The return of Individual Participant Data in clinical trial research: FACILITATE White Paper Executive Summary

Ciara Staunton, Cris Woolston, Wenkai Li, Diego Herrera, Marta Garcia, Deborah Mascalzoni, Veronica Popa, Daniela Quaggia, Paul Quinn, Jean Sposaro, David Leventhal, Paula Boyles and Johanna Blom, on behalf of the FACILITATE Consortium

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.

The return of Individual Participant Data in clinical trial research: FACILITATE White Paper Executive Summary

Ciara Staunton (UNIMORE), Cris Woolston (SARD), Wenkai Li (VUB), Diego Herrera (ALM), Marta Garcia (SERV), Deborah Mascalzoni (EURAC), Veronica Popa (EURORDIS), Daniela Quaggia (ACN), Paul Quinn (VUB), Jean Sposaro (BMS), David Leventhal (PFZ), Paula Boyles (PFZ) and Johanna Blom (UNIMORE, FACILITATE Coordinator), on behalf of the FACILITATE Consortium

Published by: FACILITATE Consortium

FACILITATE 2025

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

FACILITATE CONSORTIUM

- Università Degli Studi Di Modena e Reggio Emilia (UNIMORE), Via Università 4, Modena 41121, Italy
- Vrije Universiteit Brussel (VUB), Pleinlaan 2, Brussel 1050, Belgium
- Tampereen Korkeakoulusaatio Sr (TUNI), Kalevantie 4, Tampere 33100, Finland
- Stichting Eupati Foundation (EUPATI), Daltonlaan 600, Utrecht 3584 BK, Netherlands
- Associazione Cittadinanzattiva Onlus (ACN), Via Cereate 6, ROMA 00183, Italy
- Privanova Sas (PN), established in 34 Avenue des Champs-Elysées, PARIS 75008, France,
- Odysseus Data Services Sro (ODY), Pobrezni 249/46 Karlin, Praha 186 00, Czech Republic
- Privredno Drustvo Zentrix Lab (ZEN), Aksentija Maksimovica 3, Pancevo 26000, Serbia
- Inpeco SA (INPECO), VIA Torraccia 26, Novazzano 6883, Switzerland
- Adera SAS (BPE), Av Du Docteur Albert Schweitzer 162, Pessac 33600, France
- Azienda Ospedaliera Universitaria Policlinico Di Modena (AOU), Via Del Pozzo 71, Modena 41124, Italy
- Medizinische Universitat Graz (MUG), Auenbruggerplatz 2, Graz 8036, Austria
- Uniwersytet Jagiellonski (UJ), Ul. Golebia 24, Krakow 31007, Poland
- Institut Za Medicinska Istra Ivanja (IMR), Dr Subotica 4 Prizemlje, Belgrade 11129, Serbia
- Spitalul Clinic Colentina Bucuresti (SCC), Soseaua Stefan Cel Mare 19-21 Sector 2, Bucuresti 020125, Romania,
- St Antonius Hospital Gronau Gmbh (PZNW), Mollenweg 22, Gronau 48599, Germany
- Accademia Europea Di Bolzano (EURAC), Viale Druso 1, Bolzano 39100, Italy, VAT number: IT01659400210,
- Eurordis - European Organisation For Rare Diseases Association (EURORDIS), Rue Didot 96, Paris 75014, France
- Sanofi-Aventis Recherche & Developpement (SARD), 82 Avenue Raspail, Gentilly, 94250, France

- Mdsol Europe Ltd (MDSOL), 12 Hammersmith Grove, London W6 7AP, United Kingdom
- Abbvie INC (ABV), North Waukegan Road 1, North Chicago Il 60064, United States
- Astrazeneca AB (AZ), Vastra Maelarhamnen, Sodertaelje 151 85, Sweden
- Bayer Aktiengesellschaft (BAY), Kaiser-Wilhelm-Allee 1, Leverkusen 51373, Germany
- Pfizer Limited (PFZ), Ramsgate Road, Sandwich CT13 9NJ, United Kingdom
- Takeda Pharmaceuticals International Ag (TAK), Thurgauerstrasse 130, Glattpark 8152, Switzerland
- Almirall SA (ALM), General Mitre 151, Barcelona 08022, Spain
- Institut De Recherches Servier (SERV), 3 Rue de la Republique, SURESNES 92150, France
- Accademia del paziente esperto (EUPATI), Via Pietro De Francisci, 36, 00165 Rome, Italy
- Bristol Myers Squibb Corporate (BMS) Route 206 & Province Line Road
- Princeton, New Jersey 08543, USA
- F. Hoffmann-La Roche Ltd (Roche) Grenzacherstrasse 124 4058 Basel Switzerland
- Glaxosmithkline Research & Development Limited (GSK), 79 New Oxford Street, London WC1A 1DG, UK

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

INTRODUCTION

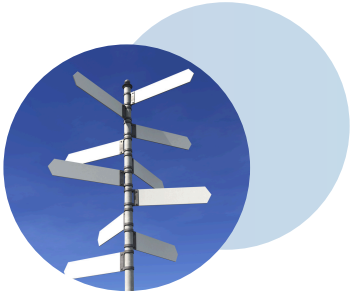
The FACILITATE project seeks to address the ethical and legal challenges surrounding the return of individual participant data (RoIPD) from clinical trials to participants aged 18 and older within the European Union (EU). Although there is growing recognition of the potential of RoIPD to empower participants, enhance healthcare decision-making, and build trust in research, its implementation remains rare. This is largely due to unclear responsibilities, limited infrastructure, and the absence of clear legal or regulatory guidance. Critically, RoIPD is not yet integrated into the design of most clinical trials. FACILITATE aims to change this by establishing a clear, ethical, and practical framework that supports the routine incorporation of RoIPD into trial planning and conduct.

FACILITATE'S ROIPD APPROACH

FACILITATE's RoIPD framework is underpinned by three key features:

1. Participant-Centric Design: Participants are positioned as active and equal partners in the research process. This model promotes shared decision-making, transparency, and respect for autonomy by aligning clinical trials with participants' needs, preferences, and expectations.

2. RoIPD by Design: RoIPD should be incorporated into the trial lifecycle, including protocol design, consent, and post-trial communication, rather than treated as an afterthought.



3. Flexibility: Clinical trials differ vastly in design, scope, and legal context. FACILITATE offers guidance, not a rigid protocol, allowing sponsors to adapt RoIPD processes to their specific needs and resources.

LEGAL AND REGULATORY CONTEXT

FACILITATE acknowledges that there is currently no legal mandate for RoIPD under the EU Clinical Trials Regulation (CTR) or General Data Protection Regulation (GDPR). While RoIPD shares similarities with the GDPR's right of access, it is operationally distinct: RoIPD is sponsor-initiated, not participant-requested. Due to this regulatory uncertainty, FACILITATE recommends **consent as the legal basis** for RoIPD under both Article 6(1)(a) and Article 9(2)(a) of the GDPR.

FACILITATE recommends consent to be the lawful basis for RoIPD

ETHICAL FRAMEWORK

Ethical framework builds upon core substantive principles and procedural values

In the absence of binding legal rules, FACILITATE has developed an ethical framework that builds upon **foundational ethical principles**. Core substantive principles include rights and respect for individuals and wider society, beneficence, non-maleficence, privacy and confidentiality, utility, empowerment, data custodianship, justice, and public value. Procedural values such as transparency and accountability guide implementation.

OPERATIONALISING ROIPD

To support implementation, FACILITATE outlines steps for sponsors to consider:

- **Co-creation of protocols for RoIPD**: The co-creation of RoIPD protocols, particularly with investigators and patient groups, are strongly encouraged as a means to enhance transparency, participant agency, and ethical alignment without compromising trial integrity.
- **Consent**: RoIPD must be clearly explained during trial enrolment and should be ongoing, informed, and adaptable to digital or in-person modalities.
- **Roles and Training**: The protocol should clearly articulate the roles of all parties involved, including sponsors, investigators, participant representatives. ethics committees, data managers.
- **Timing of data return**: 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.
- **Data to be returned**: The protocol should define the data to be returned and data that will not be returned.
- **Adherence to Ethical and Legal Standards**: All processes should align with ethical and legal requirements, including GDPR, national laws, and ICH GCP, to protect participant privacy and ensure data security, quality, and integrity.
- **Contracts with sites**: To ensure the operationalisation of RoIPD, study site contracts will need to explicitly reflect the additional responsibilities and resource needs involved.
- **Training and Support Systems**: Comprehensive training should be provided 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.

- **Shared knowledge building:** The RoIPD process should be evaluated for effectiveness and improvements, with findings shared publicly where possible to support a community of practice.

- **Privacy Notices:** Where RoIPD is managed via digital platforms, tailored and accessible privacy notices must be provided, detailing data processing, retention, rights, and access.

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. FACILITATE considers the following to be pertinent during the consent process:

- **Health literacy:** Health literacy, the ability of participants to understand and act on health information, is critical to RoIPD and should be supported through tailored tools (e.g. glossaries, multimedia aids), delivered in accessible language, and adapted to individual needs and circumstances, recognising that both provider and participant factors (such as stress, education, or language) influence comprehension.

- **Skills and knowledge for those discussing RoIPD with participants:** Discussions on RoIPD, including its timing, method (via platform, person, or both), and content, should be led by individuals with the appropriate skills to support health literacy, manage emotional responses, and ensure informed decision-making. FACILITATE emphasises competence over profession and recommends the involvement of healthcare professionals where clinical interpretation is needed.

- **Data returned via an online interface**: Data may be returned during 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.

- **Responsibilities of participants**: Participants are to be reminded that they are responsible for keeping their contact information up to date on the designated tool to ensure continued access to their clinical trial data

- **Rights under GDPR**: RoIPD does not override participants' existing rights under the GDPR, which remain fully intact.

- **Who will have access to the data**: Participants must be clearly informed that their data will not be shared with third parties, beyond those managing the trial.

- **How personal data will be protected**: Participants should be assured that appropriate safeguards, such as pseudonymisation, will be used to protect their personal data.

- **Withdrawal of consent**: Participants can withdraw their consent to RoIPD at any time without affecting their trial participation or GDPR rights, but they will no longer receive returned data.

- **Compliance with national law**: RoIPD processes, including data storage and retention, must comply with the applicable national legal requirements.

- **Signing of ICF**: Participants must be given the opportunity to ask questions and should only sign the informed consent form if they agree to receive their clinical trial data.

- **Changes to RoIPD processes**: If there are any significant changes to the RoIPD processes, participants will need to be informed about these changes and potentially reconsent.

- **Guidance on text to be included in privacy notices:** A privacy notice must clearly explain how participants' personal data will be processed when using an online platform for RoIPD.

CONCLUSION

FACILITATE calls for a shift in clinical trial culture to make RoIPD routine, ethical, and participant-centred. By embedding RoIPD into trial design, and grounding it in both legal and ethical standards, FACILITATE envisions a clinical research landscape that respects participant rights, enhances transparency, and fosters long-term public trust.

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.