# Patient agreement to systemic anti-cancer therapy (SACT)

Cabozantinib	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 (include	de brief explanation if medical term not clear)
Cabozantinib for the treatment of hepatocellular call	rcinoma.
Cabozantinib is taken orally once each day.	
☐ Each treatment cycle lasts for 28 days.	
☐ Treatment is continued until disease progression, u	inacceptable side effects or withdrawal of consent.
Where will I have treatment?	
Outpatient Day unit/case Inpatient	Other:

**Patient details** 

Patient's first name(s):

Patient's surname/family name:

### 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)

$\checkmark$	Tick	all	relev	vant	boxes
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I confirm	the	natient l	has (	capacity	to	aive	consen	t
i commini	uic	patient	iias (	capacity	w	give	COHSCH	ι.

П	I have explained th	e course of treatmen	it and intended	benefit to t	he natient
	I Have explained ti	ic course or irealine	il and intended		.iic baliciii

#### **The intended benefits** (there are no guarantees about outcome)

	•	_		
Curative – to give you	ı the	best possible	chance of being	cured

Adjuvant – therapy given after surgery or radiotherapy to reduce the risk of the cancer coming back.

Neo-adjuvant – therapy given before surgery or radiotherapy to shrink the cancer, allow treatment

and reduce the risk of the cancer coming back

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Disease control or palliative – the aim is not to cure, but to control or shrink the disease and improve both quality of life and survival.

### Statement of health professional

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	Cancer and treatment with Cabozantinib can
Diarrhoea, feeling sick (nausea), being sick (vomiting), poor appetite, sore mouth and ulcers, taste changes with a tingling or stinging sensation in the mouth.	increase your risk of developing a blood clot (thrombosis), causing pain, redness, swelling in an arm or leg, breathlessness, chest pain, a stroke. Tell your doctor straight away if you have symptoms.
Indigestion, weight loss, tummy (abdominal) pain, constipation.	Other risks:
High blood pressure.	Higher or lower blood sugar levels than usual.
<ul> <li>Soreness, redness and peeling on the palms of the hands and soles of the feet, skin rash.</li> <li>Tiredness and feeling weak (fatigue), headache, dizziness, pain in the hands and feet.</li> </ul>	<ul> <li>Slow wound healing. You may be asked to stop treatment before an operation or procedure, including dental work. Speak to your doctor.</li> <li>Side effects with anti-sickness medication include: constipation, headaches.</li> </ul>
Anaemia (due to low red blood cells), bruising or bleeding (due to low platelets).	Rarely, changes in the brain (posterior
Low thyroid hormone levels, low electrolyte levels (magnesium, potassium) picked up in blood tests.	reversible encephalopathy syndrome, PRES) causing seizures, confusion, headaches or vision changes.
Build-up of fluid causing swelling in the ankles and legs.	☐ Jaw problems (osteonecrosis) are rare but serious. Healthy jaw bone tissue becomes damaged and dies. Gum disease, problem with
Shortness of breath, cough, a hoarse voice.	dentures and some dental treatments (such as having a tooth removed) raise the risk. See
Occasional side effects:	your dentist before treatment.
Affecting between 1-10 in every 100 (1-10%) people	An enlargement and weakening of a blood
<ul> <li>☐ Hair thinning or hair loss, change in hair colour, skin changes (dryness, itching, thickening).</li> <li>☐ Dry mouth, difficulty swallowing, dehydration, piles (haemorrhoids).</li> <li>☐ Ringing in the ears.</li> <li>☐ Numbness and tingling in the hands and feet,</li> </ul>	vessel wall or tear in a blood vessel (aneurysm or artery dissection) is very rare. High blood pressure and smoking may increase the risk.  Changes in memory, concentration, or ability to think clearly. There can be many causes of this including your treatment, diagnosis, or both.
muscle spasms, joint pain.  Feeling drowsy, confused, or loss of consciousness due to liver problems.	Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility in and/or early menopause.
<ul> <li>☐ Higher risk of infection (due to low white blood cells).</li> <li>☐ High cholesterol levels, low electrolyte levels (sodium, calcium, phosphate) picked up in blood tests, protein in the urine (picked up in</li> </ul>	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 4 months after. Use effective contraception.
urine tests).  Inflammation of the pancreas (pancreatitis), which may be serious.  A hole or abnormal opening in the intestine (fistula or perforation). Tell your doctor if you have intense tummy pain or blood in the vomit or stool.	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 side effects may also be life-threatening.

To be retained in patient notes

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Prepared by Pharmacist: Lucy Cox, Alia Nizam

Checked by Pharmacist: Aneri Shah Checked by Consultant: Paul Ross Date of issue: Sept-24; Version 1; Review date: Sept-27 Approved by: Janine Mansi UK SACT Board

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## Statement of health professional

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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 in timing of the treatment, blood and any additional test	s, follow-up appointments etc) and location.		
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	•		
☐ I have discussed concerns of particular important	ce to the patient in regard to treatment		
(please write details here):			
Clinical management guideline/Protocol com	npliant (please tick):		
☐ Yes ☐ No ☐ Not available If No please	e document reason here:		
The following written information has been provided:	Health professional details:		
☐ Information leaflet for Cabozantinib	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 ap	propriate)		
Interpreter booking reference (if applicable):	p. op. a.o.		
I have interpreted the information above to the patient believe they can understand.	t 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 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)	Further information for patients  Contact details (if patient wishes to discuss
On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of	options later):
treatment/procedures to go ahead. Signed:	Contact your hospital team if you have any 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
Job title:	nurses on freephone 0808 800 4040, Monday to 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.

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taking part in a clinical trial.

Cabozantinib

### **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 (www.gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (www.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: www.medicines.org.uk/emc
- Cancer Research UK: www.cancerresearchuk.org/aboutcancer/treatment/drugs
- Macmillan Cancer Support: www.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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