DSSG

Spring 2023

Outcome Report

CANCER TRIALS  & DATA PROTECTION

cancer trials ireland

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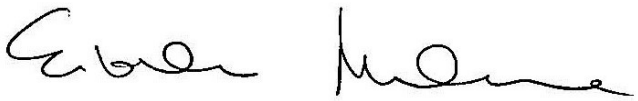
Introduction:

For the second year running, “Cancer Trials & Data Protection” was the title of the Cancer Trials Ireland Spring Stakeholder Session. This pertinent topic continues to have a negative impact on clinical trials, causing significant delays and resulting in administrative and organisational headaches for all concerned. The goal of the session was to take a closer look at what efforts are being made by the various stakeholders to combat these challenges.

Cancer Trials Ireland advocates for fast delivery of clinical trials in Ireland for patients. For example, one of those endeavours has been the bid to increase protected research time for consultants, and also, 11 more medical oncologists have been appointed in recent years which will help with this. Another issue previously dealt with was NREC and its efficiency, which has also improved in recent times.

Data protection is the next issue we are focusing on, and we have assembled a picture of how it is impacting the smooth opening and running of cancer clinical trials, by speaking to those working in cancer units where trials have been stymied by the differing interpretation of GDPR by hospitals even after NREC and regulatory approval.



Eibhlín Mulroe

CEO, Cancer Trials Ireland

Panel 1:

Data Protection Commission & HSE Research Office

On the first panel for the session was Rachel Batten, National Lead for Legal Support and Data Protection from the HSE Research Office. Batten noted her function is relatively new within the HSE, having opened in February 2022; ultimately, it exists to ensure there are better streamlined processes for research in healthcare in both data protection and legal.

"The goal is to understand it better in order to make it more practical and user-friendly and not reduce the compliance and regulation element."

David Murphy, Data Protection Commission's Deputy Commissioner with responsibility for supervision of the Public, and Health Sectors was also on the panel and he noted that he has led a unit within the Commission dealing solely with health since 2019. "Healthcare and in particular health research presents such complicated issues, you need a dedicated team," he said, noting that this team has expanded in the interim. The DPC is prioritising health research and wishes to engage closely with those involved to overcome any difficulties, he added: "We want to hear what the issues are and help people find solutions to overcome those… we do not want the regulatory framework preventing health research."

David Murphy, Data Protection Commission's Deputy Commissioner with responsibility for supervision of the Public, and Health Sectors

The implementation of GDPR has not been smooth; Murphy noted that the Health Research Regulations, introduced in 2018, was not without its difficulties and amendments had to be made in order to fix these. He and his colleagues are drafting the guidelines on scientific research under GDPR on behalf of the European Data Protection Board, and he pointed out that every member state is struggling with the same questions. Ireland is "not some sort of outlier where nothing works" and these problems are not unique to here, he stated. The regulations raise questions that are often "knotty and difficult" and each member state has its own interpretation despite GDPR aiming to bring a harmonised approach. In Ireland this is further complicated by Ireland's complex and fragmented healthcare structure. The aim is that the guidelines will be available in draft form by this summer, when they will seek feedback, Murphy said. "The hope is that they will be comprehensive and answer a lot of people's questions."

The HSE is cognisant of these challenges, and Batten reiterated the action it has taken in terms of establishing her unit, but she added that the skillset in this area is very difficult to find, given that it is both complex and niche. The HSE has approved six roles in data protection and contract management specifically for health research, aligned by the six Regional Health Authorities. They are currently attempting to establish the data protection teams linked to the six Regional Health Areas (RHAs) under Slaintecare, she explained. This led Ms Mulroe to ask if these teams will be empowered to make a risk/benefit decision, given that it is "not always black and white". Batten noted that as part of the RHA there are leadership posts, including a director of research, a half post consultant and a chief academic officer. "They will be the champions in this area," she explained, adding that the expectation is that the people interested in these posts will be research active clinicians.

Various efforts have been made to streamline processes yet Mulroe said she believed pharmaceutical companies aren't using the Model Clinical Trial Agreement template provided by IPHA. Batten responded that her understanding is there was a need for the HSE to ensure more stakeholder engagement takes places - they are now trying to improve this via the CRO sponsor and organisation template, which is being developed, this time with extensive engagement. "This will be subjected to feedback to ensure it can be used by Section 38 and 39 organisations."

Although the DPIA process is very stringent, Mulroe noted that the major roadblock to the opening of a trial can be when the CEO of a particular hospital refuses to sign a contract. "What's different for a CEO of a hospital and the NREC - what are the different considerations from a GDPR perspective?," she asked. "If we get approval for a study with

the DPIA we are using, why is it perceived differently in different sites?"

Murphy suggested that the hospital CEO is looking at it from the view of "organisational and corporate risk" and in that case may be very risk averse. "When you consider the major data breaches that have happened in this country have been in the health space - the risk should personal data become exposed to the individuals is massive because it is very sensitive data. He stressed the consultation function of the DPC and urged those involved in trials to "pick up the phone and ask us a question". "We can't tell you 'yes' or 'no' but can give advice on how to get to compliance in this space in a risk-based manner… It's about safeguards that are proportional to the risk." He added that they have engaged extensively with patients, and stressed that patient interests are their priority. "And it is not in their interests if their data protection rights are getting in the way of their wish to participate in health research," he said. "Patients want security and assurance that their data is being treated in a responsible and transparent way - this is also the goal of GDPR."

Batten agreed, saying it is impossible to eliminate all risk, "but the benefit of the trial going ahead may outweighs that risk". The problem is one of communication, she said. "The skill base and the knowledge base that it takes to clearly outline the mitigating factors are that have been put in place to ensure the hospital is being protected are unfortunately missing in some cases." She added that one of the misconceptions is that the DPO does that but they aren't an operational function.

- During the Q&A, medical oncologist Dr Grainne O'Kane from St James's Hospital noted GDPR has caused "huge problems" for clinical trials in Ireland. She asked if Irish timelines and specific GDPR requirements were being benchmarked against those of our European counterparts. Murphy admitted this hasn't been part of their work to date, noting that the intersection between what GDPR says and what happens in member state law is the "complicating factor". He added that they see difficulties arising in multi-jurisdiction studies, where DPIAs can be rejected in Ireland despite being accepted elsewhere. Benchmarking may be something they can do via stakeholder engagement through the public consultation process once feedback is being sought on the draft guidelines - this could provide solutions that would help DPOs, he noted. O'Kane emphasised the need to learn from different experiences elsewhere and added that while DPO support is being addressed, specific support for hospital CEOs might be needed in terms of building confidence.
- Medical oncologist and CTI Clinical Lead Ray McDermott highlighted the establishment of the central ethics committee, which means just one application is now required for the whole of Europe. He asked if this could be applied to the DPIA, given that the legislation is Europe-wide. Murphy responded that the requirement to conduct the DPIA falls upon the data controller - who exactly this is is complicated in health research given the level of collaboration. He added that the current legislative framework does not provide scope for a "cover-all" agreement that would allow this. Yet he pointed out there is no need to "go back to the drawing board with DPIAs" - they can be copied at least partly in many circumstances - hence the eagerness to develop standardised templates. According to Batten, it is often seen that organisations get "bogged down" in the DPIA. Where there is a commercial sponsor, the onus is generally on them to carry out the DPIA but they are required to give trial sites sufficient information in order for the data to be processed. On that basis, the HSE are now piloting a process instruction form, which may be a more efficient way of solving this problem. Mulroe commented that these idiosyncrasies is why she believes there is a requirement for health research-specific legislation.
- Dr Emily Vereker, head of NREC noted that many member states are moving away from the DPIA and instead submitting a statement of compliance. A similar model is now being explored here. "What [people] really need is assurance that there are no ethical implications to the data that is being processed."

Rachel Batten, National Lead for Legal Support and Data Protection from the HSE Research Office

"The HSE has approved six roles in data protection and contract management specifically for health research, aligned by the six Regional Health Authorities."

NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

"Research Ethics & Data Protection"

A briefing note by

Dr Emily Vereker, Head of Office

The National Research Ethics Committee's (NREC)[1] have a legislative mandate to ensure regulated research studies are conducted ethically to safeguard the well-being, safety and dignity of research participants. The NRECs must consider the ethical integrity of data processing and protection during the conduct of research studies.

The interplay between ethics, data protection and the right to privacy, autonomy and self-determination is set down in national and international instruments, setting out suitable and specific safeguarding measures to ensure the fundamental rights and freedoms of the research participants.

The Declaration of Helsinki[2] states that:

> **'Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information'.**

EU legislation transposed into Irish law[3] further provides for the NRECs to have regard for:

> **'the arrangements for the protection of research participants' privacy and confidentiality'**

In a document commissioned by the European Commission[4], it is stated:

> **'Data protection is both a central issue for research ethics in Europe and a fundamental human right. It is intimately linked to autonomy and human dignity, and the principle that everyone should be valued and respected.'**

Where research entails processing of 'high risk' personal data, such as health data[5], Sponsors (Data controllers) must identify and analyse potential risks and the corresponding mitigating actions to be implemented to minimise data processing and ethical risks and harms to the research participants.[6]

Importantly, it is not the responsibility of the NRECs to verify or oversee data protection compliance. It the responsibility of the Sponsor to ensure compliance with all applicable data protection legislation, including within the jurisdiction of Ireland.[7] However, assurances must be provided to the NRECs that robust data protection measures are in place to safeguard the interests and rights of research participants and inform the NREC of any ethical considerations regarding the data collection and processing operations.

These assurances can be provided to the NRECs through i) the provision of a Data Protection Impact Assessment (DPIA)[8] form, with ii) accompanying feedback from the Sponsor Data Protection Officers (DPO)[9], or suitable qualified individual. The NRECs are not responsible for approving a DPIA, but rather use the information within to inform its ethics assessments.

Many EU Member States are not submitting a DPIA form for ethical consideration under the Clinical Trial Regulations, but rather a 'statement of compliance', a procedural change that the National Office is currently considering in consultation with the NRECs. Importantly, the requirement for a statement of compliance cannot be a substitute for conducting the necessary risks assessments as documented in a DPIA.

The DPO of the lead study site in Ireland should also be afforded the opportunity to review and provide comment on the study DPIA, or other relevant study documentation[10], to ensure the data protection rights of research participants it has a duty of care to, are safeguarded. The Data Protection Commission further advises[11] that study sites that are 'processors' should be involved in the DPIA development, as appropriate.

In summary, the compliant use and safeguarding of personal data is a core component ethics assessments by NRECs and informs how research participants rights, freedoms and dignity are respected and enabled during the conduct of research studies.

1. https://www.nrecoffice.ie/committees/
2. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
3. https://www.irishstatutebook.ie/eli/2022/si/257/made/en/pdf, and https://www.irishstatutebook.ie/eli/2022/si/41/made/en/pdf
4. https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-and-data-protection_he_en.pdf
5. https://www.dataprotection.ie/en/organisations/know-your-obligations/lawful-processing/special-category-data
6. https://ec.europa.eu/assets/rtd/ethics-data-protection-decision-tree/index.html
7. https://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf
8. https://www.dataprotection.ie/en/organisations/know-your-obligations/data-protection-impact-assessments
9. https://gdpr-info.eu/art-37-gdpr/
10. Eg Participant information leaflets and consent/assent forms as relevant to the study
11. https://www.dataprotection.ie/en/dpc-guidance/guide-data-protection-impact-assessments: pg13 and pg15.

Panel 2:

Clinical Trials Unit Team Leaders & Site Staff from Tallaght University Hospital & University Hospital Limerick

The second part of the panel discussion focused on what is happening on the ground at sites. Members of the research office from Tallaght University Hospital including team leader Ashley Bazin, research officer Sadhbh O'Neill and contracts officer Deirdre O'Brien outlined how they have overcome the difficulties presented by GDPR to ensure trial decisions are expedited.

Bazin recalled the difficulties the introduction of GDPR posed for those involved in research. "It took about a year just to understand how it worked in practice," she admitted. "Even knowing who should carry out the DPIA was an issue." DPOs were immediately overburdened given that clinical trials was a "tiny" part of their job, while amendments to trials "flooded" in. Tallaght went from dealing with 30 amendments in a year to 90; one particular study had 17 amendments and Bazin recalled the "enormous" administrative burden as a result.

Bazin pointed out that in 25 years of her doing her job, "not one patient has raised a query about the use of their data - what they want is the newest treatment available to them as soon as possible".

O'Neill also spoke of the learning curve associated with the introduction of GDPR but said the process they have since put in place has led to significant streamlining and efficiencies. "Everything is now under one umbrella," she said, noting that a fragmented approach makes it more difficult. O'Brien has a half-time post and works with contracts specifically "from submission to signature". She explained that, just like with ethics, there is now an online portal for sponsors to submit their contracts through. Their posts are funded directly by the hospital and Mulroe praised Tallaght for recognising the importance of this work. A different experience, one that's more representative of research units around the country was described by Maureen O'Grady, University Hospital Limerick Team Leader.

O'Grady noted the very protracted delays to opening trials and said she feels helpless in the face of the lack of administrative support. "The timelines are absolutely horrendous," she said, and noted that studies have been pulled due to these delays. Unacceptable and protracted delays in opening studies in certain centres are placing untenable pressure on patients to access trials elsewhere, she added. O'Grady offered the example of a study that Limerick has consistently failed to open but is already open in a number of sites across Ireland. "An end stage lung cancer patient was referred to Beaumont Hospital for the trial last May and we expected to bring him back - we did not open until January [of this year]." Despite huge efforts to speed up contracts, this could not be expedited. Another study, which ultimately did not open and was lost, was subject to 21 different reviews. These roadblocks and bottlenecks mean that the na-

Maureen O'Grady, Team Leader, UHL

Ashley Bazin, Team Leader, TUH

Deirdre O'Brien, Contracts Officer TUH

Sadhbh O'Neill, Research Officer TUH

tional goal of six per cent of cancer patients in clinical trials will not be achieved, at least not in every centre; "it's not that we are not trying", O'Grady said. Benchmarking within Ireland would highlight significant disparities between centres, she said. “Access to an IMP is now becoming an address lottery.” She added that as the HRB looks at performance when deciding on funding, this will no doubt impact the recruitment of new oncologists. “We want help and we want it now.”

Batten reiterated the lack of applications for the open roles in data protection, despite this being a “growing area” that is fulfilling to work in. This means change is difficult to expedite.

In the Q&A, Katie Conway, academic studies coordinator for the UCC Cancer Trials Group and CRF-UCC, echoed O’Grady’s frustration saying they have similar challenges in terms of trials being pulled due to delays. This is causing significant frustration within the cancer unit. “CUH… doesn’t have the facilities there or the support that we need.”

Niamh Clarke from TILDA noted their similar problems, despite not being focused on oncology research, and echoed panellists saying the “recruitment issue is huge here”. Instead of looking for legal people to understand science, she suggested that scientists be trained in the legal requirements, which could help solve the recruitment issues plaguing this area.

Dr Sinead Noonan, medical oncologist at CUH asked if there could be a contract with standardised language national approval which would avoid the need for secondary local approval? Panellists agreed this would be ideal, if possible.

In her closing remarks, Mulroe noted that a letter had been sent to the Minister for Health Stephen Donnelly earlier in the year in relation to this issue. The disparity between Dublin and other areas in terms of access is obvious for a variety of factors, she said and added there is a need for the National Cancer Control Programme to help fund dedicated staff on site. “We will continue to advocate for this.” A key message from the session was that collaboration is essential, as everyone has the same goal - bringing clinical trials to cancer patients with the promise of better treatments and outcomes.

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"It's not that we are not trying... Access to an IMP is now becoming an address lottery.”

“We need clarity and support regarding the approval process and we need it now .”

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