Cancer Clinical Research in Northern Ireland

Cancer Research UK Roundtable: February 7th, 2023

Full report

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CANCER RESEARCH UK
Northern Ireland

Foreword

Research is vital for improving cancer services and treatments. We are in a new age of scientific research with rapid advances in genomics and Artificial Intelligence leading to novel approaches for cancer detection, screening, diagnosis and drug discovery. Such discoveries happen through global research and strong clinical research networks. To transform cancer services in Northern Ireland, we must ensure our scientific and clinical researchers are fully supported so that patients can benefit from and participate in worldwide research.

However, right now, Northern Ireland, like other UK nations, is facing numerous challenges related to facilitating research, including capacity in the health system and pressures on clinicians. Research funding also poses challenges. While a larger proportion of NI Health and Social Care Research and Development (HSC R&D) research expenditure is on cancer research than elsewhere in the UK, overall expenditure is lower. Northern Ireland has a small baseline research budget of £12m per year. Per head of population this is around 50% of expenditure in Scotland and Wales, and less than one third of expenditure in England.

That must be of concern when the Northern Ireland Cancer Registry has published figures showing growth in cancer diagnoses[i] . And on average patients have better outcomes when they are treated in hospitals that are research active, hence doing more research should be a priority for HSC. Developing and implementing a strong, well-funded, action-based cancer research strategy, focussed on helping more patients in NI to survive cancer has never been more important.

I was delighted to speak at and take part in this roundtable event - a deep dive into the current cancer clinical research environment in Northern Ireland, examining both issues and solutions. Those discussions are summarised in this report along with sound recommendations and together they provide an important foundation and key insights from which to implement Northern Ireland's first cancer research strategy.

Professor Ian Young
Chief Scientific Advisor, Northern Ireland

Foreword

Research has driven dramatic progress in cancer over the last 50 years, including helping to double the chances of survival across the UK. It was therefore great to be in Stormont earlier this year for our cancer clinical research roundtable. Whether talking to researchers, clinicians, patient representatives, MLAs, or policymakers, the goal was always the same: better outcomes for the 9,250 cancer patients diagnosed each year in Northern Ireland.

Our ambition is that 3 in 4 people will survive their cancer by 2034. However, the lack of an Executive and budget to fully implement the Northern Ireland cancer strategy means progress like this will be almost impossible to achieve in Northern Ireland. The wider economic environment is adding to these challenges, forcing those in power to make difficult decisions.

Our analysis clearly shows that research is an investment: in people but also the Northern Irish economy. For instance, every £1 invested in cancer research in 2020/21 generated £2.80 of economic benefit in the UK. Similarly, in 2018-19 alone, clinical research supported over 47,500 jobs and generated £2.7 billion in Gross Value Added for the UK economy.

Clinical research improves clinical outcomes and saves lives. Engagement in research and clinical trials ensures that NI patients have early access to innovative treatments. If we get cancer clinical research right, the potential is enormous. We hope this paper will help set Northern Ireland on the right path to realising that potential.

Dr Owen Jackson
Director of Policy, Cancer Research UK

Executive summary

Cancer clinical research (research in which people, or data or samples of tissue from people, are studied to understand health and disease) is important in the development of new treatments for cancer, but also a critical element of patient care, particularly for those who have exhausted other treatment options.

Action 55 of the Northern Ireland Cancer Strategy (March 2022)[ii] calls for the development of a cancer research strategy in partnership with key stakeholders. Cancer Research UK's (CRUK) roundtable event was organised to help contribute to the development of this strategy. The roundtable was attended by clinicians and other experts in cancer trials, Department of Health (DoH) officials, Members of the Legislative Assembly (MLAs), patient representatives and others from across the sector.

The event enabled a range of voices to contribute their views on this topic. **This report is a summary of discussions during the event and aims to contribute to the Department of Health's work to develop a cancer research strategy.**

Guest speakers included:

- Paula Bradshaw, MLA, Alliance Party Spokesperson on Health and Chair of the All Party Group on Cancer
- Professor Ian Young, Chief Scientific Advisor, Northern Ireland
- Dr Tomas Adell, Director of Elective Care and Cancer Policy, DoH
- Dr Melanie Morris, Operations Director, Northern Ireland Clinical Trials Network
- Margaret Grayson, former chair Northern Ireland Cancer Research Consumer Forum; Patient and Public Involvement (PPI) volunteer for CRUK Grand Challenges; member of Public Involvement Enhancing Research (PIER NI)
- Paul Givan, MLA and DUP Spokesperson on Health

The half-day event involved expert presentations followed by more in-depth group discussion. Administrative assistance and note-taking was provided by Stratagem

The event was divided into three focus areas:

1. Cancer clinical trials set-up and delivery

- How cancer clinical trials are set up and run in Northern Ireland.
- How Northern Ireland compares to other UK nations.
- The impact of molecular genomic testing on clinical trials.

2. Funding for cancer clinical trials

- How clinical trials are costed and funded.
- Funding Northern Ireland's clinical trial infrastructure.

3. Public involvement and participation in clinical trials

- The Cancer Patient Experience Survey (CPES): why are Northern Ireland cancer patients not asked about research participation as frequently as in other nations?
- The role of public and patient involvement (PPI) in cancer research and trials.

There was wide-ranging and robust discussion in all sessions, with summaries provided in this report. There was good engagement from all participants, with many suggestions on how to increase and improve cancer clinical trials in Northern Ireland. Broadly, these suggestions can be distilled into three main areas for consideration.

1. Cancer Clinical Research must be recognised as part of core business and not be treated as an 'add-on' to cancer services.

The Department of Health should develop and lead a programme to promote clinical trials as integral to core cancer services. Clinical research must be more recognized and valued within the health service. Trusts should increase attention on clinical research and trials, including having Trust Research Directors sit on Trust Executive Boards. All Trusts across Northern Ireland should participate actively in cancer clinical research to provide equity of access to the entire population. Clinician participation in trials is currently hampered by service pressures; Trusts must acknowledge that research is part of cancer treatment and care and provide protected time for research.

2. Northern Ireland cancer trials core funding from Public Health Agency Research and Development (PHA R&D) should be increased to similar levels to Scotland and Wales.

Clinical research infrastructure funding in Northern Ireland is currently significantly lower than other UK nations on a per-capita basis. While there are budgetary pressures in the health service, it is important that research is not forgotten, and additional funding should be provided. Ideally, over time, Northern Ireland should be at the same level of funding as Wales and Scotland. This additional funding must be recurrent and be used primarily to increase staff capacity so more trial applications can be processed. A clear plan is required to ensure all core funding is spent in a way to help more patients and achieve best value. Trials staff currently on temporary contracts should be made permanent. Opportunities such as improved facilities within the Institute for Research Excellence in Advanced Clinical Healthcare (iREACH) and for cross-border trials should be proactively explored.

3. Every cancer patient should be given the opportunity to discuss options in research.

DoH, via the Public Health Agency (PHA), should publish and make widely available easily understood information about cancer clinical trials in order to promote participation. The Northern Ireland Cancer Research Consumer Forum coordinates patient and public involvement for cancer trials; this work should be more widely promoted and used to recruit new members to the Forum. All cancer patients should have the opportunity to participate in discussions about their suitability to participate in a trial.

1. Cancer clinical trials set-up and delivery

Introduction

Dr Melanie Morris, Operational Director of the Northern Ireland Cancer Trials Network (NICTN) gave an overview of cancer trials in Northern Ireland, highlighting the patient and economic benefits. For instance, research-active hospitals attract and retain high calibre staff, which is essential in Northern Ireland, particularly given ongoing staffing pressures. It was also emphasised that access to clinical trials is what patients want.

She noted, however, that setting up trials takes time and resource. Clinical trials must be ethical and are highly regulated. This is not only to ensure patient safety but also to ensure that the results obtained are reliable and that the hospitals hosting these trials are not put at risk, for example by providing treatments without regulation. To mitigate risk it must be ensured that staff are available and appropriately trained, Health and Social Care (HSC) services are accessible and the costs associated with conducting a trial can be covered. Setting up clinical trials requires discussions with a variety of HSC departments, including diagnostics, cardiology and others. This is necessary to secure the service support required throughout the patient's trial journey. These discussions can be protracted, particularly when they are already under immense pressure to delivering routine activity.

Cancer trials are conducted by interdisciplinary teams which include principal investigators, research nurses, radiographers, administrators and data managers, laboratory technicians, pharmacy staff and a range of others. The team cannot work in isolation to deliver cancer trials but is reliant on being able to work alongside the many clinical services that exist within the HSC.

Although trials are conducted in all five Northern Ireland Health Trusts, over the past 14 years, 67% of trial participants have been recruited in Belfast based clinics. This has primarily been due to the clinical trials service being mapped on to Cancer Services, which was historically a hub and spoke model. With limited research infrastructure available outside of Belfast, the number of clinical trials that can be delivered safely in the other hospitals is restricted. This clearly raises an issue regarding equality of access for patients living outside Belfast.

Most patients in Northern Ireland are recruited to observational trials (those that don't test potential new treatments but where researchers observe patients and measure certain outcomes) as opposed to interventional trials (those that that test potential new treatments). Although the NICTN trials portfolio workload is dominated by complex interventional trials, 70% of overall recruitment is to observational trials which are less resource intensive, less complex and much easier to recruit to.

While not solely a Northern Ireland problem, average patient numbers per trial have been falling for some time due to changes in the drug development landscape. In the past, everyone with breast cancer could be offered the same trial. Today trials are specific to certain sub-groups of patients, and only patients with a specific gene mutation will be eligible to participate in certain trials. Many patients may be screened before an eligible patient is recruited. Add to that Northern Ireland's small population, and recruitment to interventional trials is now much more challenging and Northern Ireland needs to open many more trials, each recruiting fewer patients. The impact of this is that more resource is needed to deliver an increasingly complex trials portfolio.

Trials are not always available for every disease site. For it to be viable, a suitable trial needs to be awarded, with a research active consultant willing to oversee the trial and importantly a pool of potentially eligible patients. In interventional trials those disease sites with the highest portion of trials are multi-site (23%), breast (19%), leukaemia (16%), urology (14%), and gynae (10%). For non-interventional or observational

trials, the spread is different with the largest portion of trials conducted in urology (42%), multi-site (13%), lung (13%) and skin (11%). To be eligible for trial participation a patient must also be fit enough for any new treatment. This is not equally so across different disease types.

In 2021/22 Northern Ireland lagged behind other UK nations in terms of trial participants per 1000 population. However, if the figures are based on Belfast-only activity and standardised for the population served by Belfast Health and Social Care Trust, performance per 1000 population is comparable to Wales. (data from Dr Morris's presentation using figures from NIHR annual report and NICTN calculations)

Nation	No of Participants	No of studies recruited	Recruitment per 1000 population
UK	87,566	1,159	Data not available
England	80,218	798	1.4
Wales	3,613	158	1.2
Scotland	3,598	182	0.7
Northern Ireland	369	90	0.2
Republic of Ireland	1,447	182	Data not available

Dr Morris highlighted a range of challenges within the current system including access to support services, navigating the R&D approval process, staff capacity and lack of protected time for staff to support trials. A major concern however was that research is not seen as a core business within the HSC, but instead is often seen as an 'add on' and so is not prioritised. Similar attitudes were also highlighted in CRUK's **Creating Time for Research** Report[iii] . Dr Morris was hopeful that the development of a Cancer Research Strategy for Northern Ireland could help remove some of these barriers. Also, iREACH, which includes a state-of-the-art clinical trials facility due to open in Belfast in 2026, aims to integrate the activities of clinicians, life scientists, data scientists and patients and the public with industry partners to increase both NI research capacity and capability for global benefit.

Discussion: Key themes

Weak research culture in an overwhelmed clinical system

There was broad agreement among attendees that the current culture in the HSC does not sufficiently value clinical research. Instead, the view was that research is often seen as an 'optional extra' rather than as a core part of healthcare provision that provides vital benefits to patients and HSC. Attendees felt that when the health system is under pressure - as it is now – research often suffers.

One of the specific challenges highlighted was that research is not embedded into everyday practice and decision-making, with the lack of metrics for research identified as a potential factor. For instance, care service metrics, such as cancer waiting times, play a crucial role in informing decisions, evaluating performance, and motivating improvements. Given there are not currently metrics for cancer research , attendees suggested it is perhaps unsurprising that when HSC is faced with a lack of resources, decision-makers experience a disproportionately strong incentive to prioritise services over research.

- **DoH should lead a programme of work to increase the visibility of research's benefits and the accountability for clinical research delivery at senior levels of DoH and HSC Trusts.**
    - **Make HSC Trust Research Directors full members of Trust Executive Boards.**
    - **Prioritise existing plans to develop research metrics for use across Trusts.**

Insufficient time for research

One of the key consequences of HSC's weak research culture is that very few doctors, nurses and AHPs have enough time to conduct and support research. One attendee noted that it was not uncommon for the pressures described to leave HSC staff feeling guilty about pursuing research opportunities. As well as directly impacting the speed and number of trials that can be set-up and delivered, this also limits the ability of clinicians to meaningfully engage patients with potential research opportunities.

- **Future HSC NI workforce plans, developed within DoH, should recognise the importance of research and establish ways to ensure clinicians have ring-fenced time to conduct research.**

Delays in approval and set-up

Concerns were also raised by attendees about the speed and bureaucratic nature of trial set-up in Northern Ireland. Examples were given of studies that have been approved in other parts of the UK being held-up by potentially duplicative approval processes. Several potential explanations were discussed. These included legislative differences between Northern Ireland and other UK countries and a lack of local alignment within Northern Ireland around regulatory and R&D processes, such as the requirement for time-consuming and inefficient negotiations across different HSC departments. Some were concerned that the level of bureaucracy involved in HSC research can often deter healthcare staff from getting involved.

- **DoH, Trusts and the NI Cancer Clinical Trials Network should review and learn from the successes during the pandemic, which saw innovative trial design and faster regulatory approvals.**

Data

Attendees identified better use of data as a major opportunity for cancer research in Northern Ireland. The Cancer Registry was held up as the data guardian for research, and Encompass mentioned as the future for patient data in NI. The latter is HSC's programme to create a single digital care record that covers everyone in Northern Ireland currently receiving health and social care.

Despite substantial optimism about the potential of these data platforms, discussions were grounded in understanding of the present and future challenges. For instance, attendees shared concerns about sharing data across borders post-Brexit, with specific complications related to GDPR highlighted. The lack of secondary use of data legislation (although it was given Royal Assent in 2016) was also discussed, with attendees noting that this frustrates not only research, but also international data sharing and audits. This lack of regulatory legislation is primarily due to the lack of an Executive.

Above all else, though, attendees emphasised the importance of establishing and maintaining the public's trust in relation to data use. There was a particular keenness to learn lessons from the difficulties encountered by the UK Government which recently attempted to implement plans that to give commercial companies increased access to patient data for research. Some attendees felt it should be up to the individual to consent, but others raised concerns about whether this would lead to a high number of patients opting out. Either way, attendees agreed that clear and honest communication is vital.

- **In consultation with clinicians and data experts, the coordination and use of data across Trusts should be improved to maximise the potential of the NI Cancer Registry and new Encompass programme.**

- **New regulations which enable the secondary use of health data in Northern Ireland should be drafted by the DoH and passed in the Assembly as soon as possible to ensure patients in Northern Ireland have the same access to treatments and diagnostics as patients in the rest of the UK.**
- **All changes to how patient data will be used for research in NI should be communicated clearly, thoughtfully, and honestly to ensure the public trusts that data will be used responsibly and securely.**

Equitable access to trials in and across Northern Ireland

Cancer research has been central to driving life-changing improvements in cancer care and survival. However, there was a strong feeling among attendees that such advances have not, and are not, being distributed equitably across Northern Ireland. At a basic level, attendees noted that because most trials take place in Belfast, those living in other parts of the country are more likely to experience time, distance and financial burdens when accessing clinical trials, or be unable to access them at all.

- **DoH and Trusts should review capacity for all trusts to fully participate in clinical trials and consider opportunities for different types of trials.**

The case for a strategy that is tailored to Northern Ireland

Finally, while it was acknowledged that many of the challenges described apply across the UK - like the pressures on research capacity - attendees also emphasised that a tailored approach is needed alongside a more UK-wide one. A challenge that is less relevant to England, for instance, is that the patient pool in Northern Ireland is sometimes considered too small to justify the resource to open a trial. If too many trials are turned down, this can lead to tension and potential reputational damage.

- **To enable the NI Executive to target the specific challenges facing cancer patients in Northern Ireland, the DoH should work closely with nations across the UK to ensure the NI Cancer Research Strategy is aligned with existing commitments in the clinical research space.**

2. Funding for cancer trials

Introduction

Dr Morris also presented an overview of funding for cancer trials. She began with an explanation of the difference between commercial and non-commercial trials. The primary difference is that for non-commercial trials, some costs may be covered, but not all. Commercial trials operate on a 'full cost recovery' model whereby all costs incurred for patients on a trial are reimbursed to the Trust. In addition, commercial trials cover overheads and will often pay an additional capacity building element that generates revenue for the HSC. This income is extremely welcome as it allows Trusts to strengthen research infrastructure.

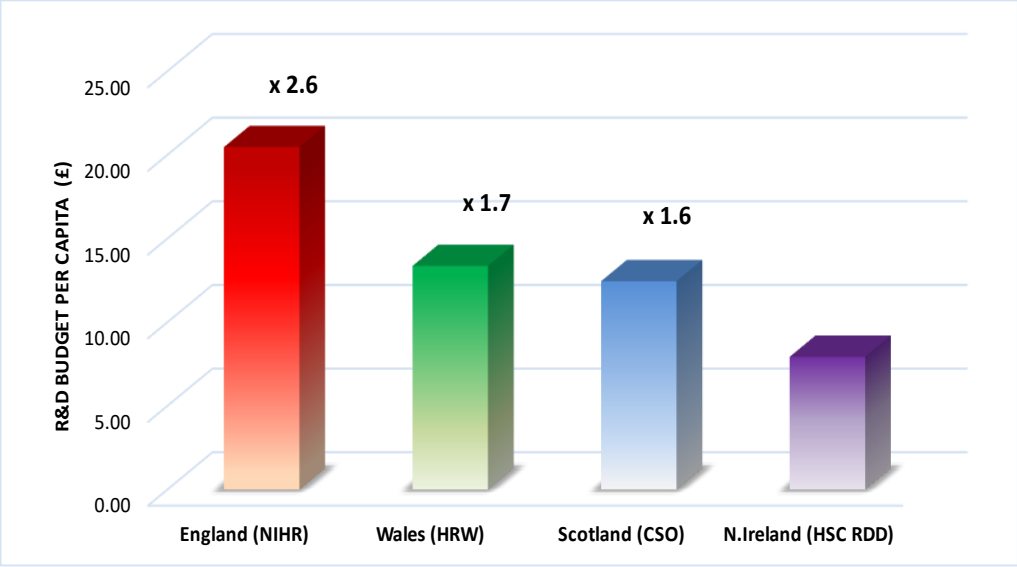
The current cancer trials portfolio in NI is mostly non-commercial. These trials may be sponsored for example by a university, health trust or charity, with funding provided by a research grant or charitable funding. Although many trials will provide a drug or medical device free of charge, there are additional costs associated with running clinical trials that need to be covered. These include patient care costs, particularly those treatment costs that are above the normal standard of care ('excess treatment costs'), research costs, HSC support service costs and the use of private sector services if required.

NICTN staff are core funded by several funding streams, with HSC R&D being the main funder. It was noted that 40% of the NICTN infrastructure funding is non-recurrent in nature, mostly coming from charitable sources (29%), research grants and commercial funding. The current infrastructure supporting cancer trials is therefore very vulnerable. Charity income was severely impacted by Covid-19 (no public participation

fundraising events, charity shops closed etc) and there are fewer funding initiatives available as a result. It was also noted that research grants do not cover wage inflation, which is challenging to predict, particularly in the current climate.

Dr Morris highlighted that Belfast had recently been successful in retaining its Experimental Cancer Medicine Centre Grant (co-funded by Cancer Research UK and PHA R&D). She also remarked that there were potential new cross-border funding initiatives following the resigning of the renewed Cancer Consortium partnership between Ireland, Northern Ireland and U.S in March 2021.

As illustrated by the graph below[iv], the Northern Ireland Executive spent less on R&D in 2021/22 than any other nation in the UK on a per-capita basis. This deficit means less funds available for core staff, basic infrastructure and ongoing work in trial set up.



Discussion: Key themes

Low core Infrastructure Funding

All attendees agreed that additional infrastructure funding for cancer clinical trials is required, but many also cautioned that increasing funding alone will not provide improvement, saying that there should be clear priorities for any additional funding, and accountability around how it is used.

There was general agreement that NI core funding from HSC R&D should increase to be in line with Wales and Scotland on a per-capita basis. However, there was also recognition that additional funding alone will not improve the performance of the current trial portfolio, nor recruitment levels. Increased funding and system change and must work hand-in-hand; in addition to additional funding, NICTN must streamline trial set-up for a carefully selected trials portfolio, underpinned by a culture that sees research as an integral part of the patient care pathway.

There was some discussion about overlap and duplication in trials. Commercial trials are registered centrally via an accessible portal which can avoid duplication. But in non-commercial trials there are more possibilities for duplication. Discussion suggested this is not a significant issue for NI right now. It is not desirable to have

several trials competing for the same patient pool at the same time; NI has a relatively small number of eligible patients and so avoiding duplication is important.

Many attendees made the point that Trusts are naturally risk averse and can sometimes be reluctant to accept more trials when clinical pressures could prevent adequate staff participation. One table discussed whether funding for cancer clinical research could be part of regular 'cancer service delivery' funding, rather than as something totally separate from treatment and care funding. Building on this, it was suggested that NI could be smarter about how research is funded by 'repurposing finances' in a wider way within Trusts. This would require Trusts to be willing to consider managing finances in potentially new ways. However, repurposing of finances must not be allowed to manifest itself in the opposite direction (e.g., taking research funding for regular service delivery).

The UK-led O'Shaughnessy Review[v] of commercial clinical trials was discussed generally, though the final report and recommendations were not published until after the roundtable event (26 May). The review's purpose was to identify how to ensure the UK remains an attractive destination for industry clinical trials. It is not clear yet what the report outcomes will mean for NI, but attendees agreed it is important that R&D are involved to maximise its value for NI and to ensure no unintended consequences. The outcome of this review should be considered within NI's development of a cancer research strategy.

Many references were made to what could be done better if infrastructure funding were increased. These were primarily related to setting up trials quicker and facilitating delivery of additional trials. Many thought additional staff should be the main use of any additional funding. It was also felt that Trusts should be held accountable and that any additional funding should have strings attached to maximise impact.

As described above, given the financial benefits of commercial trials to the health service, attendees raised whether we should try to increase the level of commercial trials, thereby maximising income.

- **Core infrastructure funding from HSC R&D should ultimately be increased to match per capita spend in Scotland and Wales.**
- **Cancer trial set-up and running procedures should be reviewed regularly to identify opportunities for improvement in efficiency; any such opportunities identified should be followed by plans for change.**
- **The NI Cancer Trials Network should participate fully in any UK-wide reviews of clinical trials and use review outcomes to improve trials set up**
- **Where possible and appropriate, focus should be given to securing participation in commercial trials.**

Recruitment and retention of staff

Attendees agreed that it is critical to have experienced, well-trained staff working in cancer trials. Currently, almost all research staff are on temporary contracts. Though temporary, in practice they are almost always renewed and funding very rarely withdrawn. However, advertising roles as temporary means vacancies are not as attractive or inclusive as they could be, with many people wanting and often needing a permanent position.

- **Contracts for essential research staff should be made permanent as soon as possible.**

Maximising iREACH

There was a lot of discussion about the potential benefits of the Institute for Research Excellence for Advanced Clinical Healthcare (iREACH), which refers to the plans to create a unique ecosystem to test new drugs through their development life cycle, which includes clinical trials. iREACH is one strand of the Belfast City Deal which was signed officially in December 2021. It is a partnership between central and local

government and regional partners. The goals of iREACH are economic growth, with more and better jobs, and positive impact on deprived communities, with benefits spread across the region. The iREACH website states they will provide 'unified capability for clinical trials within the Belfast Region and augment the ability to take on larger and more complex trial studies'.

Attendees saw iREACH as a significant opportunity for increased capacity in trials with the development of a state-of-the-art trials facility and the ability to attract wider research opportunities.

There was wide agreement that HSC R&D should be closely involved with the development and progress of iREACH to ensure NICTN can take advantage of all new developments within this programme.

- **NICTN management and HSC R&D should be actively involved in iREACH discussions around planning for future clinical trials and infrastructure development.**

Opportunity for cross-border trials

There was discussion about the potential opportunities for cross-border trials, particularly at the North West Cancer Centre, which treats a substantial number of cancer patients from the Republic of Ireland.

However, it was also mentioned that the two jurisdictions have their own regulatory system and different trial approval processes. This can make it more difficult to set up and manage cross-border trials. Many believed that effective joint working is possible with good cross-border working and that it would be worth the effort to expand the range of cross-border trials.

As part of any next steps, attendees agreed there would need to be a review of the post-Brexit landscape and the impact of the Windsor Framework on cross-border working.

- **Where regulatory issues permit, NICTN should look to expand the number of cross-border trials, particularly in the North-West Cancer Centre.**

3. Public involvement and participation in clinical trials

Introduction

Margaret Grayson, former Chair of the NI Cancer Research Consumer Forum and member of Public Involvement Enhancing Research (PIER) NI presented a session covering PPI in research.

PPI is active involvement in research decisions and partnership working. It provides different perspectives on research development and analysis, can identify different funding areas to be prioritised and provide more practical trial methodology. PPI is involved in all stages of trial development from initial concept through identifying research questions, data requirements, methodology, recruitment, and dissemination. The NI Cancer Research Consumer Forum is the PPI group for the NI Cancer Trials Network, and members assist with design, communication and methodology for cancer clinical trials in NI.

The Cancer Patient Experience Survey (CPES) is the only measure of whether patients noticed information about clinical research or were approached about research. The most up-to-date survey is from 2015, with findings summarised below, found that NI compares poorly to England on a number of research engagement measures. The red, amber and green blocks are the scores for lowest 20%, average 60% and highest 20% respectively, of English Health Trusts. The black dot is the score for Northern Ireland (all Trusts).

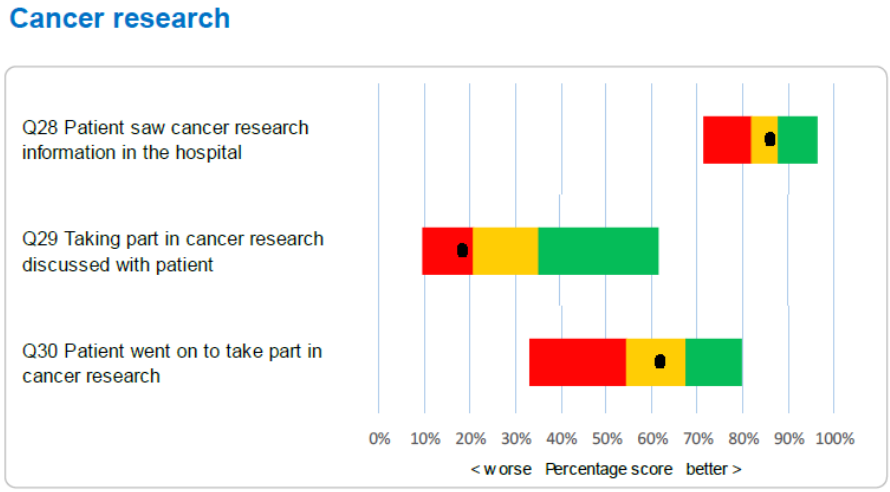


Chart 7 – RAG - Cancer research

Margaret provided quotes from patients regarding what patients felt were the benefits of being on a trial. Some of these were receiving treatment they would not otherwise have been able to receive; friendly, helpful and supportive staff; knowing the trial will help others; and regular contact with staff provided reassurance. She also pointed out that Northern Ireland lags behind other nations in not providing any trials for metastatic disease.

Discussion: Key themes

Patient and public knowledge of trials

There was broad agreement that current awareness and understanding of clinical trials amongst both patients and the public is poor and a key factor driving the low numbers taking part in clinical trials. There were also strong views that if the public was more educated about research and clinical trials, then patients would also be better placed to make informed decisions about participation and often more likely. Again, the current research culture in the HSC was highlighted as a significant barrier and one that was a particularly frustrating to patient representatives.

Several attendees reported that explaining the details of a clinical trial made for a complex conversation with patients, often requiring high levels of literacy and considerable time. The paperwork alone routinely runs to more than 20 pages. They felt that this contributes to inequitable opportunities, with patients from more deprived areas or where English is not someone's first language, often appearing less interested in taking part in clinical trials. One group also discussed the underrepresentation of older patients and whether there should be specific trials for older people.

Despite the unavoidable complexity of trials, there was agreement that information could, and should, be simplified for patients. In addition, all groups agreed that is a clear need to run regular public campaigns to show the value and importance of cancer clinical trials, highlighting both how they can provide hope for patients with few other approved options, but also in helping drive innovation and developing kinder treatments. Information should also describe how patients can get involved and support trials, even when there is no suitable trial for them.

- **DOH (via PHA) should publish widely available and easily understood information and educational materials about cancer clinical trials.**
- **DOH (via PHA) should deliver:**
    - **Public campaigns about the impact and progress made because of clinical trials.**
    - **Targeted community led campaigns that focus on reaching patients from underserved groups, including people from more deprived areas and older patients.**
- **All patients with a cancer diagnosis must receive clear and easily understood information about the value of taking part in cancer clinical trials or other cancer research.**

Increasing participation in trials

There was consensus that the current number of patients taking part in trials was too low and the gold standard should be for every patient to be asked if they wanted the opportunity to take part in a trial. However, it was also accepted that this would not be possible in the current circumstances, with service capacity the main barrier, particularly in pharmacy and radiology. Alongside this, level of satisfaction with treatment is as good in NI as in other parts of GB and this leads to the perception that taking part in trials is only for those for whom it is the last option.

The issue of the accessibility of trials in NI was brought up in one group. Travel was cited as a barrier to participation in clinical trials and there was discussion about why most clinical trials take place in the Belfast Trust. The view was that this again relates back to the current perception of research as an optional extra rather than as a core activity.

It was also discussed at what point patients should be involved in decisions about trial suitability. Clinicians explained that they do not want to give false hope and so typically look to see if a suitable trial was open and appropriate in the first instance. However, patient representatives present felt that the decision should be discussed with them. One patient representative added that trials had not been offered to him but said he would have been keen to participate in some way even if there was no suitable trial for him. For example, patients can also feel empowered by providing consent for collection of biopsies tissues for the NI Biobank. One attendee suggested many other cancer patients would also be willing to do this.

Views were mixed on the current levels of support among patients for their medical records to be used for research. Some cited trust issues, while others felt securing secondary use of data legislation at pace was critically important as it would enable clinicians from NI to input into national studies.

Either way, Encompass was seen as an opportunity to increase participation in trials as it will include an app where patients can opt into research, express interest in trials as well grant access to their medical records.

- **All patients should have the opportunity to participate in decisions about suitability for a trial.**
- **Options to consent to collection of samples and access to medical data should be offered to all cancer patients whether they are in a trial or not.**

Maximising the value of PPI

There was a clear view that research should be front of mind throughout the treatment process. That is, even if a clinical trial is unavailable, every decision made in the treatment journey should be research based and involve patients.

Again, there was discussion about the public's perception and understanding of research and the need to do more to raise awareness and actually engage the public in designing research. There was a recognition that the NI Cancer Research Consumer Forum, which is the PPI group for the NI Cancer Trials Network is relatively

unknown. Their members' role in assisting with the design, communication and methodology for cancer clinical trials in NI should be more widely publicised.

There was also discussion about system failures and dysfunction. There was agreement that the right components are all there, the expertise, the intellect and the will, but no mechanism to bring it all together. One patient representative talked about their "frustration at being restricted from contributing to change at certain times" rather than allowing patient voices to highlight where things are not working and challenge the system.

There was a shared desire to move towards a process where patients are not just participants in trials but are key to the whole research process: developing protocols, sitting on steering committees and panels that award funding. This approach would mirror the co–design nature of the Cancer Strategy.

- **Need to build public awareness of how to get involved in PPI and designing research.**
- **There is a need for the research community to build trust with patients in understanding how their data would be used (and how it will not be used).**
- **Develop plans and target timescale for patients to be integral to entire end to end research process.**

For further information contact margaret.carr@cancer.org.uk or barbara.roulston@cancer.org.uk

Cancer Research UK Cancer Clinical Research Roundtable

7 February 2023

Attendees

Cancer Research UK	Dr Owen Jackson Graham Cadwallader Andy Glyde Joe Kiely
NI Department of Health	Prof Ian Young Dr Tomas Adell Taryn McKee Gay Ireland
NI Assembly	Paula Bradshaw MLA Paul Givan MLA Ciara Ferguson MLA Diane Forsythe MLA Harry Harvey MLA Stewart Dickson MLA Danny Donnelly MLA Cllr Carl White (for Colin McGrath MLA) Aimee May Dornan (for Nick Mathison MLA)
NI Cancer Trials Network	Dr Melanie Morris
Belfast Trust	Dr Paula Scullin Prof Suneil Jain Prof Vicky Coyle Dr Martin Eatock Dr Oonagh Sheehy
NI Cancer Registry	Damien Bennett
Association of British Pharmaceutical Industry	Marian Laverty

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