GDPR

Position paper

cancer trials ireland

Together, we're finding answers to cancer.

October 2024

CALL TO ACTION:

1. The government must create conditions that are conducive to conducting research in Ireland, whereby sponsors (both industry and academic) view Ireland as an attractive site for opening trials. Such conditions can be created by developing a code of conduct relating to data processing in health research / clinical trials which enables Ireland to open trials within a timeline equal to that of the top 10% of EU countries.

   Such a code of conduct could reflect a consensus view between relevant agencies such as the Department of Health, the Data Protection Commission and the Office for National Research Ethics Committees (NREC) and the research community (sponsors, researchers, patient representatives).

2. The government must regularise guidance building on guidance provided by groups such as the Health Research Data Protection Network (HRDPN), on the following areas:
   - the legal basis underpinning data processing on trials and secondary data
   - the role of the sponsor and clinical trial sites vis-à-vis data controller and data processor
   - controller/processor responsibilities regarding document provision/input
   - broad consent for compatible future research and limitations thereof
   - modifiable language for clinical trial agreements relevant to the sponsor and hospital organisation
   - boilerplate language for the PIL/ICF
   - acceptance of Statements of Compliance from Data Controllers, in lieu of reviewing, amending, and/or demanding bespoke documentation (i.e. DPIAs, TIAs, PIL/ICFs).

   In the absence of such guidance, role specific responsibilities will continue to be a source of confusion and therefore continue to cause delays in the system.

3. Compel the HSE through the Regional Executive Officers of the Health Regions to formally recognise a new environment, thereby enabling HSE Hospital General Managers to promptly approve trials.

4. Support Voluntary Hospitals in adopting the guidance.

5. Move to a system of one legal review and approval with respect to clinical trial agreements to allow for activity relating to that trial to take place at any Irish hospital that falls under a common governance.

6. The government must underpin exceptions 9(2)(g) and 9(2)(i) of Article 9 of the GDPR by enacting Member State Law that provides for the processing of personal health data for health research, including clinical trials and compatible secondary research.

INTRODUCTION & LEGAL ANALYSIS

With respect to the implementation of GDPR as it pertains to health research, Ireland has lost sight of its mission: to provide the people of this country with access to the best possible new treatments corresponding to their illnesses, in line with expectations in other EU countries.

Fundamentally, this is a problem of perspective. The solutions to this problem do not require more public expenditure, nor do they come with an 'opportunity cost'. However, while the following solutions are simple to understand, they are perhaps not so easy to implement.

- Revision of the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 to enable personal health data to be processed more easily under the provisions of GDPR Article 9(2)(g) for health research, including clinical trials.

- In particular, adjustments to law and the development of protocols that will enable:
  - the re-use of health information, suitably anonymised or pseudo-anonymised as appropriate, without a requirement to seek fresh and successive consents to such re-use;
  - the health information of deceased persons – which is outside the scope of GDPR but under confidentiality law – respectfully anonymised or pseudo-anonymised as appropriate, to be used without a requirement for a consent, e.g. of the deceased person's executor or administrator.

- A change in the procedures involved in review of data protection impact assessments (DPIAs) by clinical trial sites (hospitals) as processors:
  - to eliminate duplication of processes and delays in the start-up of clinical trials
  - to standardise the approach taken by clinical trial sites regarding their role as a data processor.

THE LEGAL POSITION

Ahead of a meeting on the Department of Health's National Clinical Trials Oversight Group (NCTOG), Cancer Trials Ireland submitted a letter which provided a legal overview of the spirit and purpose of GDPR as it relates to health research, and the opportunity for resolution of the legal and procedural impediments affecting clinical trials.

That letter was written by Mr Paul Egan, SC, of Mason, Hayes & Curran LLP, who is a non-executive director of Cancer Trials Ireland, to Cancer Trials Ireland's Chief Executive Eibhlín Mulroe, for onward transmission to the NCTOG.

28 August 2024

Dear EibhlÍn,

I write with a number of points in relation to the General Data Protection Regulation (EU) 2016/679 ("GDPR") to feed into the discussion as to how to facilitate an improvement in the volume of trials in Ireland and an improvement in the time frame for commencement of such trials. The GDPR is identified as a blockage to the commencement of trials in Ireland, in a way that does not appear to arise in other EU member states.

Context

Standing back from the law for a moment, we need to appreciate the context in which this issue is arising.

- *One in three of us will develop cancer at some stage in our lives. Beyond that one in three are the families, friends and colleagues of cancer patients, such that at some stage in our lives, close to all of us will be dealing either with our own cancer diagnosis, that of a family member, or of a friend, or of a work colleague.*
- *Approximately 30% of deaths in Ireland are due to cancer, making it the leading cause of death, ahead of cardiovascular diseases.*
- *Accordingly, any analysis of the legal issues cannot take place in a vacuum, in disregard of the public health issue posed by cancer diagnoses. Trials of medicines constitute an indispensable element in addressing the health challenge posed by cancer, and in the general public interest.*

Cont...

GDPR

The GDPR arises in the context of the medical histories of patients who participate in trials. What is clear is that there is much duplication of tasks, and a strict, timid, interpretation that appears focused more on preventing the initiation of hypothetical legal proceedings than on construing the GDPR in the public interest. The objective of those addressing the interplay of GDPR and the public interest should, I submit, be more concerned with making people well than in conforming to a uniquely Irish over-interpretation of the GDPR. I break this down under three headings:

- *Interpretation*
- *Duplication of tasks*
- *Scope of consents*

Interpretation

Article 9 of the GDPR provides for exceptions to the prohibition on processing of personal data. The exception that one first looks at, perhaps because it is first listed at paragraph (a) of art. 9.2 is where "the data subject has given explicit consent to the processing of those personal data for one or more specified purposes".

However at art. 9.2(g) and (i) are two other exceptions, where:

(g) "processing is necessary for reasons of substantial public interest, on the basis of Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject"; and

(i) "processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy".

On the face of it therefore, given the crucial importance of medical histories of all cancer patients participating in a trial, it is clearly in the public interest that processing of suitably anonymised medical histories fall within these exceptions. Both of these exceptions provide for the public interest to be underpinned by "Member State law". Therefore, it is within the capacity of the Oireachtas to enact such laws. If we had such law, we would not need to be so concerned about the whole issue of consent.

Cont...

Duplication of tasks

At present there will be a multiplicity of Data Protection Impact Assessments ("DPIAs") in relation to the one trial, carried out at separate venues. This is simply unnecessary duplication. One DPIA is enough for the one trial.

Scope of consents

Insofar as consents are relevant, the GDPR provides that consent can be for "one or more specified purposes". The word here is "specified" – it is not "restricted" or "limited". It is open to a data subject to specify many purposes – the GDPR does not police that.

I am happy for you to share this with the Department of Health working group that is discussing this issue.

Yours sincerely,

Paul Egan SC
Non-executive Director, Cancer Trials Ireland

WHAT CAN BE DONE?

Cancer Trials Ireland acknowledges that the current legal framework around GDPR has its complexities. It builds on Article 8 of the EU Charter of Fundamental Rights (which states that everyone has the right to the protection of personal data concerning him or her), and is supplemented by Irish legislation, the Data Protection Act 2018 and, in the area of health research, the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (HRR). Cancer Trials Ireland is conscious also of opinions and guidelines issued by the European Data Protection Board that are relevant to the area of health research.

However, it is in both the drafting and interpretation of, and the procedures under the 2018 Regulations, that we find blockages in the undertaking of clinical trials of medicines, medicines which have the potential to save and ameliorate the lives of patients. We believe that there is scope, within the legal framework, to improve and protect the vital interests of patients and society generally by focused changes in that law and those procedures.

HOW IRELAND CURRENTLY INTERPRETS AND APPLIES GDPR IN COMPARISON TO OTHER EUROPEAN COUNTRIES

GDPR

A survey of European Countries on Data Protection Law in Clinical Trials (Taylor Wessing, March 2023) asked three questions (listed below in bold):

1. **What are the common data protection roles (controller or processor) typically assigned to sponsors and sites in practice with respect to the processing of personal data in the context of clinical trials?**

Of 19 European countries surveyed, Ireland is one of five countries that considers sponsors to be **Joint or Independent Controllers** of data. This is the same approach adopted by Denmark, Poland, Slovakia and the UK.

Ireland considers trial sites to be **data processors**, as does the Czech Republic, France, Greece, Portugal and the UK.

2. What are the common legal bases relied upon in practice for the processing of personal health data in the context of clinical trials (e.g., informed consent or research privilege)?

Ireland is one of 13 countries that is reported as using Explicit Consent (per GDPR Article 9(2)(a)) as the legal basis for processing health data within clinical trials. The report states that the NREC guidance emphasises this; however, there is no requirement per the HRR that states that explicit consent is to be used as the legal basis. Explicit consent is considered a safeguard. Six countries are reported as using interests of public health (GDPR Article 9(2)(i) or scientific research purposes (GDPR Article 9(2)(j) as the legal basis which on the face of it appear to be in line with the EDPB Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) although in most countries there is no clear legal framework or guidance on this aspect.

3. What are the common legal bases relied upon in practice for the processing of personal health data in the context of secondary use for research purposes (e.g., informed consent or research privilege)?

While the Taylor Wessing report shows that Ireland among others require data subjects to provide explicit consent in the context of secondary uses of health data and in some countries is the legal basis (GDPR Article 9(2)(a)) for the processing of personal health data for secondary research, explicit consent is not the only means by which secondary use of data generated in the context of a clinical trial could be deemed lawful. For example, Belgium, France, Slovakia and Sweden allow use for secondary research purposes under scientific research purposes (Article 9(2)(j)) with adequate safeguards as per GDPR Article 89(1). At the same time, Sweden also allows secondary use under Art 9(2)(i) interests of public health.

IMPACTS

What is the impact of GDPR interpretation in Ireland?

In a word, considerable – and it impacts patients and clinicians directly.

- Trials may not be opened in certain hospitals or regions, denying patients in those regions access to potentially life-saving treatments.
- Trial openings are significantly delayed, meaning patients in Ireland have a much shorter window of access (see the table on page 14/15 for examples) compared to EU counterparts.
- In some cases, a trial scheduled to open may not open at all.
- Faced with an unpredictable system, trial sponsors (i.e. pharma companies and academic collaborative groups) are discouraged from opening trials in Ireland. This puts Irish patients at a distinct disadvantage compared to EU counterparts, and damages Ireland's reputation as a research host country.
- Actual or perceived damage to clinicians' reputation, as a result of long delays with opening studies in Ireland (leading to a shortened accrual window and subsequently poorer accrual than originally anticipated.)

FACTORS

What are the impacting factors?

The primary factor is the variability that exists within the hospital system with respect to the hospitals' role as clinical trial sites and data processors in clinical trials. The role of a hospital acting as a clinical trial site and as a data processor of personal health data has become the common practice and is in line with the roles and responsibilities of key stakeholders detailed in the HSE National Framework for the Governance, Management and Support of Health Research (RGMS Framework) as well as the Health Research Data Protection Network (HRDPN) Practical Guide On Data Protection For Health Researchers.

GDPR Article 35 is clear in that the responsibility for conducting a data protection impact assessment (DPIA) rests with the controller (usually the clinical trial sponsor). Per GDPR Article 28, it is clear that the processor should assist the controller in ensuring compliance with the controller's responsibilities, and furthermore it is clear from GDPR Article 35 that the controller in conducting a DPIA must satisfy itself that the processor can implement appropriate safeguards for the personal data they process.

It has become common practice for the hospital clinical trial site as a processor to request a DPIA (which in their role they are not responsible for), and in some cases to request that this be completed on a site-specific template. While the requirement for review of a DPIA by the NREC has been replaced by the requirement to submit a statement of compliance with data protection laws (using NREC's National Statement of Compliance Template), hospital sites in the most part still seek to review a DPIA and, as mentioned earlier, in some cases on their specific template. In some cases, the sites request amendments or updates to the completed DPIA which do not impact their role as a processor.

Furthermore, sponsors of clinical trials (particularly overseas sponsors), do not in general have a readily available DPIA in the format that has become the norm in Ireland (HSE DPIA template or hospital-specific DPIA template).

The same applies to the Transfer Impact Assessment (TIA) which is a Controller's responsibility and is conducted to ensure the European Essential Guarantees for international data transfers to countries whose data protection laws have not yet deemed adequate by the EU Commission (non-EU countries). Some hospital sites request to review and amend the TIA and in some cases insist on the HSE TIA template or hospital-specific TIA being used.

While some hospitals accept documents provided directly on the Sponsor's template (or another common template such as Cancer Trials Ireland's where the DPIA/TIA has been developed in collaboration with the Sponsor), some hospitals continue to insist on their own templates being completed by the Sponsor.

Experiences among the cancer clinical research community also point to inefficiencies within the hospital system with delays in providing feedback on clinical trial agreements and data protection provisions within these agreements and the review of DPIAs / TIAs when provided.

With no uniform approach, or clear guiding principles - and perhaps driven by fear of litigation - in the main, hospital sites feel compelled to regularly review clinical trial documents and seek amendments to them. In some cases, the lack of official guidance around the data processor role in health research compounds the issue.

A survey of Irish hospital sites running trials demonstrates additional variability in the system, resulting from the uncertainty described above.

Survey respondents were classified into three groups: 1) HSE hospitals; 2) Voluntary Hospitals; 3) Private Hospitals. In summary (full tables in Appendix 1, page 23):

- **Data Protection Impact Assessment (DPIA):** While 73% of hospitals running trials accept DPIAs that are completed by the trial sponsor/data controller, the vast majority of the 11 responding hospitals seek to review DPIAs (91%) and request changes to DPIAs (91%).

- **Transfer Impact Assessments (TIA)**: While 78% of hospitals accept Transfer Impact Assessments that are completed by the trial sponsor/data controller, most of the nine respondents (91%) seek to review the TIAs, while six of eight responding hospitals (75%) sought amendments to the TIA.

- **Statement of compliance (SOC):** Of the ten hospitals responding to this question, 30% sought to review the sponsor/data controller's SOC.

- **Patient Information Leaflet / Informed Consent Form (PIL/ICF):** The Sponsor develops this important document, which is the key document supporting the informed consent process for potential patients to consider volunteering to participate in a trial. It is reviewed in detail by the relevant Ethics Committee (NREC or other). On this survey six of eleven hospital (55%) sought review of PIL/ICFs, with five of ten respondents (50%) seeking changes to PIL/ICFs.

- **Contracts:** Voluntary Hospitals were asked if they accept the unmodified IPHA/HSE agreement; 50% said yes, 50% said no. Three voluntary hospitals accept use of the IPHA/HSE agreement with some of their own modifications, with two out of three private hospitals doing the same.

It is hardly surprising that bespoke requirements from hospital to hospital, as outlined above, cement a lengthy, unsystematic process that significantly impacts patients and Ireland's reputation as a research destination.

SECONDARY USES OF DATA

The rigid interpretation of and practices developed in the light of GDPR / HRR have created a situation where secondary uses of data (even with identifiable information removed) requires patients to be consented (with prior consent required to be re-contacted) every time a future research opportunity arises, where it has been considered that the information provided on the Patient Information Leaflet (PIL)/Informed Consent Form (ICF) provided to the patient for the original study was not specific enough to enable their upfront consent for use of secondary data. Broad consent as currently interpreted means that data may only be used *in research projects that relate to the trial or study that the patient took part in and not to further uses that may lead to benefits for public health.*

The notion of broad consent detailed in the 'Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research Adopted on 2 February 2021' indicates that GDPR provides some flexibility in applying broad consent to a secondary use whereas the HRR ('for the purpose of specified health research, either in relation to a particular area or more generally in that area or a related area of health research, or part thereof') and the HSE National Policy for Consent in Health and Social Care Research restrict the application of broad consent ("For broad consent to be valid, researchers must ensure that secondary use of personal data or biological material continues to be within the area of research specified in the original consent").

While accepting that broad consent should not be so broad as to constitute a blanket consent and that the information given while seeking consent needs to be sufficiently transparent as to constitute informed consent, other countries appear to have adopted different approaches. For example, per the Taylor Wessing report cited earlier, in the Austrian Research Organisation Act, broad consent includes broad areas of research without the need for detailed specification of the exact scope. In Germany some local state laws allow secondary use under what is termed 'research privilege'. Anonymisation of data appears to be a possible safeguard for some areas while some countries have no specific local legal framework or regulatory guidance in relation to secondary use of data from clinical trials.

The requirement to obtain successive consents and/or to re-contact for consent for secondary research is in direct conflict with the evolution of cancer research and treatment, which has shown real progress by targeting gene mutations that may have commonalities across different types of cancer.

For example, a trial or treatment targeting a specific gene mutation in a subset of breast cancer patients may yield promising data / indications of how the same treatment might benefit patients with another type of cancer with the same mutation, e.g., lung cancer patients.

Under Ireland's HRR, this data—even with all identifiable information removed—could still not be used to support current or new research being conducted in lung cancer patients with the same mutation without seeking further consent from the data subjects.

As mentioned above, anonymisation of personal data - which then falls outside the scope of GDPR - is a technique which could be used to enable data to be further used for research that is specified at a later stage within the data retention period, However, consent to anonymise data is currently a requirement under the National Policy on Consent in Health and Social Care Research, as anonymisation is a data processing activity. While consent for anonymisation of personal data can be built upfront into the PIL/ICF for new or currently ongoing trials as a planned data processing activity, it is a burdensome process for trial sites and their patients to return to the original participants of completed studies or trials to seek consent for anonymising data where it is not considered possible to seek a consent declaration.

Furthermore, where patients are now deceased, and while processing of personal data of deceased persons fall outside the scope of GDPR, researchers are currently required to obtain consent from the deceased person's next of kin or legal representative, under current confidentiality laws, to make further use of their data, e.g. where the data could be used to support a marketing authorisation application or a licensing extension for a potentially effective treatment or treatment combination, arising from the research that the patient participated in.

Another factor that can cause delays in receiving ethics approval of clinical trials is the discrepancy between sponsors regarding the interpretation of broad consent which frequently leads to RFIs related to the associated wording in the PIL/ICF being issued by ethics committees, and requiring resubmission of amended documents for approval. There can be inconsistencies between submissions in NREC's approach to wording regarding future research - greater consistency in this regard would be welcomed.

The overall approach to secondary uses of health data in research is out of step with the dynamics of scientific inquiry, and once again highlights the sector's current bias towards prioritisation of GDPR compliance over public health.

Secondary uses of data are absolutely vital and central to 'translational' research. To understand why cancer cells respond to treatment, we need to look at them in the lab. Laboratory research is the fundamental building block of new science and new treatment breakthroughs. Future trials depend on laboratory research. If Ireland has ambitions of becoming a leader in health research globally, the Government must act to resolve the current situation.

DPIA: SUMMARY OF STAKEHOLDER VIEW

Cancer Trials Ireland has reached out to stakeholders who have reached a clear consensus on the following points:

- *In line with GDPR legislation and the Health Research Regulations 2018, current NREC guidance (see page 7) places the obligation of completion of a DPIA with the sponsor, as controller of the data being used for research purposes.*

- *However, a condition set by the sites' Data Protection Officers (DPOs) is to have a DPIA submitted on the individual site's DPIA template. As it is solely the sponsor's responsibility (as data controller) to ensure compliance of the processing of clinical trial data collected from the sites, this condition, which the DPOs require in order to have the site initiated (i.e., open a study in a specific site) is unjustified. It creates additional, time-consuming work for both the sponsors and their CROs.*

- *Ireland is the only country in Europe (if not globally) which sets the above requirements i.e., site-specific templates.*

- *This requirement by sites in Ireland for sponsors to complete study-specific DPIAs on site-specific DPIA templates has no legal justification, particularly considering that the sites position themselves in the Clinical Trial Agreements as data processors acting on behalf of the study sponsors.*

- *The DPIA templates provided by individual sites are very long documents (frequently 30 pages +) and require detailed information which are not relevant for the site's privacy compliance.*

- *The study start-up process is delayed as a result of Ireland's specific requirements for study-specific DPIAs completed on site-specific DPIA templates. As previously stated, there is no legal justification (or practical added value) for these requirements. The impact, however, is that at a global level, it can be an argument for limiting the opening of trials in Ireland due to the unnecessary delays arising from Ireland's requirements.*

CONSEQUENCES

The processes and administration outlined in the previous section have very real consequences for patients as exemplified through specific trial case studies in the table below.

Trial case study	# of patients who could benefit	Problem
Breast cancer (drug trial)	**12-15**	Delay in obtaining final ethics committee approval due to wording around broad consent for future research requiring submission of amended PIL/ICF.
Breast cancer (drug trial)	**140**	Delay in obtaining final ethics committee approval due to RFIs regarding broad consent for future research wording requiring submission of amended PIL/ICF. Sponsor decided that the requirement to re-contact patients for future research related to other cancers was unfeasible and removed the future research participation option on biological samples in Ireland. Up to five months to receive feedback on clinical trial agreements from sites. Sponsor not familiar with Irish site requirements regarding DPIA which required guidance in its development and finalisation over four months.
CNS metastases (radiotherapy trial)	**126**	Approximately six month delay receiving feedback on data processing agreement.
Lung cancer (targeted drug trial)	Up to **10**	Trial unable to open in one HSE hospital site due to contractual issues regarding site role.
Pancreatic cancer (interventional trial)	**70**	External collaborator's organisational requirements for separate review regarding data protection risk assessment/ DPIA (following legal department and agreement execution) were not identified until a very late stage in the trial set-up delaying study start-up for approx. two months.

Trial case study	# of patients who could benefit	Problem
Prostate (radiotherapy trial)	**33**	Delay incurred of approx. three months in assisting to develop and finalise DPIA due to sponsor unfamiliarity with Irish sites requirements for DPIA.
Prostate (drug de-escalation trial)	**100**	Discrepancy between sponsor wording regarding broad consent for future research and compatibility with the original trial and the requirements regarding specified area of research per the HRR led to two rounds of RFIs from the NREC and requiring amended wording in the PIL/ICF.
Radiotherapy trials (breast, prostate cancer)	**141, 45**	Delays in progressing the set-up of two radiotherapy clinical trials with a collaborative group via Cancer Trials Ireland's membership of an NCI collaborative group, one more than 3 years since first approved by the Cancer Trials Ireland Scientific Management Group, due to GDPR requirements for transfer of data internationally.
Multiple US National Cancer Institute (NCI) Cooperative Group trials in • **breast (imaging trial)** • **ovarian (drug trial)** • **head and neck (drug trial)**	**35, 20, 179 respectively**	Delays in the opening of three trials between 2-3 years each due to issues surrounding transfer of data to the US. While the issue is largely resolved under the GDPR Article 49 derogation of explicit consent, further solutions should be sought building on the memorandum of understanding (MoU) between the National Cancer Institute (NCI) and the Departments of Health of the Republic of Ireland and Northern Ireland updated in 2021 to ensure the delivery of MoU output of progressing collaboration in cancer trials. For one trial instead of a recruitment target of 35, only two patients were enrolled as the trial closed to recruitment within weeks of opening in Ireland.

WHAT DOES THE PUBLIC THINK?

Public attitudes to GDPR and secondary uses of data in health research

In July 2024, Cancer Trials Ireland commissioned Coyne Research to conduct a nationally representative survey of people in Ireland, as part of Cancer Trials Ireland's annual 'Just Ask' campaign. The overall purpose of the 'Just Ask' campaign is to raise public awareness of cancer clinical trials.

Survey participants were asked a series of questions relating to GDPR, health research in general, and secondary uses of health information. The headline results are listed below:

Attitudes to GDPR

- 89% of people in Ireland believe that GDPR is important
- 76% of people say they understand GDPR (14% say they do not)
- Significantly, 50% of people think GDPR can hamper / hinder healthcare. *When asked to rate how GDPR affects a range of areas, respondents clearly identified healthcare as the most impacted sector, with the second-placed response for 'at work' being 36%)*
- Almost half of respondents (48%) agree the Government should simplify how GDPR is applied in some areas, and remove some restrictions (18% disagree)

Attitudes to Health Research

In general, people in Ireland are highly supportive of health research, as the results below demonstrate:

- 80% think it's important that medical professionals have access to the health information (HI) of patients with the same conditions
- 79% agree it's important that HI is used for research
- 76% are willing to share HI if they are informed how it will be kept safe
- 74% willing to share HI if they know (& agree) what it will be used for
- 74% think it's important that companies / researchers have access to HI of patients with the same conditions
- 73%: Ireland should be doing more health research
- 72% willing to supply personal HI for research if done confidentially
- 64% support use of their HI after death indefinitely without restriction
- 61% willing to share HI in general
- 59% agree HI should be available unless opted out

Public attitudes to secondary uses of health information

To gauge public attitudes to how their information might be used for research, survey respondents were presented with a scenario and asked in which cases / to what extent they agreed or disagreed with statements about how their data could be used when all identifiable information had been removed. For the purposes of transparency, this scenario, and the statements associated have been included below:

Consider the following scenario – you have been diagnosed with cancer and your treating doctor has offered you the opportunity to participate in a clinical trial / other research project (e.g. changes in your lifestyle, nutrition, exercise, etc.) After having all aspects of the trial / research explained to you by your medical team, you agree (consent) to take part in the trial, which involves the collection of your past, current and future health information while you are taking part in the trial, as well as the collection of biological samples from you (e.g. blood, urine, tumour tissue) to study the effects of the trial treatment or to study the specific type of cancer.

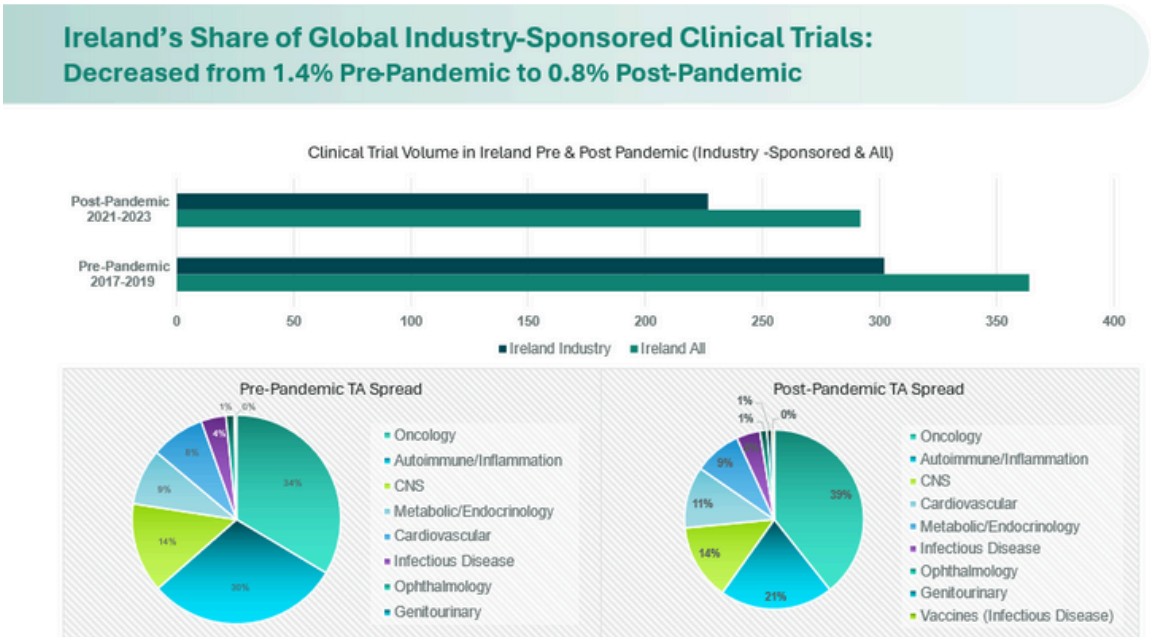
In this scenario, to what extent do you agree or disagree with each of the following statements.

Statement	Agree	Do not agree
If all my identifiable information (i.e. name, address, contact details, record numbers) was removed, my consent to participate in the trial/research includes use of my health information/samples **for any future research arising directly from my trial/research.**	67%	9%
If all my identifiable information was removed, my consent extends to include use of my health information/samples for existing or **future unrelated research projects in my specific form of cancer.**	67%	10%
If all my identifiable information was removed, my consent extends to include use of my health information/samples for existing, or **future unrelated research projects in any form of cancer.**	67%	10%
In the event of my death, my health information may be used for health research indefinitely without restriction.	64%	15%

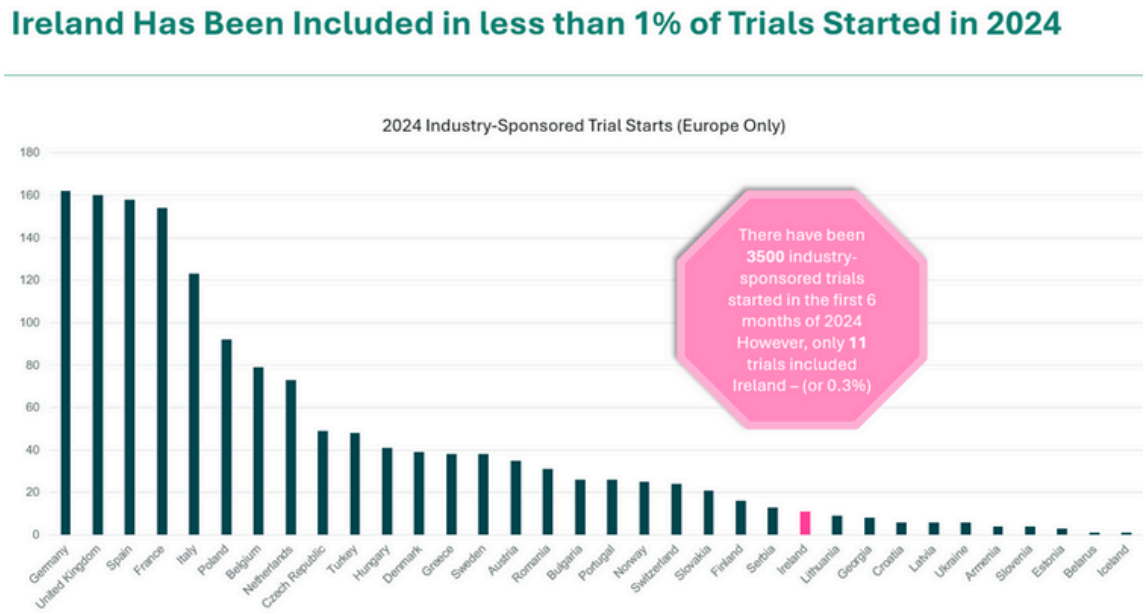
IRELAND VS EUROPE

IMPORTANT: The following information is provided by ICON, a leading healthcare intelligence and clinical research organisation (CRO) employing 40,000 people globally with HQ in Ireland. ICON operates and oversees clinical trials on behalf of its pharmaceutical and biotech customers. Unless otherwise stated, the data provided relates to 'industry' trials, and does not include 'academic' or not-for-profit trials run by groups like Cancer Trials Ireland. This data relates to trials in all disease areas, not just in cancer.

Ireland: pre & post-pandemic:

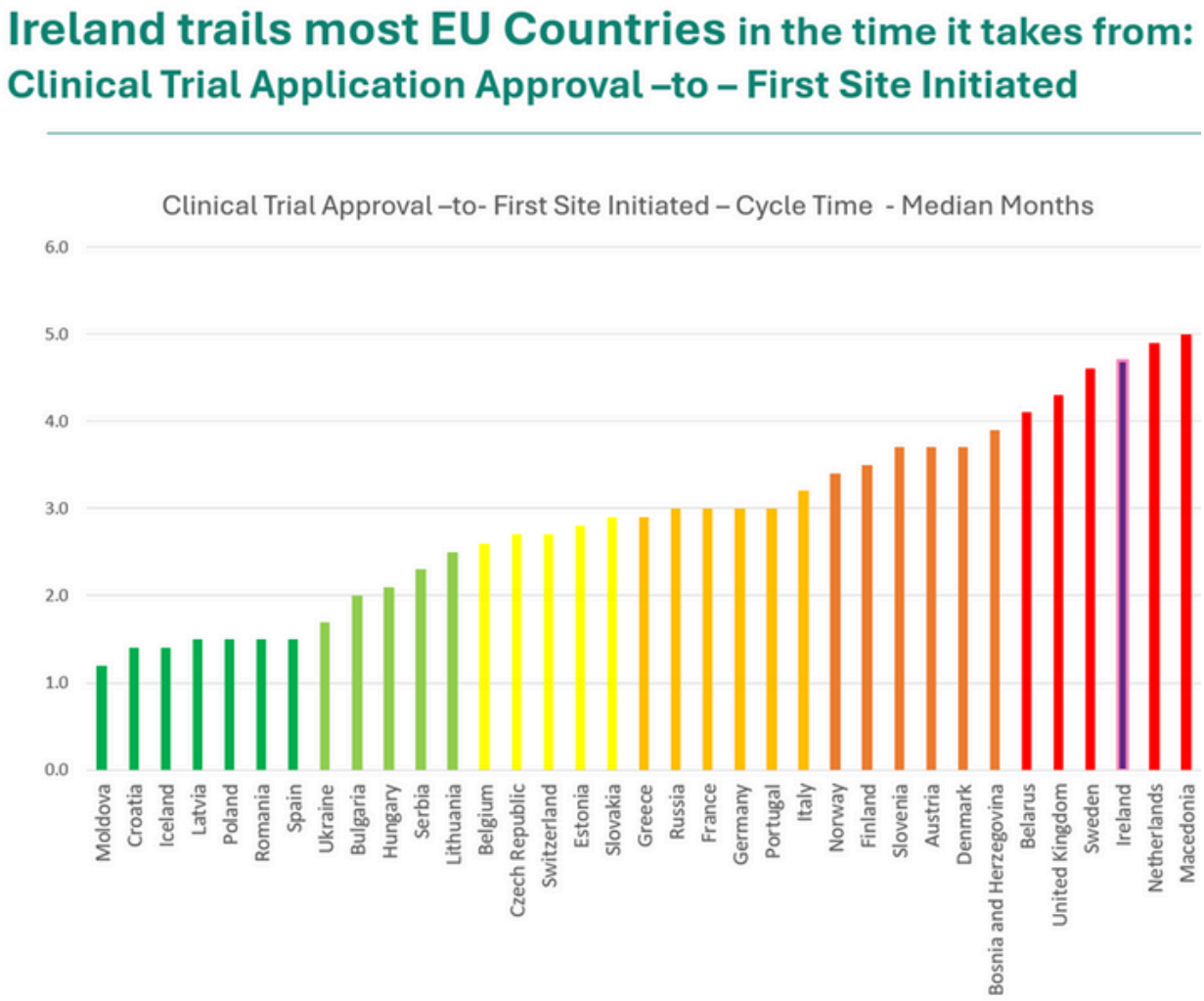


Ireland in 2024 (first six months):



Considering Industry Sponsored Trial starts (Jan-April 2024) other EU Nations have more traction re. attracting Clinical Trials even when compared to other EU countries with similar populations – Denmark, Norway, Bulgaria, Finland & Serbia.

Ireland vs Europe – from trial application approval to first site initiated



The median (50% of studies) cycle time from the clinical trial approval to the First Site Initiated in Ireland is 4.7 months.

The median, however, masks a more interesting view – which is:

- The fastest 10% of studies in Ireland had completed First Site Initiated within 1.8 months of CTA Approval
- The fastest 25% of studies in Ireland completed First Site Initiated within 3.1 months of CTA Approval

SOLUTIONS

How can the government create conditions that are conducive to conducting research in Ireland, whereby sponsors (both industry and academic) view Ireland as an attractive site for opening trials?

In the long term, as Mr Paul Egan's letter recommends, the government can and must enact law to solve the problem.

In the short-term, the government could act through the relevant agencies. Joint guidance from these organisations, co-ordinated by Government, will provide the assurance needed in the system to quickly and significantly improve the trial approval and opening process.

Any one of the actions outlined below has the potential to immediately improve an unpredictable system that delays or, in some cases, blocks clinical trials from being opened in Ireland. In concert, all of the actions set out in this document would dramatically transform the system, the range of options open to patients, and Ireland's reputation as a research destination.

CALL TO ACTION

1. The government must create conditions that are conducive to conducting research in Ireland, whereby sponsors (both industry and academic) view Ireland as an attractive site for opening trials. Such conditions can be created by developing a code of conduct relating to data processing in health research / clinical trials which enables Ireland to open trials within a timeline equal to that of the top 10% of EU countries.

Such a code of conduct could reflect a consensus view between relevant agencies such as the Department of Health, the Data Protection Commission and the Office for National Research Ethics Committees (NREC) and the research community (sponsors, researchers, patient representatives).

2. The government must regularise guidance building on guidance provided by groups such as the Health Research Data Protection Network (HRDPN), on the following areas:

- the legal basis underpinning data processing on trials and secondary data
- the role of the sponsor and clinical trial sites vis-à-vis data controller and data processor
- controller/processor responsibilities regarding document provision/input
- broad consent for compatible future research and limitations thereof
- modifiable language for clinical trial agreements relevant to the sponsor and hospital organisation
- boilerplate language for the PIL/ICF
- acceptance of Statements of Compliance from Data Controllers, in lieu of reviewing, amending, and/or demanding bespoke documentation (i.e. DPIAs, TIAs, PIL/ICFs).

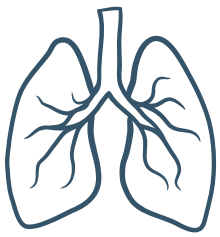
3. Compel the HSE through the Regional Executive Officers of the Health Regions to formally recognise a new environment, thereby enabling HSE Hospital General Managers to promptly approve trials.

4. Support Voluntary Hospitals in adopting the guidance.

5. Move to a system of one legal review and approval with respect to clinical trial agreements to allow for activity relating to that trial to take place at any Irish hospital that falls under a common governance.

6. The government must underpin exceptions 9(2)(g) and 9(2)(i) of Article 9 of the GDPR by enacting Member State Law that provides for the processing of personal health data for health research including clinical trials and compatible secondary research.

Up to 914 patients not getting timely access to trials...

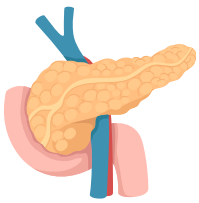


Lung = 10

Head & Neck = 179

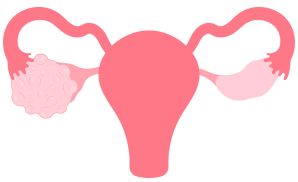
CNS = 126

Breast = 331



Pancreas = 70

Prostate = 178



Ovarian = 20

REFERENCES

- Taylor Wessing: A survey of European Countries on Data Protection Law in Clinical Trials, March 2023

- EDPB Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR)

- National Policy on Consent in Health and Social Care Research
- HSE National Framework for the Governance, Management and Support of Health Research (RGMS Framework)

- HSE DPIA template

- HSE TIA template

- Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research Adopted on 2 February 2021

- The challenge for Cancer Trials Ireland (CTI) to sponsor NCI and non-EU sponsored trials in the EU

APPENDIX 1

Survey of hospital sites, conducted by Cancer Trials Ireland June 2024.

Data Protection Impact Assessments (DPIA)

Q: Does your site request review of the DPIA associated with a given study?

	Yes	No
All hospitals (total)	**10**	**1**
HSE hospitals	5	0
Voluntary Hospitals	3	1
Private Hospitals	2	0

Q: Does your site accept a DPIA completed by the sponsor/data controller on the sponsor template?

	Yes	No
All hospitals (total)	**8**	**3**
HSE hospitals	3	2
Voluntary Hospitals	3	1
Private Hospitals	2	0

Q: Does your site request the DPIA to be updated?

	Yes	No
All hospitals (total)	**9**	**2**
HSE hospitals	4	1
Voluntary Hospitals	3	1
Private Hospitals	2	0

Transfer Impact Agreements (TIA)

Q: Does your site request review of the TIA for a given study?

	Yes	No
All hospitals (total)	**9**	**2**
HSE hospitals	5	0
Voluntary Hospitals	2	2
Private Hospitals	2	0

Q: Does your site accept the TIA completed by the sponsor/controller on the sponsor template?

	Yes	No
All hospitals (total)	**7**	**2**
HSE hospitals	4	1
Voluntary Hospitals	1	1
Private Hospitals	2	0

Q: Does your site request the TIA to be updated?

	Yes	No
All hospitals (total)	**6**	**2**
HSE hospitals	4	1
Voluntary Hospitals	1	1
Private Hospitals	1	0

Statements of compliance (SOC)

Q: Does your site request review of the SOC completed by the sponsor/controller?

	Yes	No
All hospitals (total)	**3**	**7**
HSE hospitals	2	3
Voluntary Hospitals	1	2
Private Hospitals	0	2

Patient Information Leaflets / Informed Consent Forms (PIL/ICF)

Q: Does your site request review of the PIL/ICF prepared by the sponsor?

	Yes	No
All hospitals (total)	**6**	**5**
HSE hospitals	3	2
Voluntary Hospitals	1	3
Private Hospitals	2	0

Q: Does your site request changes to the PIL/ICF prepared by the sponsor?

	Yes	**No**
All hospitals (total)	**5**	**5**
HSE hospitals	2	2
Voluntary Hospitals	1	3
Private Hospitals	2	0

Clinical Trial Agreement

Q: Does your site accept the IPHA/HSE clinical trial agreement unmodified?

	Yes	**No**
Hospitals (total)	**2**	**2**
Voluntary Hospitals	2	2

Q: Does your site accept the IPHA/HSE agreement with modifications?

	Yes	No
All hospitals (total)	**5**	**1**
Voluntary Hospitals	3	0
Private Hospitals	2	1

cancer trials ireland

Together, we're finding answers to cancer.

Since 2017, Cancer Trials Ireland has rolled out an annual campaign (Just Ask) to promote public awareness and understanding of clinical trials and associated issues. The GDPR Position Paper & Launch event are elements of the 2024 Just Ask campaign, which is supported by:

abbvie AstraZeneca BAYER NOVARTIS Pfizer

Cancer Trials Ireland is supported by:

Irish Cancer Society & HRB Health Research Board