirm the patient has capacity to give consent. I have explained the course of treatment and intended benefit to the patient. **The intended benefits** (there are no guarantees about outcome) Prolong survival. Control symptoms, reduce transfusion needs and improve quality of life. Induction – therapy given in the acute state of the disease, aiming to shrink the tumour. Curative – to give you the best possible chance of being cured. Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control

Disease control / Palliative – the aim is not to cure but to control the disease and reduce the

symptoms. The aim is to improve both quality and quantity of life.

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the symptoms.

Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version Liposomal Daunorubicin and Cytarabine (Vyxeos)

Patient identifier/label

| You may have one or more of the side effects listed   |  |  |
|---|--|--|
| Common side effects:  | Occasional side effects continued:   |  |
| Affecting more than 10 in every 100 (>10%) people  An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.  If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:   | redness or swelling around the vein. It's uncommon but important to deal with quickly.  Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have   |  |
| <ul> <li>your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team</li> <li>you suddenly feel unwell (even with a normal temperature)</li> <li>Nausea (feeling sick), vomiting (being sick), sore mouth and ulcers, reduced appetite, abdominal (tummy) pain, diarrhoea, constipation.</li> <li>Allergic reactions (including rash), shortness of breath, cough, fluid in the lungs, generalised swelling with swelling in your arms and legs.</li> <li>Itching, excessive sweating, feeling tired and weak (fatigue), pain in muscle and joints, changes in eye sight.</li> <li>Headache, dizziness, difficulty sleeping, feeling anxious and confused with reduced awareness of environment.</li> <li>Changes in the way the heart works, abnormal heart rhythm (fast heart rate), chest pain, low or high blood pressure.</li> <li>Changes in kidney function (monitored), bleeding (most commonly nose bleed).</li> </ul> | medicines to prevent or treat infection.  Recovery of blood counts may be very slow and in rare cases recovery may be incomplete.  Late effects include a very rare chance of a second cancer (years later) and problems with your heart.  Side effects of anti-sickness medication include diarrhoea, constipation, headache.  Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.  Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.  Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.  Some anti-cancer medicines can damage |  |
| Occasional side effects:  Affecting between 1-10 in every 100 (1-10%) people  Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged and may require transfusion.  Thinning of the hair or hair loss, night sweats, indigestion.  There is an increased risk of tumour lysis syndrome in some patients when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests.  Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.   | ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).  Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for atleast 6 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse.  Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every   |  |
| Other risks:  This treatment may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain,   | individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.  |  |

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Lisa Yuen Checked by Consultant: Eleni Tholouli Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version Liposomal Daunorubicin and Cytarabine (Vyxeos)

| D - 41 4 | identifier/ | /  _   _ |
|----------|-------------|----------|
| Patient  | IMANTITIAN  | /Ianai   |
|          |             |          |

| Any other risks and information:   |   |  |
|--|---|--|
|  |   |  |
| ☐ I have discussed the intended benefit and risks of available alternative treatments (including no treatments)  | •   |  |
| ☐ I have discussed the side effects of the recomme<br>straight away or in the future, and that there may be<br>rare or have not yet been reported. Each patient ma | some side effects not listed because they are         |  |
| ☐ I have discussed what the treatment is likely to in timing of the treatment, blood and any additional test   | · • · · · · · · · · · · · · · · · · · ·               |  |
| ☐ I have explained to the patient, that they have the should contact the responsible consultant or team if   | · ·   |  |
| ☐ I have discussed concerns of particular importan   | ce to the patient in regard to treatment              |  |
| (please write details here):   | ·   |  |
| The following written information has  | e document reason here:  Health professional details: |  |
| been provided:  Information leaflet for Liposomal Daunorubicin and Cytarabine (Vyxeous)  | Signed:   |  |
| 24 hour alert card or SACT advice service contact details  | Name (PRINT):   |  |
| SACT treatment record (cruk.org/treatment-record)  | Job title:  |  |
| Other, please state:   |   |  |
| Statement of interpreter (where applicable): I have interpreted the information above to the patient believe they can understand.                                  |   |  |
| Signed:  | Date:   |  |
| Name (PRINT):  | Job title:  |  |

# Statement of patient

Patient identifier/label

| your own copy of the form which describes the be   | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form. |
|--|--|
| ☐ I have had enough time to consider my optio  | ns and make a decision about treatment.  |
| ☐ I agree to the course of treatment described   | on this form.  |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo   | ole to sign but has indicated their consent. A person with bung people under the age of 16 years.  |
| Patient's signature:   |  |
| Name (PRINT):  | Date:  |
| Person with parental responsibility/witness' signa   | ature:   |
| Name (PRINT):  | Date:  |
| (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)  On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of | patients Contact details (if patient wishes to discuss options later):  Contact your hospital team if you have any   |
| treatment/procedures to go ahead. Signed:  | questions about cancer and its treatment.  |
| Date:  | Cancer Research UK can also help answer your questions about cancer and treatment. If you  |
| Name (PRINT):  | want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to  |
| Job title:   | Friday, 9am to 5pm. Alternatively visit cruk.org for   |
| Important notes: (tick if applicable)  | more information.  |
| <ul><li>☐ See also advance decision to refuse treatment</li><li>☐ Patient has withdrawn consent (ask patient to sign and date here)</li></ul>  | These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.      |
| Signed:  | The project is supported by Cancer Research UK.  |
| Date:  | Cancer Research UK.  This does not mean you are taking part in a clinical trial.   |

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Lisa Yuen Checked by Consultant: Eleni Tholouli Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version Liposomal Daunorubicin and Cytarabine (Vyxeos)

### **Guidance for health professionals**

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

#### What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

#### The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

#### Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

#### When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- · retain that information in their mind
- use or weigh this information as a part of their decision making process, or

 communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

#### Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

#### **NHS Scotland**

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

#### References

- 1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
- Cancer Research UK: cruk.org/aboutcancer/treatment/drugs
- Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

| Patient agreement to systemic anti-cancer therapy (SACT)  Low dose Cytarabine (Ara C)  | Patient details Patient's surname/family name:  Patient's first name(s):  Date of birth:   |  |
|--|--|--|
| Hospital/NHS Trust/NHS Board:  | NHS number: (or other identifier)  Special requirements: (eg other language/other communication method)  |  |
| Responsible consultant: Name:  Job title:  |  |  |
| Name of proposed course of treatment (inclination of the course of treatment). Low dose Cytarabine (Ara C) is used as non-cura (intermediate, high risk disease)* or CMML-2 * (*deleting of the course | ative/palliative chemotherapy for AML* or MDS ete as appropriate). ach day* or once a day* (*delete as appropriate) on e is no maximum cycle number OR             |  |
| Statement of health profession  (to be filled in by health professional with appropriate the hospital/Trust/NHS board's consent policy)  ☑ Tick all relevant boxes ☐ I confirm the patient has capacity to give consent ☐ I have explained the course of treatment and inte  The intended benefits (there are no guarantees ☐ Prolong survival. ☐ Control symptoms, reduce transfusion needs and ☐ Induction – therapy given in the acute state of the ☐ Curative – to give you the best possible chance of ☐ Maintenance – therapy given on continuing basis the symptoms.  | e knowledge of proposed procedure, as specified in ended benefit to the patient. about outcome) d improve quality of life. e disease, aiming to shrink the tumour. |  |

Disease control / Palliative – the aim is not to cure but to control the disease and reduce the

symptoms. The aim is to improve both quality and quantity of life.

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Lisa Yuen Checked by Consultant: Eleni Tholouli Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version **Low dose Cytarabine (Ara C)** 

Patient identifier/label

| You may have one or more of the side effects listed   |   |  |
|---|---|--|
| Common side effects:  | Other risks:  |  |
| Affecting more than 10 in every 100 (>10%) people  ☐ An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.  ☐ If you have a severe infection this can be   | There is an increased risk of tumour lysis syndrome in some patients when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests. Rarely, dialysis may be needed. You may be   |  |
| life-threatening. Contact your doctor or hospital straight away if:   | prescribed medicines for prevention or treatment.  Before treatment you may have blood tests to   |  |
| your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team     you suddenly feel unwell (even with a normal temperature)  Nausea (feeling sick), vomiting (being sick), abdominal (tummy) pain, diarrhoea, difficulty swallowing.  Sore mouth and ulcers, skin rash.  Thinning of the hair or hair loss.  Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged and you may need a transfusion.  Pain, swelling and redness at the injection site.  Occasional side effects:  Affecting between 1-10 in every 100 (1-10%) people  More severe skin changes (redness, itching sometimes blisters).  Weight loss.  Inflammation and ulcers of the opening at the end of the bowel (anus).  Changes in kidney and liver function (monitored). | check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.  Side effects of anti-sickness medication include diarrhoea, constipation, headache.  Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.  Late effects include a very rare chance of a second cancer (years later) and problems with your heart.  Rarely, Cytarabine can cause changes in the lungs with shortness of breath, wheezing, cough or fever. Please inform your doctor or nurse if you notice these symptoms.  Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.  Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).  Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for up to 6 months afterwards. Use effective contraception throughout. Speak to your doctor or nurse.  Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening. |  |

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Lisa Yuen Checked by Consultant: Eleni Tholouli Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version Low dose Cytarabine (Ara C)

| Patient  | identifi | iar/lahal |
|----------|----------|-----------|
| rallelli | ıaenını  | er/laber  |

| Any other risks and information:  |   |  |
|---|---|--|
|   |   |  |
| ☐ I have discussed the intended benefit and risks of available alternative treatments (including no treatments)   |   |  |
| ☐ I have discussed the side effects of the recommendation of the straight away or in the future, and that there may be rare or have not yet been reported. Each patient may | some side effects not listed because they are                                 |  |
| ☐ I have discussed what the treatment is likely to it timing of the treatment, blood and any additional test  | ,                                       |  |
| ☐ I have explained to the patient, that they have the should contact the responsible consultant or team if  | ·   |  |
| ☐ I have discussed concerns of particular importan  | nce to the patient in regard to treatment                                     |  |
| (please write details here):  |   |  |
| Clinical management guideline/Protocol cor  Yes No Not available If No pleas  The following written information has   | mpliant (please tick): se document reason here:  Health professional details: |  |
| been provided:  | Signed:   |  |
| ☐ Information leaflet for Low dose Cytarabine (Ara C)   | Date:   |  |
| ☐ 24 hour alert card or SACT advice service contact details   | Name (PRINT):   |  |
| ☐ SACT treatment record (cruk.org/treatment-record)   | Job title:  |  |
| Other, please state:  |   |  |
| Statement of interpreter (where a Interpreter booking reference (if applicable): I have interpreted the information above to the patier believe they can understand.        |   |  |
| Signed:   | Date:   |  |
| Name (PRINT):   | Job title:  |  |

# Statement of patient

Patient identifier/label

| your own copy of the form which describes the be   | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form.               |
|--|--|
| ☐ I have had enough time to consider my optio  | ns and make a decision about treatment.  |
| ☐ I agree to the course of treatment described   | on this form.  |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo   | ble to sign but has indicated their consent. A person with bung people under the age of 16 years.  |
| Patient's signature:   |  |
| Name (PRINT):  | Date:  |
| Person with parental responsibility/witness' signa   | ature:   |
| Name (PRINT):  | Date:  |
| (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)  On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of | patients Contact details (if patient wishes to discuss options later):  Contact your hospital team if you have any   |
| treatment/procedures to go ahead. Signed:  | questions about cancer and its treatment.  |
| Date:  | Cancer Research UK can also help answer your questions about cancer and treatment. If you  |
| Name (PRINT):  | want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to  |
| Job title:   | Friday, 9am to 5pm. Alternatively visit cruk.org for   |
| Important notes: (tick if applicable)  See also advance decision to refuse treatment  Patient has withdrawn consent (ask patient to sign and date here)  | more information.  These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT. |
| Signed: Date:  | The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.  |

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Lisa Yuen Checked by Consultant: Eleni Tholouli Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version Low dose Cytarabine (Ara C)

### **Guidance for health professionals**

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

#### What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

#### The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

#### Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

#### When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or

 communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

#### Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

#### **NHS Scotland**

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

#### References

- Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
- Cancer Research UK: cruk.org/aboutcancer/treatment/drugs
- Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Lisa Yuen Checked by Consultant: Eleni Tholouli Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version **Low dose Cytarabine (Ara C)** 

### Patient agreement to **Patient details** Patient's surname/family name: systemic anti-cancer therapy (SACT) Patient's first name(s): Low dose Cytarabine (Ara C) and Venetoclax Date of birth: NHS number: (or other identifier) **Hospital/NHS Trust/NHS Board:** Special requirements: (eg other language/other communication method) Responsible consultant: Name: \_\_\_\_ Job title: Name of proposed course of treatment (include brief explanation if medical term not clear) Low dose Cytarabine (Ara C) and Venetoclax for the treatment of acute myeloid leukaemia (AML). Cycle 1: Cytarabine (Ara C) is given subcutaneously once a day on days 1 -10. Venetoclax is taken orally from days 1 to 28. Cycle 2: Cytarabine is given subcutaneously once daily on days 1-10. Venetoclax is taken orally from days 1 to 28. Your doctor may adjust the number of days, depending on your blood results. Treatment is continued until disease progression or unacceptable side effects. Where will I have treatment? ☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy) ✓ Tick all relevant boxes ☐ I confirm the patient has capacity to give consent. ☐ I have explained the course of treatment and intended benefit to the patient. **The intended benefits** (there are no guarantees about outcome) Prolong survival. Control symptoms, reduce transfusion needs and improve quality of life. Induction – therapy given in the acute state of the disease, aiming to shrink the tumour. Curative – to give you the best possible chance of being cured.

Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control

Disease control / Palliative – the aim is not to cure but to control the disease and reduce the

symptoms. The aim is to improve both quality and quantity of life.

To be retained in patient notes
Prepared by Pharmacist: Alia Nizam
Checked by Pharmacist: Elizabeth Davies
Checked by Consultant: Eleni Tholouli

the symptoms.

Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version Low dose Cytarabine (Ara C) and Venetoclax

Patient identifier/label

| You may have one or more of the side effects listed  |   |  |
|--|---|--|
| Common side effects:   | Other risks:  |  |
| Common side effects:  Affecting more than 10 in every 100 (>10%) people  An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.  If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:  • your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team  • you suddenly feel unwell (even with a normal temperature)  Nausea (feeling sick), vomiting (being sick), abdominal (tummy) pain, diarrhoea, constipation.  Sore mouth and ulcers, feeling tired and weak (fatigue), thinning of the hair or hair loss.  Anaemia (due to low red blood cells) and bruising or bleeding (due to low platelets); this can be prolonged and you may need a transfusion.  High potassium, high phosphate, low calcium levels, high bilirubin, changes in liver function – Picked up in blood tests and monitored.  Inflammation and ulcers of the opening end of the bowel (anus).  Pain, swelling and redness at the injection site, skin rash, dizziness, low blood pressure, | Other risks:  ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.  ☐ Side effects of anti-sickness medication include diarrhoea, constipation, headache.  ☐ Late effects include a very rare chance of a second cancer (years later) and problems with your heart.  ☐ Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.  ☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.  ☐ Rarely, Cytarabine can cause changes in the lungs with shortness of breath, wheezing, cough or fever. Please inform your doctor or nurse if you notice these symptoms.  ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor |  |
| Shortness of breath, joint pain.  Occasional side effects:  Affecting between 1-10 in every 100 (1-10%) people  More severe skin changes (redness, itching sometimes blisters).  There may be an increased risk of tumour lysis syndrome in some patients (when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests). Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.  Weight loss.  Changes in kidney function (monitored).  Development of gall stones, inflammation of the gall bladder.   | straight away if you have any symptoms.  Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).  Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for up to 6 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse.  Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.   |  |

| Patient identifier/label |  |
|--------------------------|--|
|--------------------------|--|

| Any other risks and information:  |   |  |
|---|---|--|
|   |   |  |
| ☐ I have discussed the intended benefit and risks available alternative treatments (including no treatments)  |   |  |
| ☐ I have discussed the side effects of the recomm<br>straight away or in the future, and that there may be<br>rare or have not yet been reported. Each patient ma   | e some side effects not listed because they are |  |
| ☐ I have discussed what the treatment is likely to it timing of the treatment, blood and any additional test  | ` • • • • • • • • • • • • • • • • • • •         |  |
| ☐ I have explained to the patient, that they have the should contact the responsible consultant or team in  | ·   |  |
| ☐ I have discussed concerns of particular importan  | nce to the patient in regard to treatment       |  |
| (please write details here):  |   |  |
| Clinical management guideline/Protocol co  Yes No Not available If No pleas   | mpliant (please tick): se document reason here: |  |
| The following written information has been provided:  Information leaflet for Low dose Cytarabine (Ara C) and Venetoclax  | Health professional details: Signed: Date:      |  |
| 24 hour alert card or SACT advice service contact details   | Name (PRINT):                                   |  |
| ☐ SACT treatment record (cruk.org/treatment-record)   | Job title:                                      |  |
| Other, please state:  |   |  |
|   |   |  |
| Statement of interpreter (where a Interpreter booking reference (if applicable): I have interpreted the information above to the patie believe they can understand. |   |  |
| Signed:   | Date:   |  |
| Name (PRINT):   | Job title:                                      |  |

# Statement of patient

Patient identifier/label

| your own copy of the form which describes the be   | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form.               |  |
|--|--|--|
| ☐ I have had enough time to consider my optio  | ns and make a decision about treatment.  |  |
| ☐ I agree to the course of treatment described   | on this form.  |  |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo   | ole to sign but has indicated their consent. A person with bung people under the age of 16 years.  |  |
| Patient's signature:   |  |  |
| Name (PRINT):  | Date:  |  |
| Person with parental responsibility/witness' signa   | ature:   |  |
| Name (PRINT):  | Date:  |  |
| (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)  On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of | patients Contact details (if patient wishes to discuss options later):  Contact your hospital team if you have any   |  |
| treatment/procedures to go ahead. Signed:  | questions about cancer and its treatment.  |  |
| Date:  | Cancer Research UK can also help answer your questions about cancer and treatment. If you  |  |
| Name (PRINT):  | want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to  |  |
| Job title:   | Friday, 9am to 5pm. Alternatively visit cruk.org for   |  |
| Important notes: (tick if applicable)  See also advance decision to refuse treatment  Patient has withdrawn consent (ask patient to sign and date here)  | more information.  These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT. |  |
| Signed: Date:  | The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.  |  |

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Elizabeth Davies Checked by Consultant: Eleni Tholouli

Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version Low dose Cytarabine (Ara C) and Venetoclax

### **Guidance for health professionals**

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

#### What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

#### The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

#### Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

#### When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or

 communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

#### Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

#### **NHS Scotland**

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

#### References

- Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
- Cancer Research UK: cruk.org/aboutcancer/treatment/drugs
- Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

| Patient agreement to systemic anti-cancer therapy (SACT) MACE (Amsacrine,   | Patient details Patient's surname/family name:  ———————————————————————————————————                |
|---|--|
| Cytarabine, Etoposide)  | Date of birth:   |
|   | NHS number: (or other identifier)  |
| Hospital/NHS Trust/NHS Board:   | Special requirements:  (eg other language/other communication method)                              |
| Responsible consultant: Name:   |  |
| Job title:  |  |
|   | chemotherapy for acute myeloid leukaemia (AML). n intravenously on days 1 to 5 (total of 5 doses). |
| Statement of health profession (to be filled in by health professional with appropriate the hospital/Trust/NHS board's consent policy)  ✓ Tick all relevant boxes  ☐ I confirm the patient has capacity to give conse                               | ate knowledge of proposed procedure, as specified in ent.  |
| The intended benefits (there are no guarantee   | ·  |
| Prolong survival.   | •  |
| <ul> <li>☐ Control symptoms, reduce transfusion needs a</li> <li>☐ Induction – therapy given in the acute state of t</li> <li>☐ Curative – to give you the best possible chance</li> <li>☐ Maintenance – therapy given on continuing has</li> </ul> | the disease, aiming to shrink the tumour.  |
| the symptoms.   | sis, anning to prevent disease naming up and to control  |

Disease control / Palliative – the aim is not to cure but to control the disease and reduce the

symptoms. The aim is to improve both quality and quantity of life.

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Elizabeth Davies Checked by Consultant: Eleni Tholouli Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version MACE (Amsacrine, Cytarabine, Etoposide)

Patient identifier/label

| You may have one or more of the side effects listed  |  |  |
|--|--|--|
| Common side effects:  Affecting more than 10 in every 100 (>10%) people  An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.  If you have a severe infection this can be lifethreatening. Contact your doctor or hospital straight away if:  • your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team  • you suddenly feel unwell (even with a normal temperature)  Nausea (feeling sick), vomiting (being sick), abdominal (tummy) pain, constipation, diarrhoea, weight loss.  Thinning of the hair or hair loss, sore mouth and ulcers, tiredness and feeling weak (fatigue), skin changes (change in colour, red or brown spots, rash).  Anaemia (low number of red blood cells) and bruising or bleeding (low number of platelets); this can be prolonged and you may need a transfusion.  Changes in liver and kidney function (monitored).  Low blood pressure, pain, redness, swelling at the injection of site.  Cytarabine syndrome can occur 6 to 12 hours after receiving cytarabine. Symptoms include a high temperature or chills, rash, pain in the eyes, bones, tummy and chest. Inform your | Occasional side effects continued:  Inflammation and ulcers of the opening at the end of the bowel (anus).  Severe skin changes (redness, itching sometimes blisters), dizziness, shortness of breath.  Sudden frequent mood swings, blood in the urine, low potassium levels.  Other risks:  All intravenous drugs may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly.  There may be an increased risk of tumour lysis syndrome in some patients (when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests). Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.  Late effects include a very rare chance of a second cancer (years later) and problems with your heart.  Side effects of anti-sickness medication include diarrhoea, constipation, headache.  Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become |  |
| doctor or nurse.  Occasional side effects:  Affecting between 1-10 in every 100 (1-10%) people  Allergic reactions to etoposide. This can be severe and can occur immediately or a few hours later. Symptoms include difficulty in breathing, rapid heart rate, sweating, temperature, high or low blood pressure, feeling sick and being sick, rash or itching affecting the whole body, occasionally swelling of the face.  Heart problems including changes in heart rhythm, risk of a heart attack, risk of heart failure with symptoms of fluid build-up and shortness of breath, high blood pressure.  Blood pressure may drop if intravenous etoposide given to quickly.  | active if you've had them before. You may be given medicines to prevent infecion.  Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.  Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.  Rarely, Cytarabine can cause changes in the lungs with shortness of breath, wheezing, cough or fever. Please inform your doctor or nurse if you notice these symptoms.   |  |

Continue on to the next page

Patient identifier/label

# Statement of health professional

#### Other risks continued:

| Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms. Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal |
|---|
| dryness).   |
| Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for up to 6 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse.     |
| Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.   |

| D-4:4   | : -1 4:4:  | /  _   _ |
|---------|------------|----------|
| Patient | identifier | /Ianei   |
|         |            |          |

| Any other risks and information:  |  |  |
|---|--|--|
|   |  |  |
| ☐ I have discussed the intended benefit and risks available alternative treatments (including no treatments)  | •  |  |
| ☐ I have discussed the side effects of the recomm<br>straight away or in the future, and that there may be<br>rare or have not yet been reported. Each patient ma   | e some side effects not listed because they are    |  |
| ☐ I have discussed what the treatment is likely to i timing of the treatment, blood and any additional test   |  |  |
| ☐ I have explained to the patient, that they have the should contact the responsible consultant or team in  | •  |  |
| ☐ I have discussed concerns of particular importan  | nce to the patient in regard to treatment          |  |
| (please write details here):  |  |  |
| Clinical management guideline/Protocol co   | mpliant (please tick):<br>se document reason here: |  |
| The following written information has been provided:  Information leaflet for MACE (Amsacrine, Cytarabine and Etoposide)  | Health professional details: Signed: Date:         |  |
| ☐ 24 hour alert card or SACT advice service contact details   | Name (PRINT):                                      |  |
| SACT treatment record (cruk.org/treatment-record)   | Job title:   |  |
| Other, please state:  |  |  |
|   |  |  |
| Statement of interpreter (where a Interpreter booking reference (if applicable): I have interpreted the information above to the patie believe they can understand. |  |  |
| Signed:   | Date:  |  |
| Name (PRINT):   | Job title:   |  |

# Statement of patient

Patient identifier/label

| your own copy of the form which describes the be   | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form. |  |
|--|--|--|
| ☐ I have had enough time to consider my optio  | ns and make a decision about treatment.  |  |
| ☐ I agree to the course of treatment described   | on this form.  |  |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo   | ole to sign but has indicated their consent. A person with bung people under the age of 16 years.  |  |
| Patient's signature:   |  |  |
| Name (PRINT):  | Date:  |  |
| Person with parental responsibility/witness' signa   | iture:   |  |
| Name (PRINT):  | Date:  |  |
| (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)  On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of | patients Contact details (if patient wishes to discuss options later):  Contact your hospital team if you have any   |  |
| treatment/procedures to go ahead. Signed:  | questions about cancer and its treatment.  |  |
| Date:  | Cancer Research UK can also help answer your questions about cancer and treatment. If you  |  |
| Name (PRINT):  | want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to  |  |
| Job title:   | Friday, 9am to 5pm. Alternatively visit cruk.org for   |  |
| Important notes: (tick if applicable)  | more information.  |  |
| <ul> <li>☐ See also advance decision to refuse treatment</li> <li>☐ Patient has withdrawn consent (ask patient to sign and date here)</li> </ul>   | These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.      |  |
| Signed:  | The project is supported by  |  |
| Date:  | Cancer Research UK.  This does not mean you are taking part in a clinical trial.   |  |

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Elizabeth Davies Checked by Consultant: Eleni Tholouli

Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version MACE (Amsacrine, Cytarabine, Etoposide)

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

#### What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

#### The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

#### Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

#### When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- · retain that information in their mind
- use or weigh this information as a part of their decision making process, or

 communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

#### Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

#### **NHS Scotland**

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

#### References

- Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
- Cancer Research UK: cruk.org/aboutcancer/treatment/drugs
- Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

| Patient agreement to systemic anti-cancer therapy (SACT)   | Patient details Patient's surname/family name:  Patient's first name(s):                                    |  |
|--|---|--|
| MEC (Mitoxantrone,   |   |  |
| <b>Etoposide and Cytarabine)</b>   | Date of birth:  |  |
|  | l   |  |
|  | NHS number: (or other identifier)   |  |
| Hospital/NHS Trust/NHS Board:  | Special requirements: (eg other language/other communication method)  |  |
| Responsible consultant: Name:  |   |  |
| Job title:   |   |  |
| <ul><li></li></ul>   | For the treatment of acute myeloid leukemia (AML). en intravenously on days 1 to 5 (total of 5 doses each). |  |
| Where will I have treatment?  ☐ Outpatient ☐ Day unit/case ☐ Inpatient   | Other:  |  |
| Statement of health professio (to be filled in by health professional with appropriate the hospital/Trust/NHS board's consent policy)  Tick all relevant boxes  I confirm the patient has capacity to give consent | e knowledge of proposed procedure, as specified in  |  |
| ☐ I have explained the course of treatment and inte  |   |  |
| The intended benefits (there are no guarantees  ☐ Prolong survival.  ☐ Control symptoms, reduce transfusion needs and ☐ Induction – therapy given in the acute state of the  | about outcome) d improve quality of life.   |  |
| Curative – to give you the best possible chance  |   |  |
|  | s, aiming to prevent disease flaring up and to control  |  |

☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the

symptoms. The aim is to improve both quality and quantity of life.

Patient identifier/label

| You may have one or more of the side effects listed   |  |  |
|---|--|--|
| Common side effects:  | Occasional side effects continued:   |  |
| Affecting more than 10 in every 100 (>10%) people   | ☐ Inflammation and ulcers at the opening end of  |  |
| An increased risk of getting an infection from a  | the bowel (anus), sometimes can be severe  |  |
| drop in white blood cells – this makes it harder  | leading to infections.   |  |
| to fight infections and you can become very ill.  | ☐ Blood pressure may drop if intravenous   |  |
| ☐ If you have a severe infection this can be  | Etoposide given to quickly.  |  |
| life-threatening. Contact your doctor or  | Severe skin changes (redness, itching  |  |
| hospital straight away if:  | sometimes blisters), eye sight changes   |  |
|   | (reversible).  |  |
| <ul> <li>your temperature goes over 37.5°C or<br/>over 38°C, depending on the advice given</li> </ul> | Change in colour of the eyes, nails and urine,   |  |
| by your chemotherapy team   | shortness of breath.   |  |
| you suddenly feel unwell (even with a   | High dose Cytarabine can cause temporary or  |  |
| normal temperature)   | occasionally permanent changes to the nervous  |  |
|   | system. Symptoms include seizures (fits),  |  |
| Thinning of the hair or hair loss, nausea (feeling  | drowsiness, unsteadiness and mood changes.   |  |
| sick), vomiting (being sick), constipation,   | Other risks:   |  |
| diarrhoea, sore mouth and ulcers, difficulty swallowing, weight loss, tiredness and feeling           | All intravenous drugs may leak out of the vein   |  |
| weak (fatigue), abdominal (tummy) pain,   | while it is being given (extravasation) and can  |  |
| change in skin colour.  | damage the tissue around the vein. Tell the  |  |
| Anaemia (low number of red blood cells),  | nurse straight away if you have any stinging,  |  |
| bruising or bleeding (low number of platelets);   | pain, redness or swelling around the vein. It's  |  |
| this can be prolonged and you may need a  | uncommon but important to deal with quickly.   |  |
| transfusion.  | Also, rarely high dose Cytarabine can cause changes in the lungs with shortness of breath, |  |
| Changes in liver function and kidney function   | wheeezing, cough or a fever. Please inform   |  |
| (monitored).  | your doctor or nurse if you notice these   |  |
| Cytarabine syndrome can occur 6 to 12 hours   | symptoms.  |  |
| after receiving Cytarabine. Symptoms include a  | ☐ There may be an increased risk of tumour lysis   |  |
| high temperature or chills, rash, pain in the   | syndrome in some patients when treatment   |  |
| eyes, bones, tummy and chest. Inform your   | destroys cancer cells too quickly for the kidneys  |  |
| doctor or nurse.  | to cope and leads to changes in blood tests.   |  |
| Cytarabine can cause inflammation of the lining   | Rarely, dialysis may be needed. You may be   |  |
| of the eye lids (conjunctiva) making eyes feel  | prescribed medicines for prevention or   |  |
| sore, red and itchy (this is temporary). Steroid  | treatment.   |  |
| eye drops during and for 3 days after   | Late effects include a very rare chance of a   |  |
| Cytarabine to prevent this will be given.   | second cancer (years later) and problems with  |  |
| Occasional side effects:  | your heart.  |  |
| Affecting between 1-10 in every 100 (1-10%) people  | Side effects of anti-sickness medication include   |  |
| Allergic reactions to Etoposide. This can be  | diarrhoea, constipation, headache.   |  |
| severe and can occur immediately or a few   | Before treatment you may have blood tests to   |  |
| hours later. Symptoms include difficulty in   | check for viruses (Hepatitis B or C, HIV, or   |  |
| breathing, increase in heart rate, sweating,  | unusual infections). Treatment may weaken  |  |
| temperature, high or low blood pressure, feeling  | your natural defence (immune) system so  |  |
| sick and being sick, rash or itching affecting the  | infections like this may worsen or become active if you've had them before. You may be     |  |
| whole body, occasionally swelling of the face.  | given medication to prevent infection.   |  |
| Heart problems with changes in the way your heart works with symptoms of fluid build-up and           | given inculation to prevent inicotion.   |  |
| shortness of breath (heart failure), risk of a  |  |  |
| heart attack, abnormal heart rhythm (fast heart   |  |  |
| rate).  | Continue on to the next page   |  |
| ,   | . 5  |  |

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Lisa Yuen Checked by Consultant: Eleni Tholouli Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version MEC (Mitoxantrone, Etoposide and Cytarabine)

Patient identifier/label

# Statement of health professional continued

#### Other risks continued:

| Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.  Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.                                 |
|---|
| Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.  |
| Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).  |
| Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for up to 6 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse. |
| Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.   |
|   |

| Patient | identific | r/lahal  |
|---------|-----------|----------|
| raueni  | Idellille | #I/Iabei |

| Any other risks and information:   |  |
|--|--|
| ☐ I have discussed the intended benefit and risks of available alternative treatments (including no treatment)☐ I have discussed the side effects of the recommendation. | ent). ended treatment, which could affect the patient                                      |
| straight away or in the future, and that there may be rare or have not yet been reported. Each patient ma  I have discussed what the treatment is likely to in           | y experience side effects differently.  nvolve (including inpatient/outpatient treatment,  |
| timing of the treatment, blood and any additional tes  I have explained to the patient, that they have the should contact the responsible consultant or team if          | e right to stop this treatment at any time and   |
| ☐ I have discussed concerns of particular importan (please write details here):  | ce to the patient in regard to treatment   |
| The following written information has been provided:  Information leaflet for MEC (Mitoxantrone,   | npliant (please tick): e document reason here:  Health professional details: Signed: Date: |
| Etoposide and Cytarabine)  24 hour alert card or SACT advice service contact details   | Name (PRINT):  |
| SACT treatment record (cruk.org/treatment-record)  | Job title:   |
| Other, please state:   |  |
| Statement of interpreter (where an interpreter booking reference (if applicable): I have interpreted the information above to the patient believe they can understand.   |  |
| Signed:  | Date:  |
| Name (PRINT):  | Job title:   |

# Statement of patient

Patient identifier/label

| your own copy of the form which describes the be   | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form. |
|--|--|
| ☐ I have had enough time to consider my optio  | ns and make a decision about treatment.  |
| ☐ I agree to the course of treatment described   | on this form.  |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo   | ole to sign but has indicated their consent. A person with bung people under the age of 16 years.  |
| Patient's signature:   |  |
| Name (PRINT):  | Date:  |
| Person with parental responsibility/witness' signa   | iture:   |
| Name (PRINT):  | Date:  |
| (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)  On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of | patients Contact details (if patient wishes to discuss options later):  Contact your hospital team if you have any   |
| treatment/procedures to go ahead. Signed:  | questions about cancer and its treatment.  |
| Date:  | Cancer Research UK can also help answer your questions about cancer and treatment. If you  |
| Name (PRINT):  | want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to  |
| Job title:   | Friday, 9am to 5pm. Alternatively visit cruk.org for   |
| Important notes: (tick if applicable)  | more information.  |
| <ul> <li>☐ See also advance decision to refuse treatment</li> <li>☐ Patient has withdrawn consent (ask patient to sign and date here)</li> </ul>   | These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.      |
| Signed:  | The project is supported by  |
| Date:  | Cancer Research UK.  This does not mean you are taking part in a clinical trial.   |

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Lisa Yuen Checked by Consultant: Eleni Tholouli

Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version MEC (Mitoxantrone, Etoposide and Cytarabine)

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

#### What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

#### The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

#### Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

#### When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- · retain that information in their mind
- use or weigh this information as a part of their decision making process, or

 communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

#### Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

#### **NHS Scotland**

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

#### References

- 1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
- Cancer Research UK: cruk.org/aboutcancer/treatment/drugs
- Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

### Patient agreement to **Patient details** systemic anti-cancer Patient's surname/family name: therapy (SACT) Patient's first name(s): MidAC (Mitoxantrone and Cytarabine) Date of birth: NHS number: (or other identifier) **Hospital/NHS Trust/NHS Board:** Special requirements: (eg other language/other communication method) Responsible consultant: Name: \_\_\_\_ Job title: Name of proposed course of treatment (include brief explanation if medical term not clear) ☐ MidAC (Mitoxantrone and Cytarabine) chemotherapy for the treatment of acute myeloid leukaemia (AML). Mitoxantrone is given intravenously on days 1 to 5 (total of 5 doses) and Cytarabine given intravenously twice each on days 1 to 3 (total of 6 doses). MidAC is usually given once only. ☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy) ✓ Tick all relevant boxes ☐ I confirm the patient has capacity to give consent. ☐ I have explained the course of treatment and intended benefit to the patient. **The intended benefits** (there are no guarantees about outcome) Prolong survival. Control symptoms, reduce transfusion needs and improve quality of life. Induction – therapy given in the acute state of the disease, aiming to shrink the tumour. ☐ Curative – to give you the best possible chance of being cured. Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control

Disease control / Palliative – the aim is not to cure but to control the disease and reduce the

symptoms. The aim is to improve both quality and quantity of life.

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Elizabeth Davies Checked by Consultant: Eleni Tholouli

the symptoms.

Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version MidAC (Mitoxantrone and Cytarabine)

Patient identifier/label

| You may have one or more of the side effects listed       |   |  |
|---|---|--|
| Common side effects:                                      | Other risks:  |  |
| Affecting more than 10 in every 100 (>10%) people         | ☐ Mitoxantrone, Cytarabine may leak out of the                                      |  |
| An increased risk of getting an infection (from a         | vein while it is being given (extravasation) and                                    |  |
| drop in white blood cells – this makes it harder          | can damage the tissue around the vein. Tell the                                     |  |
| to fight infections and you can become very ill.          | nurse straight away if you have any stinging,                                       |  |
| If you have a severe infection this can be life-          | pain, redness or swelling around the vein. It's                                     |  |
| threatening. Contact your doctor or hospital              | uncommon but important to deal with quickly.  |  |
| straight away if:   | Also, rarely high dose Cytarabine can cause   |  |
| <ul> <li>your temperature goes over 37.5°C or</li> </ul>  | changes in the lungs with shortness of breath,                                      |  |
| over 38°C, depending on the advice given                  | wheezing, cough or a fever. Please inform your                                      |  |
| by your chemotherapy team                                 | doctor or nurse if you notice these symptoms.                                       |  |
| <ul> <li>you suddenly feel unwell (even with a</li> </ul> | ☐ There may be an increased risk of tumour lysis                                    |  |
| normal temperature)                                       | syndrome in some patients when treatment  |  |
| Nausea (feeling sick), vomiting (being sick),             | destroys cancer cells too quickly for the kidneys                                   |  |
| abdominal (tummy) pain, diarrhoea, sore mouth             | to cope and leads to changes in blood tests.  |  |
| and ulcers, thinning of the hair or hair loss.            | Rarely, dialysis may be needed. You may be  |  |
| Anaemia (due to low red blood cells) and                  | prescribed medicines for prevention or  |  |
| bruising or bleeding (due to low platelets); this         | treatment.  |  |
| can be prolonged and you may need a                       | Late effects include a very rare chance of a  |  |
| transfusion.  | second cancer (years later) and problems with                                       |  |
| Cytarabine syndrome can occur 6 to 12 hours               | your heart.   |  |
| after receiving Cytarabine. Symptoms include a            | Side effects of anti-sickness medication include                                    |  |
| high temperature or chills, rash, pain in the             | diarrhoea, constipation, headache.  |  |
| eyes, bones, tummy and chest. Inform your                 | Before treatment you may have blood tests to  |  |
| doctor or nurse.  | check for viruses (Hepatitis B or C, HIV, or  |  |
| ☐ Inflammation of the lining of the eye lids              | unusual infections). Treatment may weaken   |  |
| (conjunctiva) making eyes feel sore, red and              | your natural defence (immune) system so   |  |
| itchy (this is temporary). Steroid eye drops              | infections like this may worsen or become   |  |
| during and for 3 days following Cytarabine                | active if you've had them before. You may be given medication to prevent infection. |  |
| treatment to prevent this will be given.                  | Growth factors (GCSF) may be prescribed to  |  |
| Occasional side effects:                                  | maintain number of white cells to prevent   |  |
| Affecting between 1-10 in every 100 (1-10%) people        | infection. You may experience bone pain,  |  |
| ☐ Inflammation and ulcers of the opening end of           | headaches, red and itchy skin around the  |  |
| the bowel (anus), sometimes can be severe                 | injection site.   |  |
| leading to infections.                                    | Changes in your memory, concentration or  |  |
| Skin changes (redness, itching sometimes                  | ability to think clearly. There can be many   |  |
| blisters), weight loss, shortness of breath, eye          | causes including your treatment, diagnosis, or                                      |  |
| sight changes (reversible).                               | both.   |  |
| ☐ Changes in liver and kidney function                    | Cancer and its treatment can increase your risk                                     |  |
| (monitored), high uric acid levels, change in             | of developing a blood clot (thrombosis), causing                                    |  |
| colour of the eyes, nails, skin and urine.                | pain, redness and swelling in an arm or leg,  |  |
| Heart problems with changes in the way your               | breathlessness, chest pain. Tell your doctor  |  |
| heart works with symptoms of fluid build-up and           | straight away if you have any symptoms.   |  |
| shortness of breath (heart failure), risk of a            | Some anti-cancer medicines can damage   |  |
| heart attack.   | ovaries and sperm. This may lead to infertility                                     |  |
| High dose Cytarabine can cause temporary or               | and/or early menopause (hot flushes, vaginal  |  |
| occasionally permanent changes to the nervous             | dryness).   |  |
| system. Symptoms include seizures (fits),                 |   |  |
| drowsiness, unsteadiness and mood changes.                |   |  |
| Inform your doctor or nurse.                              | Continue on to the next page  |  |

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Elizabeth Davies Checked by Consultant: Eleni Tholouli Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version MidAC (Mitoxantrone and Cytarabine)

Patient identifier/label

# Statement of health professional continued

#### Other risks continued:

| Some anti-cancer medicines may damage the        |
|--|
| development of a baby in the womb. It is         |
| important not to become pregnant or make         |
| someone else pregnant during treatment and       |
| for up to 6 months afterwards. Women of child    |
| bearing age will be tested for pregnancy before  |
| and during treatment. Use effective              |
| contraception throughout. Speak to your doctor   |
| or nurse.  |
| Complications of treatment can very              |
| occasionally be life-threatening and may result  |
| in death. The risks are different for every      |
| individual. Potentially life-threatening         |
| complications include those listed on this form, |
| but other exceedingly rare side effects may also |
| be life-threatening.                             |

| Patient identifier/labe | el . |
|-------------------------|------|
|-------------------------|------|

| Any other risks and information:  |  |
|---|--|
|   |  |
| ☐ I have discussed the intended benefit and risks of available alternative treatments (including no treatme   |  |
| ☐ I have discussed the side effects of the recommer straight away or in the future, and that there may be straight averaged and the straight away or in the future. The straight away or in the future, and that there may be straight away or in the future.   | some side effects not listed because they are            |
| ☐ I have discussed what the treatment is likely to invitiming of the treatment, blood and any additional tests  | · • • • • • • • • • • • • • • • • • • •                  |
| $\hfill \square$ I have explained to the patient, that they have the should contact the responsible consultant or team if the should contact the responsible consultant or team if the should be should b | •  |
| ☐ I have discussed concerns of particular importance  | e to the patient in regard to treatment                  |
| (please write details here):  |  |
| Yes ☐ No ☐ Not available If No please The following written information has been provided: ☐ Information leaflet for MidAC (Mitoxantrone and Cytarabine) ☐ 24 hour alert card or SACT advice service  | Health professional details: Signed: Date: Name (PRINT): |
| contact details   |  |
| SACT treatment record (cruk.org/treatment-  | 1  |
| <u> </u>  | Job title:   |
| <u> </u>  | Job title:   |
| record)   |  |
| record)  Other, please state:   |  |
| Tecord)  Other, please state:  Statement of interpreter (where applicable): I have interpreted the information above to the patient   | propriate)   |
| Other, please state:  Statement of interpreter (where applicable): I have interpreted the information above to the patient believe they can understand.   | propriate)   |

# Statement of patient

Patient identifier/label

| your own copy of the form which describes the be   | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form.  |
|--|---|
| ☐ I have had enough time to consider my optio  | ns and make a decision about treatment.   |
| ☐ I agree to the course of treatment described   | on this form.   |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo   | ole to sign but has indicated their consent. A person with bung people under the age of 16 years.   |
| Patient's signature:   |   |
| Name (PRINT):  | Date:   |
| Person with parental responsibility/witness' signa   | ature:  |
| Name (PRINT):  | Date:   |
| (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)  On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of | patients Contact details (if patient wishes to discuss options later):  Contact your hospital team if you have any  |
| treatment/procedures to go ahead. Signed:  | questions about cancer and its treatment.   |
| Date:  | Cancer Research UK can also help answer your questions about cancer and treatment. If you   |
| Name (PRINT):  | want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to   |
| Job title:   | Friday, 9am to 5pm. Alternatively visit cruk.org for  |
| Important notes: (tick if applicable)  See also advance decision to refuse treatment  Patient has withdrawn consent (ask patient to sign and date here)  Signed:   | more information.  These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.  The project is supported by |
| Date:  | Cancer Research UK.  This does not mean you are taking part in a clinical trial.  |

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Elizabeth Davies Checked by Consultant: Eleni Tholouli

Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version MidAC (Mitoxantrone and Cytarabine)

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

#### What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

#### The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

#### Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

#### When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or

 communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

#### Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

#### **NHS Scotland**

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

#### References

- Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
- Cancer Research UK: cruk.org/aboutcancer/treatment/drugs
- Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

| Patient agreement to systemic anti-cancer therapy (SACT)   | Patient details Patient's surname/family name:  Patient's first name(s):                                   |  |
|--|--|--|
| Midostaurin (+/-   |  |  |
| chemotherapy)  | Date of birth:   |  |
|  | NHS number:(or other identifier)   |  |
| Hospital/NHS Trust/NHS Board:  | Special requirements: (eg other language/other communication method)                                       |  |
| Responsible consultant: Name:  |  |  |
| Job title:   |  |  |
| ☐ Midostaurin is given orally twice daily for 14 days consent form must be completed for the chemothera ☐ Midostaurin is given as maintenance therapy after  | LT3 mutation positive acute myeloid leukaemia (AML). starting after each cycle of chemotherapy. A separate |  |
| orally every day for twelve 28 day cycles (1 year).  Where will I have treatment?  Outpatient Day unit/case Inpatient  | Other:   |  |
| Statement of health professio  (to be filled in by health professional with appropriate the hospital/Trust/NHS board's consent policy)  ☑ Tick all relevant boxes ☐ I confirm the patient has capacity to give consent ☐ I have explained the course of treatment and inte | e knowledge of proposed procedure, as specified in t.  |  |
| The intended benefits (there are no guarantees   | ·  |  |
| Prolong survival.  |  |  |
| Control symptoms, reduce transfusion needs and   |  |  |
| <ul><li>☐ Induction – therapy given in the acute state of the</li><li>☐ Curative – to give you the best possible chance of</li></ul>   | _  |  |
|  | s, aiming to prevent disease flaring up and to control   |  |
| ☐ Disease control / Palliative – the aim is not to cur   | re but to control the disease and reduce the   |  |

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symptoms. The aim is to improve both quality and quantity of life.

Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version Midostaurin (+/- chemotherapy)

Patient identifier/label

| You may have one or more of the side effects listed  |   |  |  |
|--|---|--|--|
| Common side effects:   | Other risks:  |  |  |
| Affecting more than 10 in every 100 (>10%) people  An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.  If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:  | <ul> <li>There may be an increased risk of tumour lysis syndrome in some patients when treatment destroys cancer cells too quickly for the kidneys to cope and leads to chnages in blood tests. Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.</li> <li>Side effects of anti-sickness medication include</li> </ul>   |  |  |
| <ul> <li>your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team</li> <li>you suddenly feel unwell (even with a normal temperature)</li> <li>Nausea (feeling sick), vomiting (being sick), abdominal (tummy), haemorrhoids, sore mouth and ulcers.</li> <li>Skin changes (rash with flaking, peeling or redness), excessive sweating, allergic reactions, back and joint pain.</li> <li>Nose bleed, headache, difficulty sleeping (insomnia), low blood pressure.</li> <li>Low potassium, high sodium, changes in liver function – picked up and monitored in bood tests.</li> <li>Lung changes causing shortness of breath, wheezing and/or cough with fluid build-up. Please contact your doctor or nurse if you notice these symptoms.</li> <li>Midostaurin can raise your blood sugar. If you have diabetes, it may lead to higher blood sugar levels. Please ask your doctor/nurse/GP if concerned.</li> <li>Occasional side effects:</li> <li>Affecting between 1-10 in every 100 (1-10%) people</li> <li>Swelling around the eyelids, sensitivity to light and/or eye pain (keratitis).</li> <li>Poor concentration, shaking or trembling, sudden loss of consciousness.</li> <li>High blood pressure, build-up of fluid around the lungs, high calcium, high uric acid levels.</li> <li>Pain the bones, neck, hands and feet, dry skin</li> <li>Midostaurin can cause abnormal heart rhythms (QT prolongation). Contact your doctor or nurse if you have a change in your heartbeat, or if you feel dizzy, lightheaded, or faint.</li> </ul> | diarrhoea, constipation, headache.  Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.  Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.  Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.  Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.  Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).  Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make some else preganant during treatment and for 4 months after. Women of child bearing age must be tested for pregnancy within 7 days of starting midostaurin. Use effective contraception throughout. Speak to your doctor or nurse.  Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening. |  |  |

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Elizabeth Davies Checked by Consultant: Eleni Tholouli Date of issue: Mar-24; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version Midostaurin (+/- chemotherapy)

| Patient | iden  | tifier | /lahel |  |
|---------|-------|--------|--------|--|
| rauciii | IUCII | unci   | /lauci |  |

| □ Information leaflet for Midostaurin +/- chemotherapy □ 24 hour alert card or SACT advice service contact details □ SACT treatment record (cruk.org/treatment- record) □ Other, please state:  Statement of interpreter (where appropriate) Interpreter booking reference (if applicable): I have interpreted the information above to the patient to the best of my ability and in a way in which believe they can understand.  Signed: Date:   | Any other risks and information:  |  |
|---|---|--|
| available alternative treatments (including no treatment).    I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.    I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.    I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.    I have discussed concerns of particular importance to the patient in regard to treatment (please write details here):    Yes |   |  |
| straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.    I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.    I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.    I have discussed concerns of particular importance to the patient in regard to treatment (please write details here):    Clinical management guideline/Protocol compliant (please tick):   Yes  |   | •  |
| timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.    I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.   I have discussed concerns of particular importance to the patient in regard to treatment (please write details here):   | straight away or in the future, and that there may be   | some side effects not listed because they are        |
| should contact the responsible consultant or team if they wish to do so.    I have discussed concerns of particular importance to the patient in regard to treatment (please write details here):   |   | ,  |
| Clinical management guideline/Protocol compliant (please tick):  Yes No Not available If No please document reason here:  The following written information has been provided: Information leaflet for Midostaurin +/-chemotherapy 24 hour alert card or SACT advice service contact details  SACT treatment record (cruk.org/treatment-record) Other, please state:  Statement of interpreter (where appropriate) Interpreter booking reference (if applicable): I have interpreted the information above to the patient to the best of my ability and in a way in which believe they can understand.  Signed: Date:   |   | ·  |
| Clinical management guideline/Protocol compliant (please tick):  Yes No Not available If No please document reason here:  The following written information has been provided: Information leaflet for Midostaurin +/- chemotherapy  24 hour alert card or SACT advice service contact details  SACT treatment record (cruk.org/treatment-record) Other, please state:  Statement of interpreter (where appropriate)  Interpreter booking reference (if applicable): I have interpreted the information above to the patient to the best of my ability and in a way in which believe they can understand.  Signed: Date:  Date:   | ☐ I have discussed concerns of particular importan  | ce to the patient in regard to treatment             |
| Yes   No   Not available   If No please document reason here:    The following written information has been provided:   Signed:   Date:   Name (PRINT):     24 hour alert card or SACT advice service contact details   Job title:     SACT treatment record (cruk.org/treatment-record)   Other, please state:   Job title:     Statement of interpreter (where appropriate)     Interpreter booking reference (if applicable):   I have interpreted the information above to the patient to the best of my ability and in a way in which believe they can understand.     Signed:   Date:   Date:   | (please write details here):  |  |
| Contact details  SACT treatment record (cruk.org/treatment-record)  Other, please state:  Statement of interpreter (where appropriate) Interpreter booking reference (if applicable): I have interpreted the information above to the patient to the best of my ability and in a way in which believe they can understand.  Signed:  Date:  | The following written information has been provided:  Information leaflet for Midostaurin +/- chemotherapy                          | Health professional details: Signed:                 |
| Other, please state:  | contact details   |  |
| Statement of interpreter (where appropriate) Interpreter booking reference (if applicable): I have interpreted the information above to the patient to the best of my ability and in a way in which believe they can understand.  Signed: Date:   | SACT treatment record (cruk.org/treatment-record)   |  |
| Statement of interpreter (where appropriate) Interpreter booking reference (if applicable): I have interpreted the information above to the patient to the best of my ability and in a way in which believe they can understand.  Signed: Date:   | Other, please state:  | -  |
| Interpreter booking reference (if applicable):  I have interpreted the information above to the patient to the best of my ability and in a way in which believe they can understand.  Signed: Date:   |   | 1  |
| I have interpreted the information above to the patient to the best of my ability and in a way in which believe they can understand.  Signed: Date:   | Statement of interpreter (where ap  | opropriate)  |
|   | Interpreter booking reference (if applicable): I have interpreted the information above to the patient believe they can understand. | at to the best of my ability and in a way in which l |
|   | Signed:   | Date:  |
|   | Name (PRINT):   | Job title:   |

# Statement of patient

Patient identifier/label

| your own copy of the form which describes the be   | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form.  |  |
|--|---|--|
| ☐ I have had enough time to consider my optio  | ns and make a decision about treatment.   |  |
| ☐ I agree to the course of treatment described   | on this form.   |  |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo   | ole to sign but has indicated their consent. A person with bung people under the age of 16 years.   |  |
| Patient's signature:   |   |  |
| Name (PRINT):  | Date:   |  |
| Person with parental responsibility/witness' signa   | ature:  |  |
|  | Date:   |  |
| (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)  On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of | patients Contact details (if patient wishes to discuss options later):  Contact your hospital team if you have any  |  |
| treatment/procedures to go ahead. Signed:  | questions about cancer and its treatment.   |  |
| Date:  | Cancer Research UK can also help answer yo<br>questions about cancer and treatment. If you  |  |
| Name (PRINT):  | want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to   |  |
| Job title:   | Friday, 9am to 5pm. Alternatively visit cruk.org for  |  |
| Important notes: (tick if applicable)  See also advance decision to refuse treatment  Patient has withdrawn consent (ask patient to sign and date here)  Signed:   | more information.  These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.  The project is supported by |  |
| Date:  | Cancer Research UK.  This does not mean you are taking part in a clinical trial.  |  |

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Elizabeth Davies Checked by Consultant: Eleni Tholouli

Date of issue: Mar-24; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version Midostaurin (+/- chemotherapy)

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

#### What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

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- understand information about the decision to be made
- · retain that information in their mind
- use or weigh this information as a part of their decision making process, or

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Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

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#### References

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- Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

| Patient agreement to systemic anti-cancer therapy (SACT)  | Patient details Patient's surname/family name:   |  |  |
|---|--|--|--|
| Midostaurin +   | Patient's first name(s):   |  |  |
| chemotherapy (DA and High dose Cytarabine)  | Date of birth:  NHS number: (or other identifier)  |  |  |
| Hospital/NHS Trust/NHS Board:   | Special requirements: (eg other language/other communication method)   |  |  |
| Responsible consultant: Name:   |  |  |  |
| Job title:  |  |  |  |
| Name of proposed course of treatment (inclu   | ude brief explanation if medical term not clear)   |  |  |
| treatment of FLT3 mutation positive acute myeloid leusyndrome (MDS)*(*delete as appropriate).  INDUCTION: Daunorubicin given intravenously on on days 1 to 7. Midostaurin taken orally twice a day freques.  CONSOLIDATION: Cytarabine (high dose) intrave Midostaurin orally twice each day from days 8 to 21.  MAINTENANCE: Midostaurin orally twice a day up Where will I have treatment?  Outpatient Day unit/case Inpatient  | a days 1 to 3 together with Cytarabine intravenously from days 8 to 21. This is given for a maximum of 2 enously twice a day on days 1, 3 & 5 (total of 6 doses). This is given for a maximum of 2 cycles. |  |  |
| Statement of health profession (to be filled in by health professional with appropriate the hospital/Trust/NHS board's consent policy)  ☑ Tick all relevant boxes ☐ I confirm the patient has capacity to give consent. ☐ I have explained the course of treatment and intermediate the intended benefits (there are no guarantees and the course of treatment and intermediate the course of treatment and intermediate the intended benefits (there are no guarantees and the course of treatment and intermediate the intended benefits (there are no guarantees and the course of treatment and intermediate the intended benefits (there are no guarantees and the course of treatment and intermediate the cou | knowledge of proposed procedure, as specified in nded benefit to the patient.  |  |  |
| <ul> <li>□ Prolong survival.</li> <li>□ Control symptoms, reduce transfusion needs and</li> <li>□ Induction – therapy given in the acute state of the</li> <li>□ Curative – to give you the best possible chance o</li> <li>□ Maintenance – therapy given on continuing basis, the symptoms.</li> <li>□ Disease control / Palliative – the aim is not to cure</li> </ul>  | disease, aiming to shrink the tumour.  f being cured.  , aiming to prevent disease flaring up and to control   |  |  |

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Lisa Yuen Checked by Consultant: Eleni Tholouli

symptoms. The aim is to improve both quality and quantity of life.

Date of issue: Mar-25; Version 2; Review date: Mar-28 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact\_consent for latest version

Midostaurin + chemotherapy (DA and High dose Cytarabine)

1 of 5

Patient identifier/label

| You may have one or more of the side effects listed   |  |  |  |
|---|--|--|--|
| Common side effects:  | Occasional side effects:   |  |  |
| Affecting more than 10 in every 100 (>10%) people   | Affecting between 1-10 in every 100 (1-10%) people   |  |  |
| An increased risk of getting an infection from a  | Severe skin changes (redness, itching  |  |  |
| drop in white blood cells – this makes it harder  | sometimes blisters), inflammation and ulcers at  |  |  |
| to fight infections and you can become very ill.  | the opening end of the bowel (anus).   |  |  |
| ☐ If you have a severe infection this can be  | sometimes can be severe leading to infections.   |  |  |
| life-threatening. Contact your doctor or  | Poor concentration, shaking or trembling,  |  |  |
| hospital straight away if:  | sudden loss of consciousness.  |  |  |
|   | Swelling around the eyelids, sensitivity to light  |  |  |
| your temperature goes over 37.5°C or  | and/or eye pain (keratitis), eye sight changes   |  |  |
| over 38°C, depending on the advice given  | (reversible).  |  |  |
| by your chemotherapy team   | ☐ Build-up of fluid around the lungs.  |  |  |
| you suddenly feel unwell (even with a   | Daunorubicin and Midostaurin can cause heart   |  |  |
| normal temperature)   |  |  |  |
| Nausea (feeling sick), vomiting (being sick),   | problems with changes in the way your heart works, including abnormal heart rhythms and      |  |  |
| abdominal (tummy) pain, diarrhoea,  | risk of a heart attack. Contact your doctor or   |  |  |
| haemorrhoids, sore mouth and ulcers, difficulty   | nurse if you have changes in your heartbeat, or  |  |  |
| swallowing, taste changes, loss of appetite.  Thinning of the hair or hair loss, skin changes | if you feel dizzy, lightheaded, or faint.  |  |  |
| (rash with flaking, peeling or redness, itching,  |  |  |  |
| change in colour), change in nail colour,   | Pain the bones, neck, hands and feet, weight   |  |  |
| excessive sweating.   | loss.  |  |  |
| Nose bleed, headache, difficulty sleeping   | High dose Cytarabine can cause temporary or<br>occasionally permanent changes to the nervous |  |  |
| (insomnia), high or low blood pressure,   | system. Symptoms include seizures (fits),  |  |  |
| increase in heart rate, shortness of breath   | drowsiness, unsteadiness and mood changes.   |  |  |
| Allergic reactions, shortness of breath, back   | drowsiness, unsteadiness and mood changes.   |  |  |
| and joint pain, red colour urine for 1 - 2 days   | Other risks:   |  |  |
| after treatment (due to Daunorubicin).  | ☐ All intravenous drugs may leak out of the vein   |  |  |
| Anaemia (due to low red blood cells) and  | while it is being given (extravasation) and can  |  |  |
| bruising or bleeding (due to low platelets); this   | damage the tissue around the vein. Tell the  |  |  |
| can be prolonged requiring a transfusion.   | nurse straight away if you have any stinging,  |  |  |
| Changes in liver and kidney function, low   | pain, redness or swelling around the vein. It's  |  |  |
| potassium, high sodium - monitored in blood   | uncommon but important to deal with quickly.   |  |  |
| tests.  | ☐ A condition called posterior reversible  |  |  |
| ☐ Midostaurin can raise your blood sugar. If you  | encephalopathy syndrome (PRES) is a rare   |  |  |
| have diabetes, it may lead to higher blood sugar  | side effect of Daunorubicin. Symptoms include  |  |  |
| levels.   | headaches, feeling confused, vision problems   |  |  |
| ☐ Midostaurin and Cytarabine can cause lung   | (including blindness), fits. Contact your doctor   |  |  |
| changes with symptoms of shortness of breath,   | or nurse.  |  |  |
| wheezing and/or cough with fluid build-up.  | ☐ There may be an increased risk of tumour lysis   |  |  |
| Please inform your doctor or nurse if you notice  | syndrome in some patients when treatment   |  |  |
| these symptoms.   | destroys cancer cells too quickly for the kidneys  |  |  |
| Cytarabine syndrome can occur 6 to 12 hours   | to cope and leads to changes in blood tests.   |  |  |
| after receiving Cytarabine. Symptoms include a  | Rarely, dialysis may be needed. You may be   |  |  |
| high temperature or chills, rash, pain in the   | prescribed medicines for prevention or   |  |  |
| eyes, bones, tummy and chest. Inform your   | treatment.   |  |  |
| doctor or nurse.  |  |  |  |
| Inflammation of the lining of the eye lids  |  |  |  |
| (conjunctiva) making eyes feel sore, red and  | Continue on to the next page   |  |  |
| itchy (this is temporary). Steroid eye drops  |  |  |  |
| during and for 3 days following consolidation   |  |  |  |
| treatment to prevent this will be given.  |  |  |  |

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Midostaurin + chemotherapy (DA and High dose Cytarabine)
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Patient identifier/label

# Statement of health professional continued

Other risks continued:

# ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken

unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.

Late effects include a very rare chance of a second cancer (years later) and problems with your heart.

Growth factors (GCSF) may be prescribed to maintain number of white cells to prevent infection. You may experience bone pain, headaches, red and itchy skin around the injection site.

Side effects of anti-sickness medication include diarrhoea, constipation, headaches.

Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.

Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.

Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).

Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make some else pregnant during treatment and for 6 months after. Women of child bearing age must be tested for pregnancy within 7 days of starting midostaurin. Use effective contraception throughout. Speak to your doctor or nurse.

Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

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Midostaurin + chemotherapy (DA and High dose Cytarabine)

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| Patient | identific | r/lahal  |
|---------|-----------|----------|
| raueni  | Idellille | #I/Iabei |

| Any other risks and information:   |  |
|--|--|
| ☐ I have discussed the intended benefit and risks of available alternative treatments (including no treatment)☐ I have discussed the side effects of the recomme | ent).  |
| straight away or in the future, and that there may be rare or have not yet been reported. Each patient may   | some side effects not listed because they are  |
| ☐ I have discussed what the treatment is likely to in timing of the treatment, blood and any additional test   | , •  |
| ☐ I have explained to the patient, that they have the should contact the responsible consultant or team if   | •  |
| ☐ I have discussed concerns of particular important (please write details here):   | ce to the patient in regard to treatment       |
| Clinical management guideline/Protocol com  Yes No Not available If No please  | npliant (please tick): e document reason here: |
| The following written information has been provided:  Information leaflet for Midostaurin,  Daunorubicin and Cytarabine  | Health professional details: Signed: Date:     |
| <ul> <li>24 hour alert card or SACT advice service<br/>contact details</li> </ul>  | Name (PRINT):                                  |
| SACT treatment record (cruk.org/treatment-record)  | Job title:                                     |
|  |  |
| Other, please state:   |  |
| Statement of interpreter (where ap Interpreter booking reference (if applicable): I have interpreted the information above to the patient                        | ppropriate)                                    |
|  | ppropriate)                                    |

# Statement of patient

Patient identifier/label

| your own copy of the form which describes the be   | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form. |
|--|--|
| ☐ I have had enough time to consider my optio  | ns and make a decision about treatment.  |
| ☐ I agree to the course of treatment described   | on this form.  |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo   | ole to sign but has indicated their consent. A person with bung people under the age of 16 years.  |
| Patient's signature:   |  |
| Name (PRINT):  | Date:  |
| Person with parental responsibility/witness' signa   | uture:   |
| Name (PRINT):  | Date:  |
| (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)  On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of | patients Contact details (if patient wishes to discuss options later):  Contact your hospital team if you have any   |
| treatment/procedures to go ahead. Signed:  | questions about cancer and its treatment.  |
| Date:  | Cancer Research UK can also help answer your<br>questions about cancer and treatment. If you   |
| Name (PRINT):  | want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to  |
| Job title:   | Friday, 9am to 5pm. Alternatively visit cruk.org for   |
| Important notes: (tick if applicable)  | more information.  |
| <ul> <li>☐ See also advance decision to refuse treatment</li> <li>☐ Patient has withdrawn consent (ask patient to sign and date here)</li> </ul>   | These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.      |
| Signed: Date:  | The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.  |

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Midostaurin + chemotherapy (DA and High dose Cytarabine)
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(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

#### What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

#### The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

#### Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

#### When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or

 communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

#### Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

#### **NHS Scotland**

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

#### References

- Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
- Cancer Research UK: cruk.org/aboutcancer/treatment/drugs
- Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

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Midostaurin + chemotherapy (DA and High dose Cytarabine)

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| Patient agreement to systemic anti-cancer therapy (SACT)  Mitoxantrone  | Patient details Patient's surname/family name:  Patient's first name(s):  |
|---|---|
|   | Date of birth:  |
|   | NHS number: (or other identifier)   |
| Hospital/NHS Trust/NHS Board:   | Special requirements:  (e.g other language/other communication method)  |
| Responsible consultant: Name:   |   |
| Job title:  |   |
| <ul> <li>Mitoxantrone chemotherapy for the treatment of a</li> <li>Mitoxantrone is given intravenously as a single do chemotherapy* (*delete as appropriate) on days 1, 2,</li> <li>Where will I have treatment?</li> <li>Outpatient □ Day unit/case □ Inpatient</li> </ul>   | ose in relapse* OR as induction if not fit for intensive  |
| Statement of health profession  (to be filled in by health professional with appropriate the hospital/Trust/NHS board's consent policy)  ✓ Tick all relevant boxes  ☐ I confirm the patient has capacity to give consent.  ☐ I have explained the course of treatment and interest the intended benefits (there are no guarantees and Prolong survival.  ☐ Prolong survival.  ☐ Control symptoms, reduce transfusion needs and Induction – therapy given in the acute state of the Curative – to give you the best possible chance or | knowledge of proposed procedure, as specified in .  nded benefit to the patient. about outcome)  I improve quality of life. a disease, aiming to shrink the tumour. |

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☐ Disease control / Palliative – the aim is not to cure but to control the disease and reduce the

symptoms. The aim is to improve both quality and quantity of life.

Patient identifier/label

| You may have one or more of the side effects listed   |  |  |  |
|---|--|--|--|
| Common side effects:  | Other risks continued  |  |  |
| Affecting more than 10 in every 100 (>10%) people  An increased risk of getting an infection from a drop in white blood cells – this makes it harder to fight infections and you can become very ill.  If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:   | ☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.  |  |  |
| <ul> <li>your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team</li> <li>you suddenly feel unwell (even with a normal temperature)</li> </ul>  | <ul> <li>Side effects with the anti-sickness medication may include: constipation, diarrhoea, headaches.</li> <li>Late effects include a rare chance of a second cancer (years later) and problems with your</li> </ul>  |  |  |
| Anaemia (low number of red blood cells) and   | heart.   |  |  |
| bruising or bleeding (low number of platelets); this can be prolonged and you may need a transfusion.   | Growth factors (GCSF) may be prescribed to<br>maintain number of white cells to prevent<br>infection. You may experience bone pain,  |  |  |
| ☐ Thinning of the hair or hair loss.  | headaches, red and itchy skin around the injection site.   |  |  |
| ☐ Nausea (feeling sick), vomiting (being sick).   | Changes in memory, concentration, or ability to  |  |  |
| Occasional side effects:  Affecting between 1-10 in every 100 (1-10%) people  Sore mouth and ulcers.  Constipation, diarrhoea, weight loss, feeling tired and weak (fatigue), shortness of breath,  Change in colour of the eyes, nails, skin and urine.  Heart problems with changes in the way your heart works with symptoms of fluid build-up and shortness of breath (heart failure) and risk of heart attack.   | think clearly. There can be many causes of this including your treatment, diagnosis, or both.  Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain or stroke. Tell your doctor straight away if you have any symptoms.  Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause.  Some anti-cancer medicines may damage the      |  |  |
| Other risks:  | development of a baby in the womb. It is important not to become pregnant or make  |  |  |
| <ul> <li>Mitoxantrone may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly.</li> <li>There is a risk of tumour lysis syndrome (when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests). Rarely, dialysis may be needed. You may be prescribed medicines for prevention or treatment.</li> </ul> | someone else pregnant during treatment and for at least 6 months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout.  Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening. |  |  |

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| Patient | identific | r/lahal  |
|---------|-----------|----------|
| raueni  | Idellille | #I/Iabei |

| Any other risks and information:  |  |  |  |
|---|--|--|--|
|   |  |  |  |
| f the recommended treatment, and of any ent).   |  |  |  |
| nded treatment, which could affect the patient some side effects not listed because they are a experience side effects differently. |  |  |  |
| volve (including inpatient/outpatient treatment, s, follow-up appointments etc) and location.                                       |  |  |  |
| e right to stop this treatment at any time and they wish to do so.  |  |  |  |
| ce to the patient in regard to treatment  |  |  |  |
| npliant (please tick): e document reason here:  |  |  |  |
| Health professional details: Signed: Date:  |  |  |  |
| Name (PRINT):   |  |  |  |
| Job title:  |  |  |  |
|   |  |  |  |
|   |  |  |  |
| propriate)  |  |  |  |
| t to the best of my ability and in a way in which I   |  |  |  |
| Date:   |  |  |  |
| Job title:  |  |  |  |
|   |  |  |  |

# Statement of patient

Patient identifier/label

| your own copy of the form which describes the be   | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form.  |
|--|---|
| ☐ I have had enough time to consider my optio  | ns and make a decision about treatment.   |
| ☐ I agree to the course of treatment described   | on this form.   |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo   | ole to sign but has indicated their consent. A person with bung people under the age of 16 years.   |
| Patient's signature:   |   |
| Name (PRINT):  | Date:   |
| Person with parental responsibility/witness' signa   | ature:  |
| Name (PRINT):  | Date:   |
| (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)  On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of | patients Contact details (if patient wishes to discuss options later):  Contact your hospital team if you have any  |
| treatment/procedures to go ahead. Signed:  | questions about cancer and its treatment.   |
| Date:  | Cancer Research UK can also help answer your questions about cancer and treatment. If you   |
| Name (PRINT):  | want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to   |
| Job title:   | Friday, 9am to 5pm. Alternatively visit cruk.org for  |
| Important notes: (tick if applicable)  See also advance decision to refuse treatment  Patient has withdrawn consent (ask patient to sign and date here)  Signed:   | more information.  These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.  The project is supported by Cancer Research UK. |
| Date:  | This does not mean you are taking part in a clinical trial.   |

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(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

#### What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

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#### Who can give consent

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#### When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- · retain that information in their mind
- use or weigh this information as a part of their decision making process, or

communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

#### Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

#### **NHS Scotland**

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

#### References

- Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
- Cancer Research UK: cruk.org/aboutcancer/treatment/drugs
- Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

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| Patient agreement to systemic anti-cancer therapy (SACT)  | Patient details Patient's surname/family name:                       |  |
|---|--|--|
| Sorafenib   | Patient's first name(s):   |  |
|   | Date of hirth:   |  |
|   | Date of birth:   |  |
|   | NHS number: (or other identifier)                                    |  |
|   | (or other identifier)  |  |
| Hospital/NHS Trust/NHS Board:   | Special requirements: (eg other language/other communication method) |  |
|   |  |  |
| Responsible consultant: Name:   |  |  |
| Job title:  |  |  |
|   |  |  |
| Name of proposed course of treatment (inclu   | ude brief explanation if medical term not clear)                     |  |
| Sorafenib for the treatment of FLT3 mutation posi allogeneic haematopoietic stem cell transplantation (a  | tive acute myeloid leukemia (AML) undergoing                         |  |
| Sorafenib is taken orally twice each day. Each tre  | ,  |  |
| Treatment is continued for a maximum of 2 years   | •  |  |
| Where will I have treatment?  |  |  |
| Outpatient Day unit/case Inpatient  | Other:   |  |
|   |  |  |
|   |  |  |
| Statement of health profession (to be filled in by health professional with appropriate the hospital/Trust/NHS board's consent policy)  Tick all relevant boxes | knowledge of proposed procedure, as specified in                     |  |
| I confirm the patient has capacity to give consent  |  |  |
| I have explained the course of treatment and inte   | ·  |  |
| The intended benefits (there are no guarantees a  | about outcome)   |  |
| <ul><li>Prolong survival.</li><li>Control symptoms, reduce transfusion needs and</li></ul>  | Limprovo quality of life   |  |
| Induction – therapy given in the acute state of the   |  |  |
| Curative – to give you the best possible chance of  | _  |  |
| <del></del>   | , aiming to prevent disease flaring up and to control                |  |
| the symptoms  | , ag to provent disease naming up and to control                     |  |

Disease control / Palliative – the aim is not to cure but to control the disease and reduce the

symptoms. The aim is to improve both quality and quantity of life.

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| You may have one or more of the side effects listed   |   |  |  |
|---|---|--|--|
| Common side effects:  | Other risks continued:  |  |  |
| Affecting more than 10 in every 100 (>10%) people  Higher risk of infection from a drop in white blood cells, fever (which is sometimes severe).  Diarrhoea, constipation, nausea (feeling sick), vomiting (being sick).  Skin changes (rash, dryness, itching), soreness, redness, peeling on the palms of hands and soles of the feet.  Thinning of the hair, hair loss, tiredness and feeling weak (fatigue), joint pain.  Low phosphate levels (picked up in blood tests), weight loss, bleeding.  High blood pressure. You will be monitored regularly and may be given tablets to control it. If your blood pressure is too high and cannot be controlled, treatment may be stopped permanently.  | <ul> <li>Slow wound healing. You may be asked to stop treatment before an operation or procedure, including dental work.</li> <li>A hole or abnormal opening in the intestine (fistula or perforation) is uncommon. Tell your doctor if you have intense tummy pain or blood in the vomit or stool.</li> <li>An enlargement and weakening of a blood vessel wall or tear in a blood vessel (aneurysm or artery dissection) is very rare. High blood pressure and smoking may increase the risk.</li> <li>Rarely, severe skin reactions (Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis) causing sore red patches which blister and peel. Seek urgent medical advice if you have symptoms.</li> <li>Side effects with anti-sickness medication include: diarrhoea, constipation, headaches.</li> </ul>   |  |  |
| Occasional side effects:  | Sorafenib can lower your blood sugar. If you  |  |  |
| Affecting between 1-10 in every 100 (1-10%) people  Anaemia (due to low red blood cells), bruising or bleeding (due to low platelets).  Sore mouth and ulcers, dry mouth, difficulty swallowing, taste changes, indigestion, acid reflux.  Low thyroid, low blood sugar, low calcium, potassium, sodium – all picked up and monitored in blood tests.  Changes in kidney and liver function (monitored), protein in the urine.  Change in sensation in hands and feet, flushing, hoarse voice, stuffy/runny nose, ringing sound in the ears.  Muscle pain and spasm, problems with erection.  Increase risk of skin cancers. Protect your skin from sun exposure and check your skin for any changes in appearance, new growths or lesions (that may look like a new wart), or change in the size or colour of a mole.  Changes in how well the heart works with symptoms of fluid build-up and shortness of breath (heart failure) and other heart problems (angina, heart attack).  Other risks:  Allergic reactions (which may be mild or severe) are uncommon. An irregular heart rhythm is rare. | have diabetes, please monitor your levels.  Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain or stroke. Tell your doctor straight away if you have any symptoms.  Changes in memory, concentration, or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.  Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).  Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for a few months afterwards. Women of child bearing age will be tested for pregnancy before and during treatment. Use effective contraception throughout. Speak to your doctor or nurse.  Complications of treatment can occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare |  |  |
| Changes in the lungs (inflammation or scarring) causing cough, chest pain, shortness of breath are uncommon. In men, enlarged breasts are uncommon.   | side effects may also be life-threatening.  |  |  |

Other risks continiued:

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|---------|-----------|----------|
| raueni  | IUCITUIL  | zi/iauci |

| ☐ I have discussed the intended benefit and risks of available alternative treatments (including no treatments)  |   |
|--|---|
| ☐ I have discussed the side effects of the recomme straight away or in the future, and that there may be rare or have not yet been reported. Each patient may  | some side effects not listed because they are |
| ☐ I have discussed what the treatment is likely to in timing of the treatment, blood and any additional test   | ` • • • • • • • • • • • • • • • • • • •       |
| $\hfill \square$ I have explained to the patient, that they have the should contact the responsible consultant or team if t  | ·   |
| ☐ I have discussed concerns of particular important  | ce to the patient in regard to treatment      |
| (please write details here):   |   |
| Yes No Not available If No please  | e document reason here:                       |
| _  |   |
| been provided:  ☐ Information leaflet for Sorafenib ☐ 24 hour alert card or SACT advice service  | Signed:                                       |
| been provided:  Information leaflet for Sorafenib  24 hour alert card or SACT advice service contact details  SACT treatment record (cruk.org/treatment-   | Signed:                                       |
| been provided:  Information leaflet for Sorafenib  24 hour alert card or SACT advice service contact details  SACT treatment record (cruk.org/treatment-record)  Other, please state:  | Signed:  Date:  Name (PRINT):  Job title:     |
| 24 hour alert card or SACT advice service contact details      SACT treatment record (cruk.org/treatment-record)   | Signed:  Date:  Name (PRINT):  Job title:     |
| been provided:  Information leaflet for Sorafenib  24 hour alert card or SACT advice service contact details  SACT treatment record (cruk.org/treatment-record)  Other, please state:  | Signed:  Date:  Name (PRINT):  Job title:     |
| been provided:  Information leaflet for Sorafenib  24 hour alert card or SACT advice service contact details  SACT treatment record (cruk.org/treatment-record)  Other, please state:  | Signed:  Date:  Name (PRINT):  Job title:     |
| been provided:  Information leaflet for Sorafenib  24 hour alert card or SACT advice service contact details  SACT treatment record (cruk.org/treatment-record)  Other, please state:  Statement of interpreter (where ap Interpreter booking reference (if applicable): I have interpreted the information above to the patient | Signed:  Date:  Name (PRINT):  Job title:     |

# Statement of patient

Patient identifier/label

| your own copy of the form which describes the be   | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form. |
|--|--|
| ☐ I have had enough time to consider my optio  | ns and make a decision about treatment.  |
| ☐ I agree to the course of treatment described   | on this form.  |
| A witness should sign below if the patient is unab<br>parental responsibility will be asked to sign for yo   | ole to sign but has indicated their consent. A person with bung people under the age of 16 years.  |
| Patient's signature:   |  |
| Name (PRINT):  | Date:  |
| Person with parental responsibility/witness' signa   | ature:   |
| Name (PRINT):  | Date:  |
| (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)  On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of | patients Contact details (if patient wishes to discuss options later):  Contact your hospital team if you have any   |
| treatment/procedures to go ahead. Signed:  | questions about cancer and its treatment.  |
| Date:  | Cancer Research UK can also help answer your questions about cancer and treatment. If you  |
| Name (PRINT):  | want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to  |
| Job title:   | Friday, 9am to 5pm. Alternatively visit cruk.org for   |
| Important notes: (tick if applicable)  | more information.  |
| <ul> <li>☐ See also advance decision to refuse treatment</li> <li>☐ Patient has withdrawn consent (ask patient to sign and date here)</li> </ul>   | These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.      |
| Signed: Date:  | The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.  |

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(to be read in conjunction with the hospital's consent policy)

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#### What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

#### The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

#### Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

#### When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- · retain that information in their mind
- use or weigh this information as a part of their decision making process, or

 communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

#### Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

#### **NHS Scotland**

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

#### References

- Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
- Cancer Research UK: cruk.org/aboutcancer/treatment/drugs
- Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

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