The Return of Individual Participant Data in clinical trial research: a FACILITATE White Paper

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This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 101034366. The JU receives support from the European Union's Horizon 2020 research and innovation program and EFPIA.

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Published by: FACILITATE Consortium

FACILITATE 2025

Framework for Clinical Trial Participants' Data Reutilization for a Fully Transparent and Ethical Ecosystem

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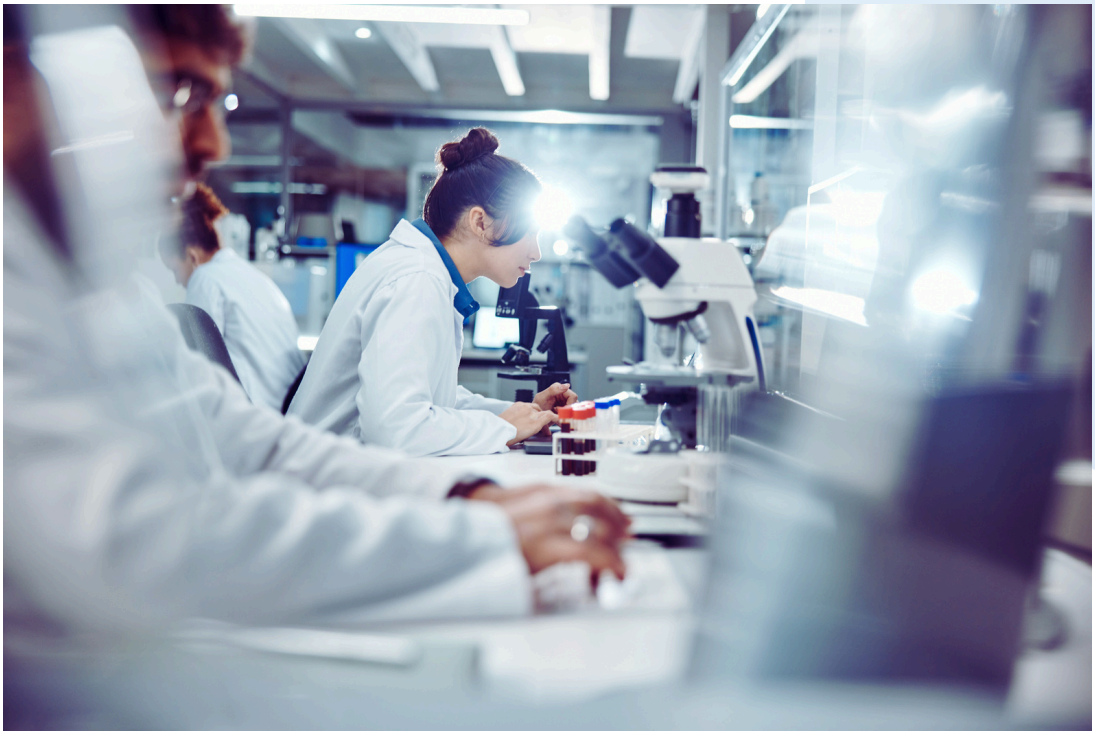
ABBREVIATIONS

CTR Clinical Trials Regulation
DPC Data Protection Commission
EDPB European Data Protection Board
EU European Union
GDPR General Data Protection Regulation
ICF Informed consent form
REC Research ethics committee
RoIPD Return of Individual Participant Data
ICH-GCP International Council for Harmonisation-Good Clinical Practice



EXPLANATIONS OF TERMS

Throughout this White Paper, FACILITATE uses certain words (framework; approach; plan; process). For purposes of clarity, the following is the meaning of these terms in the context of this White Paper.

- **Framework:** A framework is a high-level set of principles and requirements that defines what needs to be done and why. In the context of this White Paper, when we refer to "framework" we are referring to the ethical, legal, and procedural foundations of RoIPD. It includes the aims, context of FACILITATE, ethical principles, and points on the procedural aspects to operationalise FACILITATE.

- **Approach:** An approach is the overarching philosophy or strategy that guides the development and implementation of the framework, processes, and plan. In the context of this White Paper, the approach reflects what FACILITATE considers to be the methodology for developing RoIPD: participant-centric; flexible; RoIPD by design, as discussed in Section 1.

- **Process:** A process can be a series of coordinated actions or steps that can describe how something is to be done. In the context of this White Paper, it is the pathway to the operationalisation of RoIPD. This includes from developing protocols, informing participants, and obtaining consent. Some of these points are discussed in Section 4 and Section 5, but this is not exhaustive and sponsors will likely implement other actions and steps in their pathway to operationalization.

- **Plan:** A plan is a detailed document that is developed for something. It describes the who, what, when, and how. In the context of this White Paper, it refers to the plan that the Sponsor will develop for RoIPD and will include roles of all those involve, timelines, and tools. This is for each Sponsor to develop and is not the focus of the White Paper.

EXECUTIVE SUMMARY

The FACILITATE project aims to address the ethical and legal challenges of **returning individual participant data (RoIPD)** from clinical trials to participants within the European Union (EU) involving individuals who are 18 and older. Despite growing recognition of the value that such data holds for participant empowerment and healthcare decision-making, RoIPD remains rare due to unclear responsibilities, limited infrastructure, and a lack of regulatory guidance.

This White Paper presents a **flexible, participant-centric framework** for the ethical and legally compliant return of individual-level clinical trial data. It outlines the current regulatory landscape, including the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection Regulation (GDPR), and concludes that there is an absence of a legal mandate for RoIPD.

An **ethical framework** underpins the FACILITATE approach for RoIPD, grounded in principles such as autonomy, beneficence, transparency, privacy, justice, and empowerment. The FACILITATE approach to RoIPD emphasizes co-creation with patient representatives, health literacy support, and clearly defined roles and responsibilities for all stakeholders involved in implementing RoIPD.

The proposed RoIPD framework promotes **RoIPD "by design"** i.e. the integration of data return into clinical trial planning and execution. It supports flexible operationalisation of RoIPD that is tailored to diverse trial contexts while ensuring participant rights and preferences are respected. Guidance is provided on informed consent, privacy notices, and the operationalization of RoIPD through online platforms or designated individuals.

By establishing a robust and participant-informed framework for RoIPD, FACILITATE seeks to improve the ethical conduct of clinical trials, enhance trust in the research process, and contribute to more informed and equitable healthcare outcomes across Europe.

INTRODUCTION

Considerable amounts of data are generated during clinical trials that can provide important information and insights into the health of participants. Returning this **individual participant-level data** to participants can improve their understanding of any conditions they may have, enable them to better respond and manage their condition, and improve their overall health care decision-making **(1)**. Returning individual clinical trial data to participants also reinforces their role in research and respects their autonomy. It also enables them to make more informed decisions about their health. However, participants note that the routine return of such data remains rare, particularly once a trial has concluded **(2,3)**. This is partly because responsibility for data return is unclear: pharmaceutical companies cannot contact participants post-trial, hospitals often lack resources for long-term data return, and there are no standard technological solutions for secure return of individual participant data.

The FACILITATE project is dedicated to establishing a framework for the ethical and legally compliant **RoIPD** from clinical trials within the European Union (EU). RoIPD is an emerging frontier in clinical research. Despite this, FACILITATE is not developing its processes in a vacuum, but it is building upon other initiatives that are working towards making data available, including TransCelerate BioPharma Inc. and the Harvard Multiregional Clinical Trials (MRCT) Center of Brigham and Women's Hospital and Harvard University **(4–6)**. FACILITATE is also developing its processes to ensure full compliance with GDPR requirements.

RoIPD:
a process built to ensure full compliance with GDPR requirements

FACILITATE White Paper provides a guidance to ensure responsible, flexible, and impactful RoIPD

This White Paper sets out recommendations for the operationalisation of RoIPD within clinical trials that empowers participants and drives progress in medical research and healthcare delivery.

This FACILITATE White Paper is expected to provide purposeful guidance to ensure **responsible, flexible, and impactful** operationalisation of RoIPD.

The FACILITATE White Paper is intended to assist stakeholders, including participants, researchers, sponsors, healthcare providers, and regulators, in navigating the complexities of RoIPD while maximizing its potential to transform patient care and healthcare innovation. It outlines how RoIPD may be operationalised in a manner that balances ethical, legal, and practical considerations.

This White Paper sets out in detail FACILITATE's proposed RoIPD framework. It begins by setting out the key features of FACILITATE's approach. We next discuss the current regulatory status of RoIPD. Having established that there is a lack of a legal mandate for RoIPD, this White paper proceeds to outline the FACILITATE **ethical framework.** FACILITATE's processes are grounded in this ethical framework and guided by the ethical principles specified in this ethical framework. It is this ethical feature that is a novel feature of FACILITATE. In outlining the ethical principles, the White Paper also describes the process for establishing these principles. Finally, this White Paper outlines the key features of a RoIPD process that sponsors may want to consider when developing their own RoIPD plan.

PROBLEM STATEMENT

RoIPD from clinical trials can empower participants, improve health decision-making, and strengthen trust in research. However, RoIPD remains rare in the EU due to unclear responsibilities, limited infrastructure, and a lack of legal guidance. Most importantly, RoIPD is not yet built into the design of clinical trials. A clear, ethical, and practical framework is needed to make RoIPD an integral and routine part of trial planning and conduct.

1. The FACILITATE RoIPD approach

There are three key features to the FACILITATE RoIPD approach.

It is participant-centric

It is by design

It is flexible

1.1 Participant-centric

FACILITATE has adopted a participant-centric approach to the design of RoIPD and encourages such an approach in the operationalisation of RoIPD within clinical trials. A participant-centric approach means that participants are not passive actors, but active and equal partners in the research process **(7–9)**. This approach enhances the relevance, acceptability, and outcomes of research by aligning studies with participants' needs, expectations, and insights. It reflects a cultural shift from a paternalistic "we know what is best" mindset to one of **shared decision-making** and collaboration, where participants' voices and choices are central.

A participant centric approach emphasizes transparency, regular communication, and the respectful and meaningful return of personalized data to participants, ensuring that their autonomy is upheld. FACILITATE's **participant-centric approach** embodies this philosophy by co-creating a clinical trial environment with participant representatives and incorporating participants' perspectives throughout the trial planning and conduct.[1]

From this perspective, the qualitative research conducted within FACILITATE partners has highlighted the role of the "**embedded patient**" approach within a clinical trial. In the context of the FACILITATE project, the "embedded patient" refers to a participant who is not only enrolled in a clinical trial but is also actively involved in shaping the trial's design and governance.

A participant-centric approach reflects a cultural shift from a paternalistic "we know what is best" mindset to one of shared decision-making and collaboration

This role goes beyond traditional participation, enabling patients to act as internal **advocates and co-creators**, ensuring that their perspectives, particularly regarding the RoIPD, are meaningfully integrated into the trial process. By occupying this position, the embedded patient helps guarantee that the patient voice is continuously represented, fostering trust, relevance, and ethical alignment in clinical research.

FACILITATE's stakeholders with prior clinical trial experience have repeatedly emphasized that taking an embedded patient approach can help ensure the patient's voice is meaningfully included in shaping RoIPD as a core component of the clinical development process.

[1] For guidance on how this can be done see Webinars arkiv - EUPATI Toolbox

1.2 By design

FACILITATE is advocating for a **RoIPD by design approach** for clinical trials within the EU, involving adults who are 18 and older. By this we mean taking an intentional approach to RoIPD by designing the processes and planning for its operationalisation at the outset of the clinical trial.

The mechanisms for RoIPD should be embedded into the trial's design, execution, and post-trial phases

This approach will help ensure that mechanisms for RoIPD are embedded into the trial's design, execution, and post-trial phases rather than being treated as an afterthought. Ensuring that all requirements for ICH Good Clinical Practice (GCP) are met, RoIPD by design aims to create a transparent, participant-centric system where data is returned in a meaningful, accessible, respectful, and ethically responsible manner, empowering participants, and respecting their autonomy. By embedding RoIPD into trial design planning, RoIPD processes may foster participant engagement and improve trustworthiness.

1.3 Flexible

A flexible approach adapts to the diverse contexts and complexities of differing clinical trials

FACILITATE's RoIPD approach is to be understood as being **flexible**, so that it can adapt to the diverse contexts, complexities of differing clinical trials and the maturity of the product under investigation. Clinical trials can vary widely in terms of their phase of development, scope, objectives, disease area, geographic locations, amongst other regulatory parameters. As such, a one-size-fits-all approach to RoIPD is impractical and undesirable.

It is for this reason that FACILITATE is not focused on a technical solution, but rather on documents that can support the development and practical operationalization of RoIPD by design processes and capabilities. This **flexible and adaptive approach** is also important in ensuring patient safety and enabling processes which are inclusive, scalable, and capable of being effectively implemented across a wide range of trial settings, while adhering to FACILITATE's principles.

Take home messages

- FACILITATE encourages a **participant-centric** approach, meaning that participants are not passive actors, but active and equal partners in the research process
- FACILITATE is advocating for a **RoIPD by design** approach for clinical trials within the EU, according to which RoIPD should be integrated into the design, execution, and post-trial phases, rather than being treated as a secondary element.
- FACILITATE's RoIPD approach is to be understood as being **flexible**, so that it can adapt to the diverse contexts as well as complexities of differing clinical trials and the maturity of the product under investigation.

2. RoIPD: current regulatory status

The Clinical Trials Regulation (CTR) includes key transparency requirements, such as the obligation to make aggregate study results publicly available following a clinical trial. These requirements do not extend to the return of individual-level clinical trial data to participants.

The CTR is silent on RoIPD and there is no legal mandate for RoIPD within the CTR. The **Clinical Trials Information System (CTIS)**, the centralized EU platform for submitting, assessing, and overseeing clinical trials conducted in the EU now requires sponsors to indicate **whether a sponsor has a RoIPD plan (since 2024)**. If such a plan is in existence, the sponsor has the option of uploading the RoIPD plan to CTIS.

RoIPD, however, is like some of the rights under the GDPR, notably the right to access. Understanding how RoIPD relates to this right is important. If RoIPD is considered to be a right to access, this has legal implications e.g., RoIPD would not require a separate lawful basis.

2.1 RoIPD and the GDPR

Article 15 of the GDPR gives data subjects the right of access to their personal data in a clear and transparent manner. This right enables data subjects (i.e. trial participants) to not only know what personal data is being processed by a data controller, but also **exercise their other GDPR rights**, such as the right to correction and the right to objection **(10)**. The right of access can only be invoked by the data subject and it is then upon the data controller to determine each access request on a case-by-case basis.

For the GDPR, the right of access can only be invoked by the data subject

The FACILITATE RoIPD process is different from the right of access. Our approach is envisaged as a **sponsor-initiated process**, embedded into the clinical trial operational processes. It is the sponsor that asks the participant if they wish to be involved in RoIPD and not a process that the participant requests to be initiated (as in the case of the right of access). As such, while similar, the right to access and RoIPD are different processes. At this point, FACILITATE wishes to make it clear that a decision to participate or not in RoIPD does not in any way impact a participant's right to access.

The FACILITATE RoIPD process is a sponsor-initiated process

The implications of RoIPD not falling under the right to access, is that there must be a lawful basis for the processing of personal data under RoIPD. FACILITATE's RoIPD processes are expected to occur **during and after the clinical trial**, thus there must be a lawful basis for the processing of personal data for RoIPD both during and after the clinical trial. As RoIPD is not mandated within the CTR, it is unclear whether the processing of personal data for RoIPD would occur within the legal basis for the processing of personal data for the clinical trial.

As there is no specific guidance on the lawful basis for processing personal data for RoIPD, FACILITATE has referred to the guidance issued by the European Data Protection Board (EDPB) on the interplay between the CTR and the GDPR **(11)**. In this guidance, the EDPB looked at the meaning of what it considered to be **"primary use"** i.e., data processing activities that could fall within the lawful basis of the clinical trial. The guidance states that any data processing activities related to a clinical trial's lifecycle, from initiation to archiving, are considered "primary use." Thus, RoIPD that occurs after the clinical trial's lifecycle would need a separate lawful basis.

Looking to RoIPD that would only occur during the clinical trial's lifecycle, the guidance does provide some indication as to whether it would fall within the primary use of the clinical trial. The guidance emphasized the importance of distinguishing between data processing for research purposes and data processing for reliability and safety-related purposes, as each requires different legal bases. RoIPD is indeed linked to research as it is occurring due to a participant's involvement in a clinical trial. RoIPD is dependent on the existence of a clinical trial. RoIPD, however, is not essential for the conduct of a clinical trial, as clinical trials can reach their planned research outcomes without engaging in RoIPD. On this basis, it is possible that RoIPD during the clinical trial would fall out of primary use and thus require a separate lawful basis. FACILITATE discussed this point with the Irish Data Protection Commission (DPC). The DPC were of the opinion that, based on the proposed RoIPD processes at that time, **RoIPD during the clinical trial would likely fall outside of the primary use** of the clinical trial and would require a separate lawful basis.

A separate lawful basis for RoIPD should be identified

FACILITATE acknowledges that there is uncertainty on this point and that RoIPD is advancing in the absence of a legal framework and legal guidance. FACILITATE also acknowledges that whether RoIPD is a primary use may be impacted by whether a RoIPD by design approach is taken or not.

If RoIPD is included in the clinical trial protocol, clinical development plan, or asset evidence generation plan and embedded throughout the clinical trial lifecycle, a stronger case could be made for the RoIPD to be considered primary use. However, due to this uncertainty, FACILITATE recommends that a separate lawful basis for RoIPD be identified.

FACILITATE examined the possible lawful bases under Article 6 and 9 of the GDPR and concluded that, **for RoIPD, the most suitable lawful basis is consent.** Performance of a contract (Article 6(1)(b)) would not apply as the data subject is not a part to any agreement with the sponsor. As there is no legal mandate for RoIPD, Article 6(1)(c) (processing for the compliance of a legal obligation to which the data controller is subject) is not applicable. RoIPD can provide important information for participants, but it is not in place to protect vital interests of the participants. As such, Article 6(1)(d) is not applicable.

Turning to Article 6(1)(e), although it is expected that RoIPD will provide some benefits for participants, improve transparency, and foster trustworthiness in clinical trials, at this juncture, it could not be considered a task carried out in the public interest. Finally, RoIPD is unlikely to be necessary for the legitimate interests of the sponsor and thus would not fall under Article 6(1)(f).

As such, consent is the most suitable lawful basis under Article 6(1)(c). Similarly, looking at the lawful basis for the processing of special categories of data, consent under Article 9(2)(a) is most suitable for RoIPD. **Consent as a lawful basis** also very much reflects what it is that FACILITATE is trying to achieve: risk-based quality and safety by design processes to be put in place in advance of the clinical trial providing participants with the decision on whether or not to participate in RoIPD.
Thus, until such time as there is legal clarity as to whether RoIPD would fall under the lawful basis of the clinical trial, FACILITATE recommends consent to be the lawful basis for RoIPD.

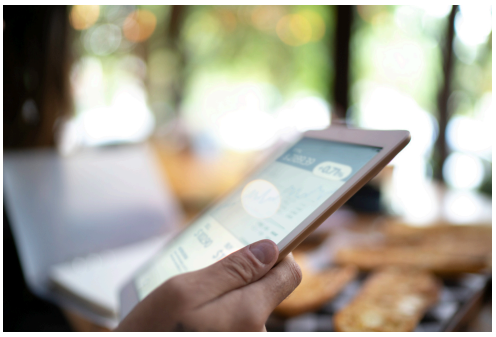
FACILITATE recommends consent to be the lawful basis for RoIPD

2.2 RoIPD and information to be provided to participants as per the GDPR

Whether RoIPD requires a separate lawful basis in the form of consent or if it is to be included in the primary use of the clinical trial, certain information will be required to be given to participants in the **informed consent form (ICF)**. The ICF wording and content will depend upon the technical solution or processes adopted for RoIPD, but the ICF will need to contain sufficient information to support participant understanding of the RoIPD and the process.

This should include information on which data will be returned, which data will not be returned, how it will be returned, by whom, the expected timing of the return, and who will have access to the data.

For RoIPD, information should be given to participants in the informed consent form



The exact content of the privacy notice will depend upon the digital solution adopted

If a **digital platform solution** is adopted for RoIPD, privacy notices will need to be developed and provided to the participants. Similar to the ICF, the exact content of the privacy notice will depend upon the digital solution adopted, but it should include details of the data controller and the information officer, information on the type of personal data being processed, the legal basis for the processing of personal data, information on the retention and storage of personal data, information on who will have access to the personal data, and information on their rights under the GDPR.

2.3 RoIPD and a legal framework

Sponsors should be encouraged to adopt RoIPD by design

As has been pointed out, there is a lack of a legal mandate for RoIPD. FACILITATE acknowledges that clarity and/or guidance on the lawful basis of RoIPD would be welcomed, but at this juncture we do not call for a legal framework or regulations on the operationalisation of RoIPD.

The reason for this is that RoIPD is at a nascent stage. The focus for now should be on encouraging sponsors **to adopt RoIPD by design.** The clinical trials community should be supported to embed RoIPD into the clinical trial lifecycle, and establish opportunities to learn from the experiences of each other. Until we have had some lived experiences from all stakeholders on RoIPD, FACILITATE considers that regulations in this space are premature.

Take home messages

- The FACILITATE RoIPD approach is envisaged as a **sponsor-initiated process**, whereby it is the sponsor who asks the participant if they wish to be involved in RoIPD.
- FACILITATE recommends that **consent** be the legal basis for RoIPD.
- The **informed consent form** should inform participants about: which data will be returned, which data will not be returned, how it will be returned, by whom, the expected timing of the return, and who will have access to the data.

3. FACILITATE's ethical framework

RoIPD is important for participant autonomy, transparency, trust and trusworthiness, amongst other important ethical principles. As such, FACILITATE considers that RoIPD is becoming a part of the ethical conduct of clinical trials. In the absence of a legal framework, it is essential that the development and operationalisation of RoIPD is supported by an **ethical framework that fills the legal gaps**. At this juncture, RoIPD processes must also be flexible so that they can adapt to the differing contexts of clinical trials. As such, the development of a FACILITATE ethical framework was seen as a critical outcome of FACILITATE.

Reflective equilibrium seeks to reach consensus on ethical reasoning amongst the stakeholders

FACILITATE's approach to developing this ethical framework began by identifying key substantiative and procedural principles for RoIPD that would inform the development of processes to operationalise RoIPD in practice. The methodology of **reflective equilibrium** was adopted. This is a method that seeks to reach consensus on ethical reasoning amongst the stakeholders (academic, EFPIA, ethics committees, healthcare providers, and participants) by following a path of reflection and discussion to reach agreement.

In the case of FACILITATE, this involved discussing principles identified in documents listed in **Table 1** that are pertinent to RoIPD. Through a process of deliberation, agreement was reached on FACILITATE's RoIPD substantive principles (**Table 2**) and procedural principles (**Table 3**).

Table 1: Documents that informed FACILITATE's ethical principles

CIOMS	International Ethical Guidelines for Health-related Research Involving Humans
MRCT Center of Brigham and Women's Hospital & Harvard University	Return of Individual Results to Participants Recommendations Document
TransCelerate BioPharma Inc.	Individual Participant Data Return (iPDR) Toolkit [2]
American College of Medical Genetics and Genomics	Recommendations for reporting of secondary findings in clinical exome and genome sequencing
World Medical Association	Declaration of Helsinki
World Medical Association	Declaration of Taipei
UNESCO	Universal Declaration on Human Rights and the Human Genome
UNESCO	International Declaration on Human Genetic Data
ICH	Guideline for genomic sampling and management of data ICH E8 R1 [3] ICH E6 R3 (Good Clinical Practice) GCP [4]
Council of Europe	Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research

[2] [3] [4] Although not part of the original documents reviewed, due to the importance of this document in the RoIPD space, it was later included.

Council of Europe	Recommendation (2006)4 of the Committee of Ministers to member states on research on biological materials of human origin
Council of Europe	Oviedo Convention
European Commission	General Data Protection Regulation
European Commission	Clinical Trials Regulation
European Commission	Draft Regulation for a European Health Data Space
National Academy of Sciences	Returning Individual-Specific Research Results to Participants: Guidance for a New Research Paradigm
Global Alliance for Health	2021 Policy on Clinically Actionable Genomic Research Results
OECD	Recommendation on Health Data Governance

Table 2. 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 to 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 to 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 the production of generalizable knowledge for the patients who will benefit from 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.

Table 3. Procedural values

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.
Accountability	It must be clear who is responsible for ensuring that clinical trial data is returned to participants.

Having identified these principles, attention then turned to how these principles could be operationalized in practice. Preliminary considerations identified in **D3.1 Report on the draft ethical frameworks for FACILITATE** focused on:

- Putting in place transparent and accountable processes that would identify the roles and responsibilities of key individuals in the decision-making process.
- Providing clear and ongoing information to participants throughout the RoIPD process.
- Ensuring that participants understand the purpose of RoIPD, the process, and what data they will receive.

Consortium partners then began to develop the FACILITATE RoIPD ethical standards and guidelines, that was published in **D3.4 Report on ethical standards and guidelines**. This deliverable identified six elements that were important for the operationalization of RoIPD in practice:

1. Processes should be co-created to ensure that they are tailored to the context and features of the specific clinical trial.
2. A clear delineation of roles and responsibilities of the differing parties involved should be made, that includes sponsors, investigators, patients and patient representatives, ethics committees, data managers, as well as new professional figures that will need to be created to streamline the trial and interact with patients, clinicians and sponsors.
3. Transparent procedures that serve to keep participants fully informed about their data return during and after the clinical trial should be developed.
4. Any RoIPD must adhere to regional and national legal and ethical requirements.
5. Training is needed for all those involved in the RoIPD process to ensure they are prepared to respond to the technical, legal, and ethical issues that can arise in the RoIPD process.
6. The RoIPD process should be evaluated to assess its operation and improvements that can be made.

In addition, FACILITATE identified six features of an ethical RoIPD process. Briefly they are:

1. A plan should be developed for RoIPD. It is the sponsor who has the responsibility for ensuring the RoIPD plan is developed and implemented. The process should adhere to the FACILITATE ethical framework, be co-created, and it is strongly advised that the RoIPD process be approved by a research ethics committee (REC).

2. Health literacy to ensure that participants can obtain, process, and understand the data that they will receive as well as its potential impact on their health is critical. It is also vital that participants understand the RoIPD process. 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.

Health literacy tools tailored to the needs of the participant can be developed to support RoIPD

3. The individuals implementing the RoIPD process are critical to the success of RoIPD. This should not be done by the sponsor, but rather by individuals who have the **necessary skills and knowledge** to enhance health literacy and respond to the potential emotional impact of the result. If a person is returning data to a participant (as opposed to when RoIPD is facilitated by a platform), the individual informing the participant about the RoIPD process may be different to the person returning the data. 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 ensure the principles of beneficence and utility, it is recommended to involve a healthcare professional in the process of returning clinical data, as they can help participants understand the data and its potential clinical implications. It is important that any return of genetic results adhere to local laws that may require the involvement of a genetic counsellor.

4. There are **three key points** at which the RoIPD processes should be discussed with the participant: the time of enrollment; the time at which the participant decides on whether they want their data to be returned; and the actual RoIPD. When these points occur, will depend on the specific requirements of the RoIPD clinical trial plan.

5. An **ethical RoIPD process** is contingent on consent mechanisms that inform participants about certain elements of the process. They include: the data that will be returned, the point(s) in time when the data be returned, and the mechanism for return. Any legal constraints on return (e.g., any national legal requirements that genetic data must be returned by a genetic counsellor) should be communicated.

6. Finally, **clinically meaningful data** should be returned to the participant.

Take home messages

- A critical outcome of FACILITATE was the development of an **ethical framework for RoIPD,** built on key substantive and procedural principles to guide the creation of processes for its practical implementation.
- RoIPD processes should be **co-created and transparent,** with clearly defined roles and responsibilities for all parties, and full compliance with legal and ethical requirements.
- Ethical RoIPD depends on health literacy, skilled communication, and proper consent to ensure **participants understand their data**.

4. FACILITATE RoIPD Framework

4.1 Context of the FACILITATE RoIPD framework

There is increasing recognition of the importance of the RoIPD during and after clinical trials. It demonstrates respect for participants, acknowledges the important role they play in clinical trials, can provide a **reciprocal benefit to participants**, and foster a more trustworthy clinical trials ecosystem. There is currently a lack of a legal mandate to return individual participant data but work on developing processes has begun that include initiatives such as TransCelerate BioPharma Inc. and the MRCT center of Brigham & Women's Hospital & Harvard University

The FACILITATE framework builds upon this work and other efforts to prioritise participants' rights, needs, experiences and engagement across the clinical research and medicines development process. It is in this light and as part of a broader movement toward more informed and transparent ethical research practices that treat **participants as active contributors** rather than passive subjects that this framework has been designed. This framework should also be seen within the EU regulatory context, specifically the GDPR, the CTR and ICH requirements. It is within this context that the FACILITATE framework has emerged, seeking to embed ethical RoIPD within the clinical trials ecosystem.

FACILITATE framework should be seen within the EU regulatory context, specifically the GDPR, the CTR and ICH requirements

4.2 Aims

The aims of this framework are:

- Identify principles to be implemented in RoIPD
- Embed RoIPD by design into the clinical trial eco-system
- Enable a participant-centric approach to RoIPD
- Identify key points to be considered in designing and operationalisation of RoIPD processes, and
- Increase opportunities for a convergence of clinical care and clinical research

4.3 Considerations in developing and operationalisation of RoIPD

In developing RoIPD plans to operationalise, sponsors should be guided by FACILITATE RoIPD substantive and procedural principles (see **Table 2 and 3**, page 24-25).

4.3.1 Co-creation of protocols on RoIPD

A co-creation process for protocols on RoIPD is strongly encouraged. This co-creation process can involve investigators in the clinical trial and patient groups. Co-creation improves transparency, confers agency on the participant, and helps ensure that the concerns, safety and needs of the participants are considered while not compromising the integrity of the trial results and subsequent outcomes for patients.

A RoIPD plan does not need to be co-created for every trial. RoIPD plans can be co-created for different types of clinical trials. These RoIPD plans are encouraged to be shared (see Section 4.6 Shared Knowledge Building).

As RoIPD will be part of the clinical trial protocol, it will require approval by a REC. Furthermore, any modifications to the RoIPD process need REC endorsement, as required by ICH GCP.
In developing RoIPD protocols, discussions within FACILITATE have considered the following to be important.

4.3.1.1 Consent process

The process for providing participants with information and obtaining their consent should be **included in the protocol**.

4.3.1.2 Defining Roles and Responsibilities

The protocol should clearly articulate the roles of all parties involved, including sponsors, investigators, participant representatives. ethics committees, data managers. This clarity will help ensure that each stakeholder understands their duties and the expectations placed upon them.
The **sponsor is ultimately responsible** for ensuring that there is a RoIPD plan in place and that this plan is operationalised at each site. The sponsor is responsible for ensuring that the RoIPD plan is co-designed. Sponsors, however, are restricted from providing any medical guidance or interpretation of the RoIPD data to the participants.

4.3.2 Timing of data return and data to be returned

Participants should be informed about what data will be returned during the clinical trial and **at what point** during the clinical trial they should expect this return. It is encouraged that there is ongoing communication during the trial with participants on when data can be made available, and this should be communicated to participants. If certain data can only be returned after the clinical trial, participants will need to be informed why this can only be made available after the trial.

4.3.3 Timing of data return and data to be returned

The protocol should define the data to be returned and data that will not be returned.

FACILITATE acknowledges that what data will be returned is a critical point and is an issue that warrants further consideration. As such, FACILITATE expects to publish guidance on this point in 2026.
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.

4.3.4 Adherence to Ethical and Legal Standards

Align all procedures with existing ethical guidelines and legal requirements, including GDPR, national ethical and legal requirements and ICH GCP. This alignment should focus on protecting participant privacy and ensuring data security, quality and integrity. In addition, the following are encouraged:

4.3.4.1 Contracts with sites

To ensure the operationalisation of RoIPD, study site contracts will need to explicitly reflect the additional responsibilities and resource needs involved. The RoIPD, whether facilitated through digital platforms or in-person engagements, constitutes new work for study sites. This includes participant communication, managing consent processes, data return logistics, and post-trial follow-up. These tasks go beyond standard trial operations and must therefore be acknowledged contractually. The contracts may need to:

- Define the responsibilities of the site in supporting RoIPD, including communication with participants, managing consent, and facilitating secure data return.
- Specify the training and staffing requirements necessary to deliver RoIPD.
- Acknowledge the need for additional time and infrastructure that sites may require.
- Include appropriate financial compensation for these additional tasks, with clear budget lines aligned with the RoIPD activities.

4.3.4.2 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.

4.3.4.3 Shared Knowledge Building

At the end of the RoIPD, the processes should be evaluated to assess the operation of the process in practice and whether changes should be made to 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.

Take home messages

- At enrollment, participants should be informed that the option to have their **clinical trial data** returned exists,
- **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.
- If data is to be returned by individuals, they should have the necessary **skills and knowledge** to enhance health literacy, respond to the potential emotional impact of the result.

5. Approaching consent

In accordance with ICH GCP guidelines, sponsors must ensure that participants **fully understand** all processes related to the clinical trial conduct at the time of enrollment, including the possibility of having their data returned to them.

There are three important junctures at which the RoIPD should be discussed with the participant: the time of enrollment; 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 duration, data generation, validation, and collection capabilities and availability.

During the clinical trial informed consent process, participants must be informed that the purpose of the clinical trial is to identify generalizable results based on statistical inference and **not individual care**. At enrollment, 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 to do so.

Participants must be fully informed about what data will be returned

Participants must be fully informed about what data will be returned, the potential implications, and their right to choose whether or not to receive it. However, **consent to RoIPD is not a one-off event** but rather an ongoing process. The consent process will vary according to whether data is returned via a platform, via an individual, or a combination of a platform and a person. Irrespective of the mode of data return, FACILITATE considers the following to be useful in the operationalisation of RoIPD.

5.1 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.

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 RoIPD process can be influenced by intrinsic and extrinsic factors

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.

Where possible, data should be returned in the local language with the recommended level of language use.

5.2 Skills and knowledge for those discussing RoIPD with participants

Discussions on RoIPD, how data will be returned, the timing, and how it will occur (i.e., via a platform, or a person, or combination of a person and platform) with the participant should be facilitated by individuals with the **appropriate skills**.

If data is returned by individuals, they should have the necessary skills and knowledge

In circumstances in which data is to be returned by individuals, they should 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.

FACILITATE considers it preferable to focus on the skills of the individual who is engaging with the participant, rather than their profession. Thus, discussions on the RoIPD can be done by a research nurse or a healthcare professional and/or supported by **communication experts** such as cultural mediators and patient organisations. To guarantee the principles of beneficence and utility it is advisable to involve a health care professional in the process of clinical data return to facilitate the understanding of the data and eventual clinical implications.

5.3 Data returned via an online interface

Data may be returned through an online interface. When this occurs, participants should be encouraged to consult with a healthcare professional who has the necessary expertise to interpret the data and understand its implications for the participant. Participants should be informed about why it is good practice for a healthcare professional to communicate this data.

If RoIPD is to be facilitated through an online interface, the following at a minimum should be discussed during the consent process:

- 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 enroll on the platform
- Who the data controller is and what a data controller is
- Their rights under the GDPR, including the right to rectification if they see any errors
- Any special requirements in national law e.g., return of genetic results requiring a genetic counsellor
- How the security of the process is maintained (e.g., multi factor authentication)
- 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
- That any withdrawal of consent to RoIPD does not impact their right of access under the GDPR
- Intended storage period
- 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

If the RoIPD is facilitated **by a person**, indicate whether it will be returned by a doctor, investigator, member /researcher of the study team, nurse, or other healthcare professionals and how they can be contacted if they have any further questions.

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, when it should be done by an individual, and who will have access to the data, Participants must be clearly informed that their clinical trial data will be returned to them (or their legal guardian or representative) and will not be shared with any other parties, including insurance companies.

If the RoIPD is facilitated by healthcare professionals, indicate how they can be contacted

5.4 Responsibilities of participants

RoIPD after the clinical trial shall be communicated to participants through a participant tool through which the participants can access their data. Participants shall be informed that it is their responsibility to ensure that their **contact details** are kept up to date on this tool. They shall be informed that failure to do so can impact their ability to receive ongoing information

5.5 Rights under GDPR

It is important to make clear to participants that they still have their rights under the GDPR and that RoIPD does not affect any of their rights.

5.6 Who will have access to the data

Participants must be clearly informed that data **will not be shared** with any other parties (not being part in the management process of the trial), including insurance companies.

5.7 How the personal data will be protected

Participants should be informed how their personal data will be protected and made secure (e.g., **pseudonymization**).

5.8 Withdrawal of consent

Participants should be informed that they have the **right to withdraw** their consent to RoIPD at any time and who to contact if they do wish to withdraw their consent. They should be informed that if they do withdraw their consent, they will no longer receive their clinical trial data, but that this will not affect their right of access under the GDPR, nor their participation in the clinical trial.

5.9 Compliance with national law

Participants should be informed that the RoIPD will be facilitated in line with national law. Any storage and retention of personal data must be compliant with national law.

5.10 Signing of ICF

Participants should be invited to ask any questions that they may have. If they wish to proceed to have their clinical trial data returned, they should be invited to sign the consent form.

5.11 Changes to RoIPD processes

If there are any significant changes to the RoIPD processes, participants will need to be informed about the change and potentially reconsented.

Take home messages

- Consent for RoIPD must be understood as **an ongoing process** discussed at key points in the trial, ensuring participants know what data will be returned, when, and how.
- Health literacy, skilled communication, and appropriate professional involvement are essential to support participants in **understanding their data** and its implications.
- Participants must be informed of their responsibilities, GPDR rights , data protection measures, and their ability to **withdraw consent** at any time.

6. Guidance on text to be included in privacy notices

If an online platform is to be used, a **privacy notice** is necessary. This guidance serves as points to consider when developing privacy notices for an online platform that may be used to facilitate RoIPD. In developing the privacy notice, it is important to remember that the purpose of the privacy notice is to inform participants about the processing of their personal data. As such, the language used must be in a manner that is accessible and understandable. Privacy notices that are unduly long, difficult to read and comprehend, and unclear may not be understandable by participants. Such privacy notices will therefore not achieve the objective of ensuring that participants understand the information surrounding the processing of their personal data.

The purpose of the privacy notice is to inform participants about the processing of their personal data

6.1 Identification of data controller

The data controller must be specified, and their contact details provided to the participant. The role of the data controller must also be explained.

6.2 Identification of Data Protection Officer

The Data Protection Officer (DPO) must be specified and their contact details provided to the participant. The role of the DPO must also be explained.

6.3 Type of personal data processed

The participant must be informed about the type of personal data that will be processed as part of ensuring that a participant's clinical trial data can be returned on the platform.

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This will include the personal data that is required for them to be enrolled on the platform (e.g., email address) and the special personal data that will be returned to them through the platform.

6.4 Legal basis of the processing

Participants can withdraw their consent at any time

Participants should be informed that the legal basis for data processing is based on consent, according to Article 6(1)(a) and Article 9(2)(a) of the GDPR. Participants must also be informed that they can **withdraw their consent** at any time. They must be informed about how they can withdraw their consent (e.g., if there is a section on the online platform that easily facilitates the withdrawal, or if there is a specific person to contact to withdraw). Participants must also be informed about the implications of their withdrawal of consent (i.e., that they will no longer have their data returned to them).

6.5 Retention and storage of personal data

Participants should be informed that to facilitate RoIPD, their personal data will be collected and stored. They should be informed how long that personal data will be stored and where it will be stored.

6.6 Access to personal data

Participants should be informed that only they (or their legal representative) will have access to the personal data and those who are required to manage the online platform.

6.7 Rights of the data subject under GDPR

Participants should be informed about their rights under Articles 15 to 22 of EU Regulation No. 2016/679. They have the right to:

- Request confirmation of the existence or otherwise of your personal data
- Obtain information about the purposes of the processing, the categories of personal data, the recipients or categories of recipients to whom the personal data have been or will be communicated and, when possible, the storage period
- Obtain the rectification and erasure of data
- Obtain the restriction of processing
- Obtain the portability of the data, i.e. receive them from a Data Controller, in a structured, commonly used and machine-readable format, and transmit them to another Data Controller without hindrance
- Object to the processing at any time and in the case of processing for direct marketing purposes
- Object to automated decision-making relating to natural persons, including profiling
- Withdraw consent at any time without prejudice to the lawfulness of the processing based on the consent given before the withdrawal
- Lodge a complaint with a supervisory authority

Participants should be informed that they may exercise their rights under GDPR by sending **an official and documented communication** using one of the following channels:

- Registered mail to be delivered at the registered office of the Data Controller.
- Sending an e-mail with notification of delivery and receipt to the Data Controller's e-mail address.
- That before being able to provide them with, or modify any information, it may be necessary to verify their identity, answer some questions and fill in an official request form that will be provided to them by the Controller. A reply will be provided as soon as possible.

Take home messages

- **Privacy notices** must be clear, accessible, and transparent, explaining who controls and protects the data, what data are processed, and the legal basis, amongst other information
- Privacy notices must also inform participants of their **GDPR rights** and provide simple ways to exercise these rights.

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FACILITATE

Framework for Clinical Trial Participants' Data Reutilization for a Fully Transparent and Ethical Ecosystem

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 101034366. The JU receives support from the European Union's Horizon 2020 research and innovation program and EFPIA.