

IMI2 Project ID 101034366
FACILITATE

FrAmework for Cllnical trlal participants daTA reutilization
for a fully Transparent and Ethical ecosystem

WP2 – Legal and Data
Privacy framework

D2.8 Outcome of consultations with local DP authorities

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Reviewers	All partners
Due date	28.02.2025
Delivery date	07.03.2025
Submitted version	1.0
Deliverable type	Report
Dissemination level	Public

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Document History

Version	Date	Description
V0.1	16.01.2025	First draft
V0.2	04.03.2025	Second draft after discussion with WP2 members
V0.3	07.03.2025	Approval from WP2 members and SCom
V1.0	07.03.2025	Final formatting

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Executive summary

Over the past 3 years, FACILITATE's legal work package (WP2) has conducted legal analysis on the current legal requirements regarding the return of individual participant data (RoIPD). Although there is no explicit legal framework for RoIPD, the Clinical Trials Regulation and the General Data Protection Regulation (GDPR) do have requirements that must be met when processing clinical trial data. A key part of this legal analysis is engagement with national data protection authorities (DPAs) to discuss the DPAs' interpretations of the GDPR as it pertains to RoIPD. On two occasions, FACILITATE has sought to engage with DPAs on its developing processes, but, with the exception of engagement with the Irish Data Protection Commission (DPC), FACILITATE has been unsuccessful in these attempts. FACILITATE is not the exception in this regard as other IHI projects have experienced similar reluctance of DPAs to engage with consortia developing frameworks.

This document reports on FACILITATE's engagement with the Irish DPC and recommendations for future IHI projects.

1. Background

During the Spring and early Summer of 2024, WP2 sought to conduct written consultations with national data protection authorities (DPAs) (reported in D2.3) as a foundation for the online consultation with the DPAs. As reported in D2.3, during the process of the written consultation, it was decided to contact Data Protection Officers (DPOs) of selected organisations, as well as DPAs. This decision was due to the fact that during the course of trying to engage with DPAs, it became evident that DPAs are reluctant to provide comprehensive responses and give concrete positions on answers to legal queries. This is a particular issue at a time of regulatory change, with the coming into force of the European Health Data Space (EHDS). During that process, two DPAs (Germany and Poland) did not respond at all, others (Spain and Belgium) did not engage with the process after initial contact, and one (Sweden) stated that it could not give a legal opinion. WP2 did receive general written feedback from the French, Serbian, Polish, and Irish DPAs, but they were generally generic in nature.

During the FACILITATE mid-term review in June 2024, issues in engaging with DPAs were discussed. In discussions with other IHI projects, it became evident that similar issues are being experienced in other IHI projects. More specifically, obtaining clear legal advice on health-related data from various national Data Protection Authorities (DPAs) is perceived by various IHI funded projects as a significant challenge. Those seeking consultations often express frustration due to the lack of responses, overly generic answers, or explanations that detailed guidance cannot currently be provided. This is often attributed to the rapid and ongoing development of frameworks like the European Health Data Space (EHDS), which leaves little room for precise or binding interpretations at this stage.

Preparatory work for the online consultation with DPAs began in September. Despite challenges experienced amongst IHI in engaging with DPAs, WP2 made the decision to attempt to engage with DPAs and invite them to an online meeting. Only the Irish Data Protection Commission (DPC) responded.

This document describes the engagement process and outcomes, with some recommendations for the role of DPAs in IHI projects.

2. Meeting 23 November 2024

On Friday 23 November 2024, a meeting was held between members of FACILITATE WP2 and the Irish DPC. From FACILITATE, the following partners were present: UNIMORE; EURAC; VUB and Pfizer. From the Irish DPC, two members were present.

In advance of the meeting, the briefing document in Annex A was sent to the Irish DPC. The meeting began with a presentation by UNIMORE and EURAC who provided an update on the current status of the FACILITATE project and ongoing work in WP2.

WP2 reviewed the legal analysis previously provided by the Irish Data Protection Commission (DPC) regarding its conclusions on the use of consent as a lawful basis for the Reuse of Individual Patient Data (RoIPD). This included examining the proposed text for inclusion in the Informed Consent Form (ICF) and the privacy notice for RoIPD, as detailed in Deliverable D2.4.

In their responses, the Irish DPC focused on their interpretation of the GDPR generally, and did not focus on any specific nuances that arise in the implementation of the GDPR in Ireland through the Health Research Regulations 2018 and 2021. The Irish DPC responded by confirming that they supported the legal reasoning as presented and noted that in their interpretation of the GDPR as it relates to RoIPD:

- Consent as the lawful basis for the processing of personal data is the most suitable legal basis as it speaks to the ethos of what FACILITATE is trying to achieve i.e., a process that is initiated by the sponsor, but participation is decided by the clinical research participant.
- It is important to ensure that there is a separate ICF and consent process to ensure that it is clear to the participant that RoIPD is a separate process distinct from the clinical trial process.

The meeting did not discuss how a separate ICF and separate consent process could be implemented. However, due to the need for flexibility at this stage of designing RoIPD processes, WP2 recommends that this should be left up to the Sponsor to decide according to the specific contexts of the clinical trial.

3. Conclusion

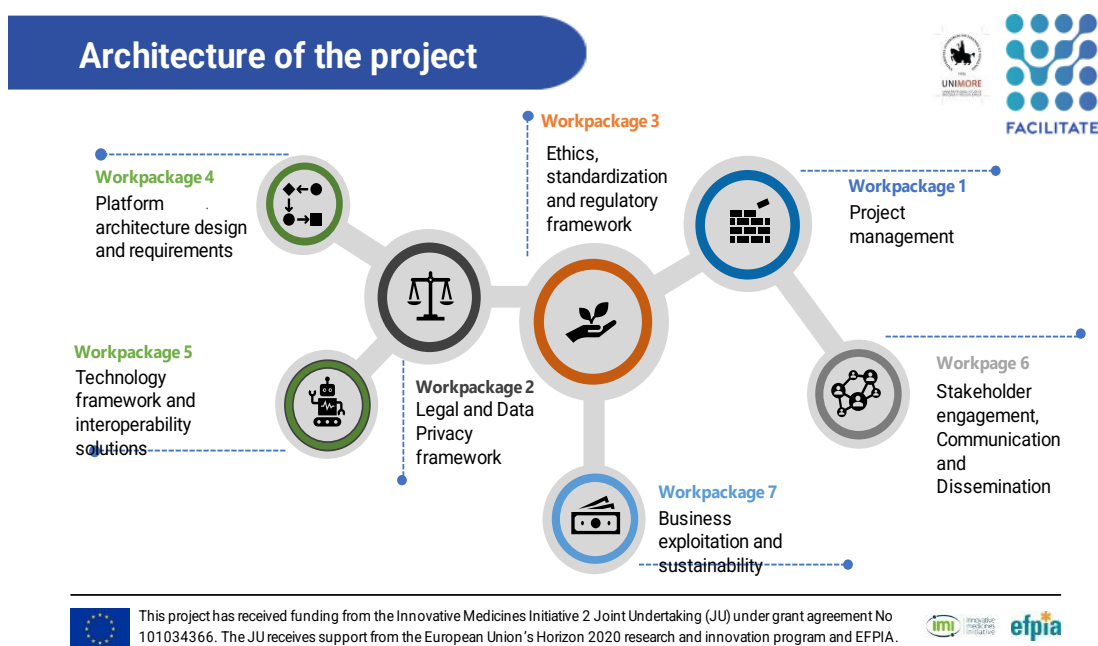
It is welcomed that the Irish DPC in their interpretation endorsed the legal analysis of WP2 on consent as a legal basis for RoIPD, the privacy notice template, and the guidance on ICF.

Beyond FACILITATE, there are ongoing issues with engagement with the DPAs. As previously explained, specific reasons may account for the lack of engagement with national Data Protection Authorities (DPAs). This perspective was emphasized by the European Medicines Agency (EMA) during a plenary meeting held in Brussels in September, where EMA representatives expressed their belief that meaningful engagement with DPAs is unlikely in the foreseeable future. One potential solution to address this critical challenge could involve establishing a dedicated working group or discussion forum that includes IHI, EMA, and other relevant stakeholders to tackle the issue at a more centralized and collaborative level.

Annex 1: Briefing document sent to Irish DPC

A1.1 The FACILITATE PROJECT

FACILITATE (FrAmework for Clinical trial participants' daTa reutilization for a fully Transparent and Ethical ecosystem) is a 4-year IMI project involving 29 partners from 21 countries (academic partners, pharmaceutical companies and service providers)¹. Its purpose is to develop a prototype process to facilitate the return of clinical trial data (RoIPD) and the secondary use of clinical trial data. As part of this will be the development of participant-centric ethical and legal frameworks to facilitate the return and secondary use of clinical trial data.



As can be seen in the above image, there are 7 work packages (WPs) to the project, with WP2 tasked with the development of the legal framework.

Since we engaged with you last, the focus of FACILITATE has moved to RoIPD data only. With the European Health Data Space (EHDS) set to change the legal framework for the secondary use of electronic health data, it proved challenging to get agreement on the legal and ethical framework for the secondary use of clinical trial data. In a time of regulatory change, it was decided that FACILITATE's efforts would be best served by focusing on RoIPD.

A1.2 The ethical principles guiding the process

The FACILITATE project is not only seeking to return clinical trial data to participants, but to achieve this by developing a bottom-up, participant-centric process that empowers study participants to exercise more control over their healthcare decision-making. To create this participant-centric ethical ecosystem centered around participants, FACILITATE has identified a set of ethical principles and a

¹ <https://facilitate-project.eu/>

framework for implementing these principles to guide the RoIPD (Annex 1). Such a framework sets out the expectations around clinical trial data use and provides guidance to fill the gaps to current legal frameworks and guidance. This ethical framework has been co-created and is evolving with stakeholders participating in the clinical trial process, in particular patients. It is for the patient's benefit that clinical trial data should be returned, thus the processes should better reflect the needs and expectations of patients. It is anticipated that this approach to the development and implementation of the ethical framework will steer us toward processes that prioritize participant-centricity while acknowledging the diverse contexts in which clinical trials may occur.

The next stage of the developing ethical framework saw the development of a guideline "Ethical considerations in the procedures to be followed for RoIPD" as set out in Annex 2. This document provides guidance to sponsors and physicians in the RoIPD process. It provides details on the informed consent process, including the timing of the informed consent. Importantly the guideline also provides details on the development and implementation of the RoIPD process.

A1.3 Work package 2 and the developing legal framework

The ethical framework is being developed within WP3 while WP2 is tasked with the responsibility of developing the legal framework. To achieve this, WP2 is ensuring that the proposed processes for RoIPD comply with the General Data Protection Regulation (GDPR), the Clinical Trial Regulation (CTR), and other relevant legal frameworks.

To date, WP2 has mapped current legal requirements at both the EU and national levels and an additional report on national legislation. WP2 has also conducted an analysis of the DO-IT ICF template (this analysis was conducted prior to the decision to focus on RoIPD only). Currently, WP2 is developing text to be included in ICF for RoIPD and also privacy notices.

Engagement is an important part of the developing frameworks in WP2. To date, WP2 has engaged with some Data Protection Authorities and the EDC(B). Engagement with patients is planned in the coming weeks for feedback on the developing ICF text and privacy notices, as well as the second EDC(B) consultation and consultations with DPAs.

The final outcomes of WP2 will be detailed in the Final Legal Report (D2.9) and a guidance document for future clinical studies.

A1.4 November 2024 consultation

For this consultation, we would like to discuss the following:

- Consent and the lawful basis for RoIPD
- Text to be included in the developing ICF
- Text to be included in the developing privacy notices
- Additional requirements that should be included in the developing legal framework

A1.4.1 Lawful basis for RoIPD

The RoIPD as proposed by FACILITATE is similar to the right of access under the GDPR. The aim of the right to access is to provide data subjects with clear, transparent, and accessible information about the processing of their personal data. It is an important right in making it easier for data subjects to exercise their other rights under the GDPR.² Similarly, FACILITATE is aiming to enable the return of clinical trial data to participants in a clear and accessible manner.

A key difference, however, between the right to access and the process as proposed by FACILITATE is that the right to access is invoked by a data subject and it is for the data controller to determine the access request on a case-by-case basis. The process as proposed by FACILITATE is to be initiated by the Sponsor.

Thus, WP2 considered whether RoIPD could fall under that consent and specifically if RoIPD would be considered to be primary use as defined under the Clinical Trial Regulation (CTR). In its Opinion on the CTR and the GDPR, the EDPB stated that the following would fall within primary use and thus fall within the informed consent as part of the CTR:

“All processing operations related to a specific clinical trial protocol during its whole lifecycle, from the start of the trial to deletion at the end of the archiving period”.

Based on this guidance, it is clear that the RoIPD data *after the clinical trial* would not fall within that informed consent and would require a lawful basis for the processing of personal data.³ The question is whether the RoIPD during the clinical trial could fall under consent under the CTR. Some clarity can be found in the following:

“When discussing the issue of the legal basis for the processing of personal data during the whole lifecycle of a clinical trial, the EDPB considers relevant to distinguish two main categories of processing activities. In particular, processing operations purely related to research activities must be distinguished from processing operations related to the purposes of protection of health, while setting standards of quality and safety for medicinal products by generating reliable and robust data (reliability and safety related purposes); these two main categories of processing activities fall under different legal bases.”⁴

It thus appears that “processing operations purely related to research activities” would fall within primary use, whereas other purposes would fall outside of primary use and require a legal basis.

The RoIPD does arise due to research, but it is not the aim of the research, and the research will continue to occur even if RoIPD does not take place. Returning the data is rooted in a recognition of the importance of the participant in the research process, the intrinsic and extrinsic value that the data can have to a participant, and a reflection of some of the principles as outline in Annex 1. Thus, while RoIPD cannot take place without the research, it is not processing related to the research, as the return or not has no bearing on the outcome of the clinical trial. As such, WP2 recommends that a lawful basis for the RoIPD is necessary for both during and after the clinical trial.

² Guidelines 01/2022 on data subject rights - Right of access

³ Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (art. 70.1.b)) Adopted on 23 January 2019

⁴ *Ibid*

Having considered the legal bases, WP2 has determined that consent is the most suitable legal basis for RoIPD. Article 9(2)(b)(d)(e) and (f) are not relevant to the context of RoIPD. Article 6(1)(b) (performance of a contract) will not be applicable because RoIPD is not a necessary element as part of the agreement between sponsors and study participants to carry out a clinical trial. Article 6(1)(e) and Article 9(2)(g)(i) and (j) will not be applicable because RoIPD does not directly concern the public interest. Article 6(1)(d) and Article 9(2)(c) (vital interest) will not be applicable in all situations because RoIPD concerns all data that are clinically meaningful or meaningful to participants, which do not always involve findings that are essential to the life of participants. Article 6(1)(f) (legitimate interest) could be used to justify RoIPD provided a three-step balancing test is carried out as suggested by the European Data Protection Board (EDPB), but it is hard to find a non-consent-based legal basis in Article 9 to be used in conjunction.

A1.4.2.Guidance on text to be included in the ICF

Introducing RoIPD to participants

The RoIPD informed consent form (ICF) should contain all the important information related to the process for the return of the clinical trial data. Sponsors should ensure that participants have the information that is needed to fully understand the RoIPD process. The following information will, at a minimum be required to be provided to the participant.

Data to be returned

Participants will need to be informed about what data will be returned during the clinical trial and what data can only be returned after the clinical trial. Participants will need to be informed about why certain data can only be returned after the clinical trial.

The timing of RoIPD

Participants must be informed about when during the clinical trial the data will be returned. For data being returned after the clinical trial, participants must be also informed how soon after the data has become available will this data be returned to the participants.

The RoIPD process

The specific information provided to participants will vary according to the process of how it is to be returned. There are generally three solutions to the RoIPD: through an online platform, by an individual that is appointed or tasked with the duty of returning the clinical trial data (e.g., it may be agreed that it is the participants health care provider, or it could be some other health care professional), or a combination of an online platform and an individual. Whatever the solution adopted, this must be explained to participants.

A. If RoIPD is to be facilitated through an online platform, the following at a minimum should be covered in the ICF:

- A clear and simple explanation of how the platform works, ensuring it is easy to access and use.
- The procedure for enrolling on the platform and when this enrolment will take place
- The personal information required to enrol on the platform
- Who the data controller is and what a data controller is
- Their rights under the GDPR

- The security of the platform
- Who has access to their data and under what circumstances
- How they may withdraw from the platform and the impact that a withdrawal will have on them.
- Contact details for updating their personal information & the importance of keeping their personal data updated so that they can continue to receive their clinical trial data after the clinical trial

B. If the RoIPD will be facilitated by an individual, indicate whether it will be handled by a doctor, nurse, or other healthcare professional and how they can be contacted if they have any further questions.

C. If there is to be a combination of an online platform and a person, it should be explained to participants when data will be returned through the online platform and when it should be done by an individual.

Who will have access to the data

Participants must be clearly informed that their clinical trial data will be returned exclusively to them and will not be shared with any other parties, including insurance companies.

Protection of privacy

As their clinical trial data contains important and sensitive information about them, it is important that participants are made aware of how their privacy will be protected. It is recommended that the following information be included:

- Who the data controller is
- Their rights under the GDPR and that this process does not affect their right of access or right to interoperability
- That only those they consent to will have access to their data Only individuals or entities to whom participants give explicit consent will get access to their data through their process.
- If data will be returned through an online platform, participants will be provided with the platform's privacy policy.

Withdrawal of consent

As consent is the lawful basis for the processing of personal data, it is important that participants can withdraw their consent at any time. This withdrawal of consent must be as easy as it is to consent to the RoIPD. The following text can be adopted:

If you agree to have your clinical data returned, you can change your mind at any time and stop receiving your clinical trial data. If you want to withdraw your consent and stop receiving your clinical trial data, you should contact [insert the name, email address and/or phone number of who to contact if they want to withdraw their consent. This withdrawal should be recorded].

Privacy notices

The GDPR requires the data controller to provide data subjects, prior to the collection of personal data, with the information required by the regulation (Article 12 GDPR). In particular, the privacy notices are communications addressed to the data subject, the purpose of which is to make the data subject aware of the purposes and methods operated by the data controller. It is the duty of the data controller to ensure the transparency and correctness of the data processing and, in particular, to

always be able to prove this (principle of accountability). In addition, the purpose of the information notice is to enable the data subject to give valid consent, which is a legal basis for processing.

In the FACILITATE project and in the light of the consultations, it has become clear that the standard models of information notices are very cumbersome, full of technicalities and unclear. For this reason, a very short model notice could be assumed to contain the following essential elements (fully complying with Articles 13 and 14 of the GDPR):

- categories of data processed and purposes of the processing (not the modalities of the processing, but what data are processed divided by categories, for what purpose, for how long they are processed, whether the data will be transferred abroad and, if so, by what means)
- the legal basis of the processing, i.e. whether the processing is based on consent or justified by law, legitimate interests (in this case specifying what the legitimate interest is), etc;
- whether the provision of data is compulsory or optional and the consequences of such refusal (specifying that it is possible to refuse consent to individual processing such as for direct marketing purposes)
- whether the data controller intends to use the data for a purpose other than that for which they were collected;
- recipients (also by categories) to whom the data may be disclosed and the scope of dissemination of the data (the indication of third parties cannot be generic)
- whether the data controller intends to transfer the data to countries outside the EU, in which case whether or not there is an adequacy decision by the EU Commission (i.e.
- whether the Commission has decided that the third country, a territory or one or more specific sectors within the third country, or the international organisation in question ensure an adequate level of protection, so that the transfer does not require specific authorisation)
- the data retention period or an indication of the criteria for determining it;
- the rights of the data subject (right of access to personal data, right to obtain rectification or erasure of personal data or restriction of processing concerning the data subject him to object to the processing, to withdraw consent, right to lodge a complaint with the supervisory authority, possible right to portability);
- identification data (name, company name or trade name, domicile or seat) of the data controller and, if designated, the contact data (i.e. not the name) of the Data Protection Officer (DPO), i.e. an address to which data subjects may refer to exercise their rights
- if the processing involves automated decision-making processes (such as profiling), it must also be specified indicating the logic of such decision-making processes and the consequences foreseen for the data subject.

The privacy policy must also indicate the cookies that the site conveys, how to disable cookies (e.g. via browser options), and in the case of third-party cookies, the link to the privacy policy pages of the third-party services.

In the case of data collected from third parties, the privacy policy must have additional content, namely:

- an indication of the categories of personal data being processed
- an indication of the source from which the personal data originate (which may also be a publicly accessible source);

- information as to whether the disclosure of personal data is obligatory or not is omitted, since in the present case the data are not collected from the data subject

The inclusion of these short but essential elements also ensures full compliance with Recital 39 of the GDPR (clear, concise, easily accessible and intelligible language).

A1.4.3 Legal clauses

Deliverable 2.6 requires WP2 to:

“Develop legal clauses to be inserted in investigators contracts to allow the returning of data. Based on expertise from EFPIA companies, develop legal clauses to be integrated in contractual agreements among parties conducting trials (in particular between sponsors and investigators/investigational sites using decision trees or other tools to assign appropriate role to each party – i.e. controller, processor, joint-controllers or co-controllers)”

As provided, D2.6 requires the development of legal clauses that are to be inserted in investigators contracts to enable the return of data. To develop this deliverable, WP2 is to draw on expertise from EFPIA partners to develop these legal clauses.

WP2 has discussed this deliverable in detail and has reached consensus in its WP2 bi-weekly meeting on Monday 23 September that D2.6 is out of scope for the following reasons:

- Partners that currently return patient data do not have any legal clauses on return of patient data in any contract.
- If contracts are to be included in the future, it very much depends on the solution to return of patient data.
- FACILITATE partners are in the process of developing their own platforms that should follow the principles and ethical frameworks as provided by FACILITATE, but there will be differences in the implementation of these platforms. As such, if partners were to include legal clauses, they will differ from partner to partner, and it would not be possible to develop template legal clauses.
- EFPIA partners were clear that the insertion of any legal clauses are not anticipated.

Given these premises, the focus, and indeed the value of FACILITATE, is on providing guidance regarding the uptake and implementation of the principles and ethical frameworks as developed by FACILITATE in the organization of Return of individual participant data processes by sponsors. As such it was agreed that WP2 will focus on the development of guidelines and recommendations for text to be included in informed consent forms and privacy notices.

Annex A: The ethical principles guiding RoIPD

Substantive principles

Rights and respect for individuals and wider society	Individuals have the right to make autonomous and informed decisions. This includes what, if any, clinical trial data should be returned to them. The return of clinical trial data must respect the right of study participants to be informed, their right to access or not their data, and respect a participant's preferences on the return of clinical trial data. The return of data should not be contingent on the participant's completion of the clinical trial.
Beneficence	The return of clinical trial data must be guided by a consideration of the best interests of the study participant.
Non-maleficence	Clinical trial data shall be returned to participants in a manner that maximizes any benefits and minimizes any risks to participants.
Privacy and confidentiality	The return of clinical trial data must respect the individual subject's privacy and the confidentiality of their data. Any limitation of that right must be necessary, limited, proportionate, accountable, and transparent with protections in place to continue to safeguard the subject's privacy and confidentiality.
Utility	The return of clinical trial data must be of value of the study participant (this should be subjective rather than objective e.g., actionable).
Empowerment	Study participants should be empowered to make informed decisions about their healthcare. The individual clinical trial data returned and the process for returning it, including who returns the clinical trial data, should enable this empowerment.
Public value	The primary goal of clinical research is production of generalizable knowledge for the patients who will benefit of the scientific knowledge. Clinical trials are critically important in improving the public's health. Any return of clinical data, and the timing of that return, must be balanced against the scientific integrity of the clinical trial.
Data custodianship	To return high quality and reliable data to a participant, it is essential to have control over the process that generates the results themselves. Traceability of the processes that generated the results can ensure the accuracy and pertinence of the data that is returned to the right clinical trial participant.
Justice	Returning clinical trial data must be done in a manner that is lawful, fair and just.

Procedural principles

Transparency	The process to be followed in the return of clinical trial data must be clear and explained to the study participants at the time of the informed consent. It must be clear to study participants the type of data that will be returned and when. The process to be followed if a participant changes their preferences must be clear and communicated to the participant.
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Accountability	It must be clear who is responsible for ensuring that clinical trial data is returned to participants.
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Ethical considerations in the procedures to be followed for Returning Individual Clinical Trial Data to Participants

The ethical imperative to return individual clinical trial data to participants is increasingly recognized within the research community. However, operationalizing this responsibility presents significant challenges, including defining the appropriate timing, agents, and processes involved, compounded by the absence of standardized procedures, the diversity of clinical trials, and the varied nature of participant demographics.

To address these complexities, it is essential to develop a participant-centric approach to the Return of Individual Participant Data (RoIPD) that considers the specific needs and circumstances of trial participants. This approach must outline clear guidelines for when and how individual data should be returned, delineate the roles and responsibilities of all stakeholders involved, and ensure that the processes are transparent, accountable and shared.

This guiding document sets out recommendations on how this process may be developed and implemented so that sponsors, researchers, and patients can proactively tackle the ethical challenges associated with RoIPD, thereby building trust, enhancing the integrity of clinical research, and improving the overall experience of the participant during and after the trial. This approach not only meets ethical obligations but also improves participant engagement and the overall value derived from clinical studies.

Proposed Strategies to include for Developing and Implementing RoIPD Processes:

1. **Co-creation of protocols on RoIPD:** Develop, cocreate and implement protocols tailored to the diverse types of clinical trials. These protocols should outline specific timelines, define the scope of data to be returned, and detail the communication methods to be used with participants.
2. **Defining Roles and Responsibilities:** Clearly articulate the roles of all parties involved, including sponsors, investigators, patients/patient representatives, ethics committees, data managers as well as new professional figures created to streamline the trial and interact with patients, clinicians and sponsors. This clarity will help ensure that each stakeholder understands their duties and the expectations placed upon them.
3. **Establish Transparency and Effective Communication:** Establish transparent procedures that keep participants fully informed about the data return processes. Effective communication strategies should be maintained throughout and after the trial to adapt to participant needs and feedback.
4. **Adherence to Ethical and Legal Standards:** Align all procedures with existing ethical guidelines and legal requirements, such as the General Data Protection Regulation (GDPR) in the EU and national ethical and legal requirements. This alignment should focus on protecting participant privacy and ensuring data security.
5. **Training and Support Systems:** Provide comprehensive training for all stakeholders involved in the RoIPD process to ensure they are well-prepared to manage the ethical, legal, and practical challenges of returning data. Support systems should also be established to assist stakeholders in addressing any issues that arise during the process.⁵
6. **Shared Knowledge Building:** At the end of the RoIPD process, it should be evaluated to assess the operation of the process in practice and whether changes should be made to

⁵ Resources are currently in existence that could be used to assess patient experience with the trial e.g., Study Participant Feedback Questionnaire [SPFQ] and the Patient Protocol Engagement Tool [P-PET].

improve the process. These findings and improvements should be made publicly available where possible to enable the development of a community of practice on RoIPD.

Ethical guidance principles

1. Developing a plan on the Return of Individual Participant Data (RoIPD):

The responsibility of planning and discussing the plan of the Return of Individual Participant Data (RoIPD) lies with the Sponsor. The Sponsor is accountable for ensuring that a plan is developed and implemented.

In developing their plan on the Return of Individual Participant Data (RoIPD), sponsors should be guided by this document and the draft Ethical Framework on RoIPD provided by FACILITATE.

A co-creation process is strongly encouraged that can involve investigators in the clinical trial and patient groups where possible. A co-creation process improves transparency, confers agency to the participant, and helps ensure that the concerns and needs of the participants are considered.

The RoIPD process will involve a platform through which data may be returned and also individuals who will support the RoIPD process. Their role will be described below.

It is strongly advised that the process for RoIPD must be approved by a Research Ethics Committee (REC). Furthermore, any modifications to the RoIPD process need REC endorsement, as required by ICH GCP.

2. Health literacy

Health literacy is the ability of participants to obtain, process, and understand health information and its potential impact to make appropriate decisions for themselves. Improving health literacy depends on a variety of factors influenced by both the individuals providing the information and the participants receiving it.

The RoIPD process will primarily be facilitated by a platform. This process will be first discussed with participants. Sponsors must ensure that those discussing the RoIPD process have the necessary communication skills and in-depth knowledge of the RoIPD process to adequately discuss the process with participants.

When the return of data is not done through a platform, but by an individual, this must not be the sponsor. This person should have the expertise to understand and interpret the data, clearly communicate its potential impact to the participant, and address any questions the participant may have. This is important in improving health literacy. This individual may differ according to the timing of the RoIPD (i.e., during or after the trial).

Basic health literacy tools, such as glossaries and links to relevant information, along with communication aids like images, audio, and video materials, tailored to the needs of the participant can be developed to support the RoIPD process. These tools help address literacy gaps and communication challenges. It is recommended that such resources be shared to foster a community of practice in this area, encouraging collaboration and the exchange of effective strategies.

The individual participant will also impact the RoIPD process. This can be influenced by intrinsic factors such as the participant's age and education level, but extrinsic factors are also crucial. For instance, if a participant is experiencing stress, emotional distress, or has already received a large amount of information, they may not be able to process additional information at that particular moment in time.

Therefore, the RoIPD process must be flexible allowing it to adapt to the unique needs, requirements and circumstances of each individual research participant.

3. The individuals implementing the RoIPD process

The RoIPD process should be facilitated and implemented by personnel with the appropriate skills. This applies to the individuals discussing the process with participants and also circumstances in which an individual is returning the data. While the Sponsor has the responsibility for ensuring that the process is implemented, the sponsor should not be involved in the implementation of the process. It is essential that the process be implemented by individuals who have the necessary skills and knowledge to enhance health literacy, respond to the potential emotional impact of the result by encouraging participants to bring a family member or a friend when results are returned and ensure that participants are adequately equipped to make informed decisions.

The individual informing the participant about the RoIPD process may not be the same person returning the data, in circumstances in which an individual is returning. What is important is that only those with the requisite skills and expertise are involved. Discussions on the RoIPD can be done by a research nurse, medical personnel and can be supported by communication experts such as cultural mediators and patient organisations. To guarantee the principles of beneficence and utility it is recommended to involve a health care professional in the process of clinical data return to facilitate the understanding of the data and eventual clinical implications.

For the RoIPD process involving the platform, participants should be encouraged to consult with a healthcare physician who has the necessary expertise to interpret the data and understand its implications. Participants should be informed about why it is good practice for a healthcare professional to communicate this data. This could involve the participant's physician, who can play a key role in the process, provided the participant has consented to share their data with them. If, after being informed about why a healthcare provider is best suited to interpret and return the data, the participant still prefers to receive the data directly, they are free to do so.

For the return of genetic results, consult local laws that may legally mandate the return of genetic results by a genetic counsellor. Any legal requirements such as this should be communicated to the participant in advance.

4. The RoIPD process

There are three important junctures at which the RoIPD should be discussed with the participant: the time of enrolment; the time at which the participant makes a decision on whether they want their data to be returned; the actual RoIPD. This process should be adapted to the study length and data generation and availability.

In accordance with ICH GCP guidelines, sponsors must ensure that participants fully understand all processes related to the clinical trial at the time of enrolment, including the possibility of having their data returned to them. At enrolment, participants should be informed that the option to have their clinical trial data returned exists, with the understanding that this process will be discussed in more detail at a later stage if they wish so. The comprehensive discussion about the RoIPD

5. Consent to RoIPD

Participants have a right to access their clinical trial data under the GDPR. The proactive process of return in this guideline is distinct from this right of access under the GDPR. As there is currently no regulatory requirement to return data and the return is not automatic, participants must consent to the return of this data.

Participants must be informed about the process of the RoIPD, including what data will be returned, when the data will be returned, and the mechanism for return. Participants will also be informed about any legal constraints on returning data e.g., any national legal requirements that genetic data must be returned by a genetic counsellor.

6. The data to be returned

Clinically meaningful data must be returned to patients.

There is data that is meaningful to patients that might not be clinically meaningful. This too should be returned