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FACILITATE

FrAmework for ClInicaL trIal participants daTA reutilization for a fully Transparent and Ethical ecosystem

WP3 - Ethics, standardization and regulatory framework

D3.4 Ethical standards and guidelines No. 2

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Abbreviations

Deliverable (D)
General Data Protection Regulation (GDPR)
Good Clinical Practice (GCP)
International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)
Informed Consent Form (ICF)
Number (No.)
Research Ethics Committee (REC)
Return of individual participant data (RoIPD)

Summary

This report will describe the background, and the methodology used to develop the ethical standards and guidelines No. 2. Deliverable D3.3 - ethical standards and guidelines No. 1- focused on the draft guideline for consent in the return of individual participant data (RoIPD). D3.4 builds upon that and drawing on the ethical principles as set out in D3.1 Report on the draft ethical framework for FACILITATE, provides a guideline for developing and implementing a RoIPD process.

1. Background: starting from ethical principles set out in the draft framework

FACILITATE's draft ethical framework emphasizes the importance of protecting participants' dignity, autonomy, privacy, and confidentiality, as well as the need to obtain informed consent when using identifiable human biological materials and data. Within this framework, the ethical return of clinical trial data to participants is guided by several Substantive Principles, outlined below in Table 1. Additionally, the framework requires adherence to certain Procedural Principles (Table 2) during the data return process. It is crucial to recognize that no single principle is more important than another; rather, a balanced approach among all principles is necessary. The draft framework provides practical guidance on applying these principles and achieving this balance.

The FACILITATE framework represents an advanced integration of traditional bioethical principles—beneficence, non-maleficence, and justice—with contemporary concepts such as empowerment and utility, reflecting the evolving dynamics of participant interaction and data management in clinical research. Central to this integration is the enhancement of traditional respect for autonomy through the principle of empowerment, which not only supports individuals' control over their decisions but actively enhances their capacity to make informed choices. This is achieved by providing necessary tools, resources, and education, ensuring individuals are not just independent in decision-making but also well-equipped and informed.

Utility, another modern principle incorporated into the framework, emphasizes the return of clinical trial data that holds subjective and actionable value for participants. This principle aligns with and extends the rights established under the General Data Protection Regulation (GDPR), particularly under Article 15, which allows individuals unfettered access to their personal data held by data controllers. The utility principle enhances this right by ensuring that data returned is not only accessible but also meaningful and relevant to the participants' health needs, thereby fostering a more participant-centered approach in clinical trials.

The implementation of these principles within the FACILITATE framework requires the establishment of transparent and accountable processes that respect participants' rights to data access while maintaining compliance with GDPR. Participants are informed at the outset of a clinical trial about the nature of the data collected, the potential for receiving individual data results during and after the trial, and the mechanisms in place for accessing these results. This approach ensures that all returned data are handled in a manner that respects the integrity of each particular trial and the privacy and autonomy of the participants.

Overall, the FACILITATE framework not only aligns with current legal standards but also pushes forward the ethical boundaries by prioritizing enhanced participant empowerment and utility in clinical trials. This approach promises to improve participant engagement and trust, which are crucial for the ethical integrity and success of clinical research.

Table 1. 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.
Autonomy	Autonomy is a fundamental ethical principle in clinical trials that emphasizes the right of individuals to make informed decisions about their participation.
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 2. 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.

2. Methodology

Immediately following the completion of D3.3, work began on building up that deliverable. A table (Appendix 2) with all key elements of D3.3 was developed and partners were asked to comment on a number of elements. The first point partners were asked to comment on was their expectation as to the nature of D3.4 i.e., whether it is to be a recommendation, a framework, or a guideline.

Following that, and to enable the further development of D3.3 into a more detailed guideline, partners were asked to comment on the specific elements (Table 1), specifically considering where more flexibility can be built in, where more precise language and instruction can be embedded, and what is needed in each partners' specific context to enable the taking up of each recommendation into future RoIPD plans.

Table 3: Elements for discussion following D3.3

	Text of D3.3	**Where can we build in (more) flexibility?** **Where should we be more precise?**	**What is needed for the next step forward according to you or your needs related to your context to be able to take this recommendation up in your future plans for RoIPD?**
1	**Sponsors of clinical trials:** The responsibility of planning and discussing the plan of the Return of Individual Participant Data (RoIPD) lies with the Sponsor, who should engage investigators and patients whenever possible. Subsequently, the RoIPD process should be facilitated through the Investigators,		

	as they are informed about the Sponsor's plans and can accordingly inform participants about the process and timing of data return.		
2	**The Investigator or the participants physician** has an important role to play in helping a participant and/or their family interpret their returned data and understanding any medical significance of these data. Participants should be encouraged to discuss their data with a healthcare professional before making any healthcare decisions based on these data.		
3	**Right to Data Return (RoIPD) Notification:** It is increasingly acknowledged that there is an ethical obligation to return individual clinical trial data to participants. At the start of their participation in a clinical trial, participants are to be informed that they will have their individual clinical trial data returned to them on request.		
4	**Informed Consent Form (ICF) Requirement:** In accordance with ICH GCP, Sponsors must ensure that the participant fully understands and specifically consents, as appropriate, to the conditions and process for RoIPD. Sponsors are encouraged to consider a co-creation process involving participants from the onset of the protocol development or earlier. This would confer agency to the participant and help ensure that the concerns and needs of the participant are considered and taken into account in the design of the consent and RoIDP processes. Such an approach ensures transparency regarding RoIPD.		

5	**Informed Decision Making: Timing for Consent and Data Return Discussion:** Participants will be told at the time of consent to the trial that they will be asked to consent to RoIPD only when they feel fully informed about the process. When signing the consent at the onset, it should be made clear to the participant that consent can be revoked or changed at any time throughout the trial or after the trial.		
6	**Option to Decline Data Return:** Ensure that participants understand that while they have the right to access their individual clinical trial data, this procedure also provides them with the opportunity to indicate if they prefer not to have some or any data returned. This choice will not impact their legal rights under data protection law and could be changed over time.		
Governance recommendations for (RoIPD) in Clinical Trials			
1	**Clarity on Data Generation and RoIPD:** At the point of obtaining consent for RoIPD, participants must be clearly informed that all activities within the study will generate data, and that they retain the right to decide if they wish to receive this data as it becomes available as explained in the study ICF.		
2	**Flexibility in RoIPD Preferences:** Communicate to participants that they have the freedom to modify their RoIPD preferences at any stage of the trial, including instructions on how to update these preferences		
3	**Separation of Consent Forms:** It is recommended that the Informed Consent Form (ICF) dedicated to		

	RoIPD should be distinct from the ICF for clinical trial participation.		
4	**Qualified Personnel for Consent Process:** The individual responsible for discussing RoIPD with participants and obtaining the ICF must be knowledgeable enough to address potential questions, fully understand the clinical trial's scope, and possess the necessary communication skills for this sensitive engagement.		
5	**Protocol and Ethics Committee Approval:** It is strongly advised that the procedure for securing RoIPD consent must be approved by and explicitly included in the clinical trial protocol and receive approval from the Research Ethics Committee (REC). Furthermore, any modifications to the RoIPD process need REC endorsement. as required by ICH GCP		

Discussions were held with all partners to further understand all perspectives. Discussions were marked by an atmosphere of collegiately, attempts to reach consensus, and at times, agreeing to compromise. Through this process, a guideline on RoIPD was developed as well as a plan for the completion of the ethical framework

3. Guideline on RoIPD

During this process, there was much discussion on the objective of this deliverable. It was ultimately acknowledged by partners that, as most sponsors are now only in the process of considering or developing RoIPD, FACILITATE could best serve this by developing a general guideline that can be adopted by sponsors.

The guideline is built upon the assumption that a online interface will be developed to facilitate the data return. This guideline does, however, acknowledge that at times, the RoIPD will be facilitated by an individual. Guidance is thus provided for both scenarios.

Guidance is provided on proposed strategies to include for developing and implementing RoIPD processes. This includes:

- Co-creation of protocols in RoIPD
- The need to define roles and responsibilities

- Establish transparency and effective communication
- Adherence to ethical and legal standards
- Training and support systems
- Shared knowledge building

Finally, the guideline outlines a proposed process for ensuring the ethical development of RoIPD. It achieves this by providing guidance on the following processes:

- Developing a plan on RoIPD
- Health literacy
- The individuals implementing RoIPD processes
- The RoIPD process
- Consent to RoIPD
- The data to be returned

The development of this deliverable also brought the consortium back to re-consider the principles as set out in D3.1. Some changes were made to the explanation of those principles, and it was decided that going into the last year of the consortium that it may be pertinent to re-consider the principles, specifically drawing upon the experience and work of the consortium over the previous years. This will be discussed at a workshop in Madrid in January 2025. Furthermore, the final guidance documents that need to be developed will be discussed at this workshop, including a discussion on the return of genetic data and the data to be returned generally.

Appendix 1

A1.1 Ethical considerations in the procedures to be followed for Returning Individual Clinical Trial Data to Participants

FACILITATE's draft ethical framework emphasizes the importance of protecting participants' dignity, autonomy, privacy, and confidentiality, as well as the need to obtain informed consent when using identifiable human biological materials and data. Within this framework, the ethical return of clinical trial data to participants is guided by several Substantive Principles, outlined below in Table 1. Additionally, the framework requires adherence to certain Procedural Principles during the data return process. It is crucial to recognize that no single principle is more important than another; rather, a balanced approach among all principles is necessary. The draft framework provides practical guidance on applying these principles and achieving this balance.

The FACILITATE framework represents an advanced integration of traditional bioethical principles—beneficence, non-maleficence, and justice—with contemporary concepts such as empowerment and utility, reflecting the evolving dynamics of participant interaction and data management in clinical research. Central to this integration is the enhancement of traditional respect for autonomy through the principle of empowerment, which not only supports individuals' control over their decisions but actively enhances their capacity to make informed choices. This is achieved by providing necessary tools, resources, and education, ensuring individuals are not just independent in decision-making but also well-equipped and informed.

Utility, another modern principle incorporated into the framework, emphasizes the return of clinical trial data that holds subjective and actionable value for participants. This principle aligns with and extends the rights established under the General Data Protection Regulation (GDPR), particularly under Article 15, which allows individuals unfettered access to their personal data held by data controllers. The utility principle enhances this right by ensuring that data returned is not only accessible but also meaningful and relevant to the participants' health needs, thereby fostering a more participant-centered approach in clinical trials.

The implementation of these principles within the FACILITATE framework requires the establishment of transparent and accountable processes that respect participants' rights to data access while maintaining compliance with GDPR. Participants are informed at the outset of a clinical trial about the nature of the data collected, the potential for receiving individual data results during and after the trial, and the mechanisms in place for accessing these results. This approach ensures that all returned data are handled in a manner that respects the integrity of each particular trial and the privacy and autonomy of the participants.

Overall, the FACILITATE framework not only aligns with current legal standards but also pushes forward the ethical boundaries by prioritizing enhanced participant empowerment and utility in clinical trials. This approach promises to improve participant engagement and trust, which are crucial for the ethical integrity and success of clinical research.

Table A1. Substantive principles

Rights and respect for individuals and wider society	Individuals have the right to make autonomous and informed decisions. This includes if the 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.
Autonomy	Autonomy is a fundamental ethical principle in clinical trials that emphasizes the right of individuals to make informed decisions about their participation in the return of clinical trial data.
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, just and equitable.

Table 2. 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 when and how. 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.

A1.2 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.[1]
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 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.

A1.3 Ethical guidance principles

A1.3.1. Developing a plan on the Return of Individual Participant Data (RoIPD)

The Sponsor is ultimately responsible for ensuring that there is a RoIPD plan in place and fully implemented. Sponsors, however, must not provide any medical guidance or interpretation of the RoIPD data directly to the participants.

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 online interface 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

[1] 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].

A1.3.2. 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 online interface. 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 online interface, 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.

A1.3.3. 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 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 medicators and patient organisations. In order 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 online interface, 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.

A1.3.4. The RoIPD process

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 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 enrollment, including the possibility of having their data returned to them. 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 so. The comprehensive discussion about the RoIPD

A.1.3.5. 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.

A1.3.6. 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

Appendix 2: Document circulated to all partners to inform the development of D3.4

A2.1 Deliverable 3.4: Ethical Standards and Guidelines No. 2

This table serves to build on the previous deliverable we have developed together and has the overall aim to improve where possible the initial recommendations set out in D3.3. Is especially important that we see this deliverable as guiding sponsors more towards proactively addressing the potential uptake of some of the recommendations, and thus improving the quality of the clinical trial. This means that nobody is pushing any organization in a direction they do not want to go in, or they are not ready for or where means are lacking to do so.
What is asked for are simple adjustments that incorporate where possible a flexible nature to the process while being as clear as possible as to what to expect on a practical level. As agreed in D3.3, what we should try to do now is take simple steps to start the journey towards future implementation (where possible, for whom possible) of these recommendations. Thus, the table below starts from what we have agreed on (Text D3.3) and asks how and where we should refine, incorporate flexibility and or more precise wording. Remember this is a process we have just started which is a continuous process.

Acknowledging that we are not all at the same place of seeing how or when we can eventually start a process of RoIPD, we ask you to think of the possible not the immediately implementable. In short, we ask you to be engaged, not pressed.

Note: Clearly indicate the partner that you are when completing this document. Other partners can reflect on what others have written, provided that you indicate the partner that is commenting.

What each partner **expects** the nature of this deliverable to be (recommendations, a framework, possible guidelines) and what is **possible for you to consider this in the future**.	
Clearly state what you can contribute to this deliverable	

	Text of D.3.3	Where can we build in (more) flexibility? Where should we be more precise?	What is needed for the next step forward according to you or your needs related to your context to be able to take this recommendation up in your future plans for RoIPD?
1	**Sponsors of clinical trials:** The responsibility of planning and discussing the plan of the Return of Individual Participant Data (RoIPD) lies with the Sponsor, who should engage investigators and patients whenever possible. Subsequently, the RoIPD process should be facilitated through the Investigators, as they are informed about the Sponsor's plans and can accordingly inform participants about the process and timing of data return		
2	**The Investigator or the participants physician** has an important role to play in helping a participant and/or their family interpret their returned data and understanding any medical significance of these data. Participants should be encouraged to discuss their data with a healthcare professional before making any healthcare decisions based on these data.		
3	**Right to Data Return (RoIPD) Notification:** It is increasingly acknowledged that there is an ethical obligation to return individual clinical trial data to participants. At the start of their participation in a clinical trial, participants are to be informed that they will have their individual clinical trial data returned to them on request.		

4	**Informed Consent Form (ICF) Requirement:** In accordance with ICH GCP, Sponsors must ensure that the participant fully understands and specifically consents, as appropriate, to the conditions and process for RoIPD. Sponsors are encouraged to consider a co-creation process involving participants from the onset of the protocol development or earlier. This would confer agency to the participant and help ensure that the concerns and needs of the participant are considered and taken into account in the design of the consent and RoIDP processes. Such an approach ensures transparency regarding RoIPD.		
5	**Informed Decision Making: Timing for Consent and Data Return Discussion:** Participants will be told at the time of consent to the trial that they will be asked to consent to RoIPD only when they feel fully informed about the process. When signing the consent at the onset, it should be made clear to the participant that consent can be revoked or changed at any time throughout the trial or after the trial.		
6	**Option to Decline Data Return:** Ensure that participants understand that while they have the right to access their individual clinical trial data, this procedure also provides them with the opportunity to indicate if they prefer not to have some or any data returned. This choice will not impact their legal rights under data protection law and could be changed over time.		

Governance recommendations for (RoIPD) in Clinical Trials			
1	**Clarity on Data Generation and RoIPD:** At the point of obtaining consent for RoIPD, participants must be clearly informed that all activities within the study will generate data, and that they retain the right to decide if they wish to receive this data as it becomes available as explained in the study ICF.		
2	**Flexibility in RoIPD Preferences:** Communicate to participants that they have the freedom to modify their RoIPD preferences at any stage of the trial, including instructions on how to update these preferences		
3	**Separation of Consent Forms:** It is recommended that the Informed Consent Form (ICF) dedicated to RoIPD should be distinct from the ICF for clinical trial participation.		
4	**Qualified Personnel for Consent Process:** The individual responsible for discussing RoIPD with participants and obtaining the ICF must be knowledgeable enough to address potential questions, fully understand the clinical trial's scope, and possess the necessary communication skills for this sensitive engagement.		
5	**Protocol and Ethics Committee Approval:** It is strongly advised that the procedure for securing RoIPD consent must be approved by and explicitly included in the clinical trial protocol and receive approval from the Research Ethics Committee (REC). Furthermore, any modifications to the RoIPD process need REC endorsement. as required by ICH GCP.		