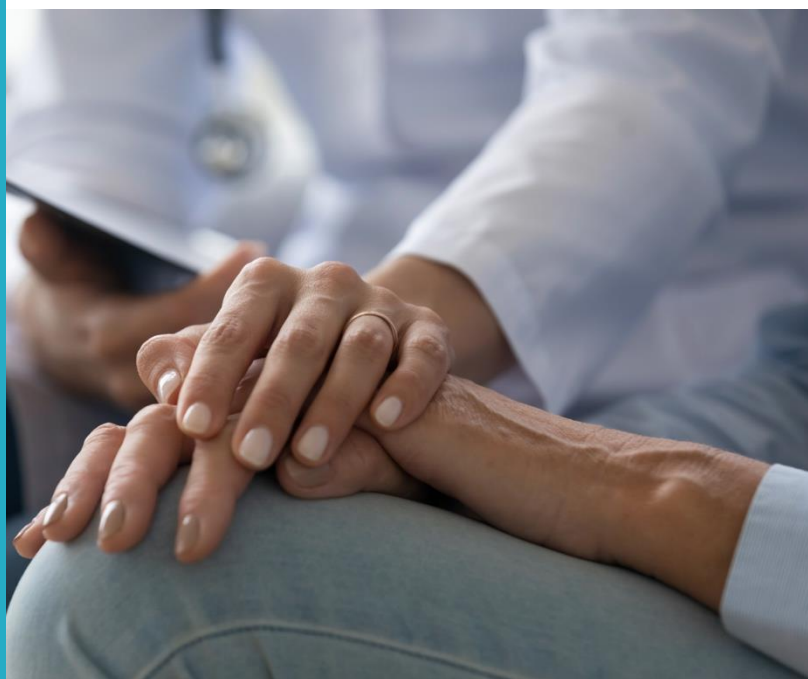




Year 2 | Issue 2  
June 2023

# let's FACILITATE



A project built  
on a patient-  
centered,  
data-driven,  
technological  
platform

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## ●●● Towards the second phase

FACILITATE is growing as a collaborative consortium and laying the groundwork for the new phase of the project with more tangible outputs. So far, it has been a great cooperative effort towards the definition of pragmatic use cases and legal-ethical frameworks, on which to build the platform for returning clinical trial data to the patient and for their secondary use.

In this regard, some important achievements have been reached on March by the BEST (Brainstorm, Express, Sort out and Translate) Working Group (WG), a transversal short-lived experts' team from different working packages, which has been set up to design various scenarios for individual return and reuse of clinical trial data, helping to demarcate FACILITATE.

The Semi-Annual Meeting held in Paris on 8 and 9 June provided an opportunity to make a step forward important goal. After a big effort and an in-depth exchange with other working packages, WP3 researchers keep on working on a report on use cases for FACILITATE development, to be submitted to IMI/IHI at the end of June at earliest. This document constitutes the basis for WP4 and WP5 groups to develop the platform architecture and the technological framework.

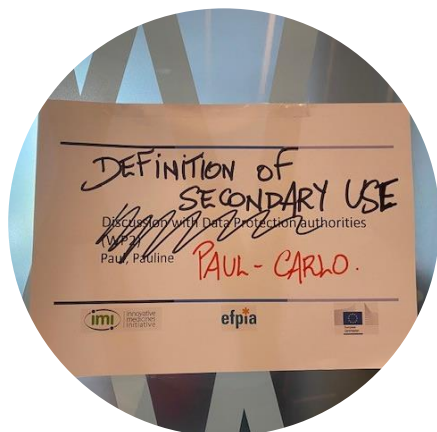
Regarding the definition of the ethical framework upon which the project is based in conjunction with the legal framework, the two days of rich and engaged discussion at the face-to-face meeting in Bolzano in March brought to an agreement on some components critical to implementing ethical processes on the return of clinical trial data to patients and their secondary use. A deliverable on the development of the ethical solutions is now at its final version, highly aligned with legal requirements and prioritizing the centrality, privacy, and autonomy of patients.

An even closer collaboration and alignment between partners will characterize the next phase of the project, with the aim of reaching a realistic and pragmatic agreement on the final passages on which to build the technological platform. The last FACILITATE meeting in Paris contributed to a first step in this direction.

Véronique Poinot and Johanna Blom



## ●●● FACILITATE meets in Paris



On June 8 and 9 the Semi-Annual Meeting 2023 of FACILITATE took place in Paris, nearly one and a half year since the virtual kick off. It was a successful roundup focusing on interactive work meetings in smaller groups and complemented by plenary sessions.

FACILITATE hosted a hybrid event with more than 50 participants from public and private partners. The meeting was chaired by Véronique Poinot (Sanofi), Prof. Johanna Blom (Modena and Reggio Emilia University) and Philippe Bordes (Sanofi). The two days meeting focused on the ethical, legal, and operational challenges posed for clinical trial data return to participant and the secondary use of these data.

Sylvain Nicolas (Sanofi Head of Clinical and Sciences Operations) introduced the meeting with his view on the importance of such initiative for patients and for industry, describing changes that occur on patients' life with digital help and specifically in clinical trials. He focused on decentralization and digital biomarkers as examples with still high variability across EU countries.

### Plenary sessions

Plenary sessions were organized to display information on key areas for clinical trials.

- The patient perspective was presented and discussed as it drives the vision of the consortium and the ongoing consultations process through the Patient Expert Group (DAG+), including 20 persons.
- The clinical trial data workflow was examined, highlighting the importance of a high-quality process using CDISC standards and other up to the data submission to the health authorities.
- The federated data model was developed to review challenges and opportunities that the project can benefit.
- Clinical data return initiative under TransCelerate initiative was presented to the team, crystalizing the importance of bridging both projects.
- Pfizer shared with us the program they are launching at the end of the month in the US on returning clinical trial data to participants, an experience that represents a good process to build upon and enrich with the variety of FACILITATE partners (patients' organizations, medical research centers, digital companies, and pharmaceutical companies).



## Breakouts sessions

Breakouts sessions were set up to facilitate interactions between all actors. They allowed to confront points of view and push boundaries related to legal, ethical and operationalization for clinical trials data return and secondary use of data.

This was also the time to test the ethical framework proposed by WP3 in use cases sessions inspired by real cases encountered. On each session one leader explained the objectives, the approach, the use case, and the methodology to discuss the process and workflow suggested by WP3. The leader was supplemented by a facilitator who helped the moderation of the session. At the end of each session all the contributions from each group were restituted to all partners.

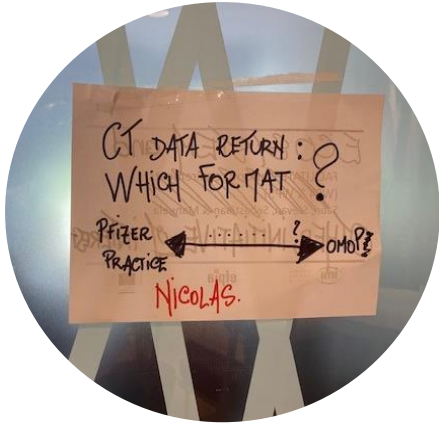
## Project Sustainability

The Sustainability Working Group's overall aim is to come up with a plan for how the outputs from FACILITATE can be sustained after the project ends, presenting the first vision of the plan.

## Communication

The communication team reviewed the Glossary for patient initiative, aiming to provide a list of key-terms for patients through a dedicated page on FACILITATE website, with an understandable, simple, and not technical content.

At the end of all these sessions the team gained clarity on ethical, legal, and operational challenges and get back to work to enrich drafted documents to propose an adaptative process which could benefit patients.



## ●●● Where we are

### FACILITATing the legal and ethical use of data

FACILITATE is working to develop a person-centric trusted legal and ethical ecosystem to sustain the return of clinical trial data and their secondary use for scientific research. The challenge is to define the rules to be followed for data sharing that complies with existing regulations. In this regard, the balancing must be done from a perspective that put the patient at the centre of the process with the necessary close collaboration and alignment of legal and ethical groups, aiming to achieve the same goal although moving from different bases.

### The legal perspective

FACILITATE aims at enabling clinical trial participants to access and use the collected health data and to allow the data to be returned to the patient and reused in future research, within an approved ethical framework in compliance with European and national regulations. In the context of this project, the role of WP2 aims to define the legal framework and rules that move its goals, also to guide the other dimensions of the project, especially the technical ones.

### Defining the rules for data sharing

Our first challenge is to define the rules to be followed for data sharing that complies with existing regulations. It must be emphasized that the context is characterized by the coexistence of the legislation on the protection and processing of personal data posed by the GDPR (General Data Protection Regulation, 2016/679) with that of the CTR (Clinical Trial Regulations) 536/2014, which specifically regulates clinical trials. In addition, intellectual property and regulations related to data exist.

The texts are not intended to protect the same interest's articulation, so the articulation of regulations can be challenging. Secondly, in transposing these regulations, each State has adopted similar but not identical solutions. WP2 analysed these solutions also through the development of questionnaires, from which legislative fragmentation emerged to complicate matters.

*The right balance of interests among the parties involved must be found, focusing on the patient, who must have the main role, while respecting the needs of stakeholders and sponsors*



## Assessing the meaning of secondary use

While the rules governing the primary use of data collected as part of a clinical trial are clearly defined in the legal texts, the same cannot be said for the secondary use of data, which is not always allowed (or only allowed for certain data or in certain circumstances) and, moreover, is not precisely defined by regulations.

The second challenge, then, will be to define what secondary use is, so that the appropriate legal provisions can be applied. On this basis, the further challenge is to suggest appropriate governance to ensure that data can be shared at the right time and in the right way, with the right communication to study participants, discussing with data protection authorities' data protection to find the best solutions to achieve the correct balance of interests among the parties involved. The balancing must be done from a patient-centric perspective with the necessary close collaboration and alignment of legal and ethical groups that, although moving from different bases, aim to achieve the same goal.

In this regard, a common glossary is being created to highlight how the same terms can take on different legal and ethical meanings, and a dynamic informed consent model will be constructed that can enable both the sharing and reuse of data while preserving the interests of scientific research and, at the same time, protecting patients' rights.

## The ethical perspective

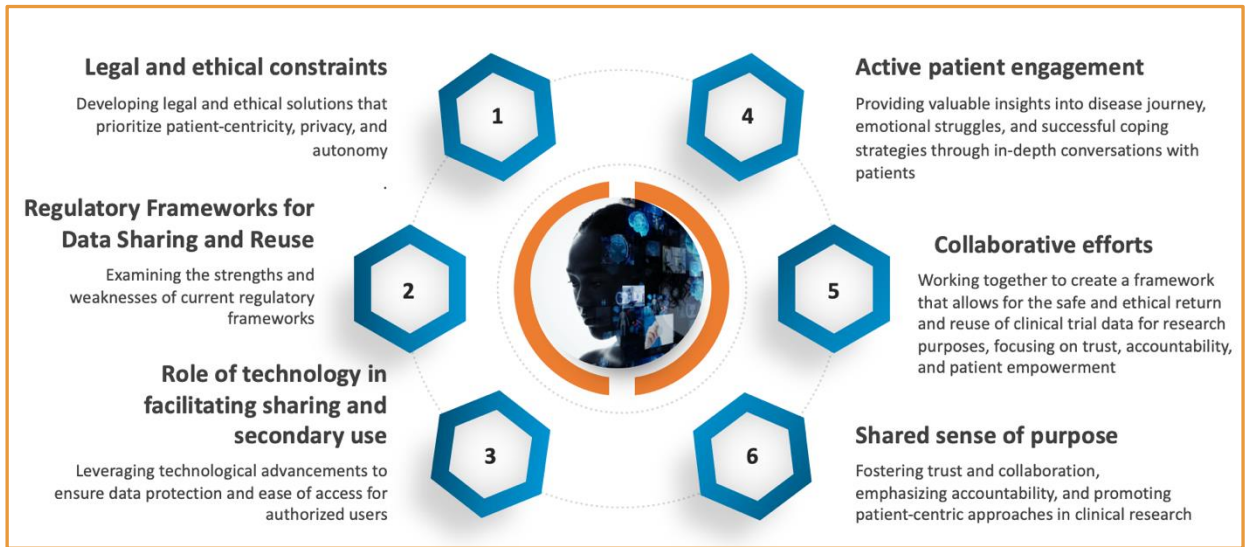
The law sets out the minimum standards expected in the use of clinical trial data but FACILITATE wants to go beyond them and ensure that the processes meet the expectations of patients and follow ethical best practice. To achieve this, WP3 is developing two ethical frameworks (the ethical framework on return of clinical trial data and the one on the secondary use of clinical trial data for scientific research).

## A novel approach in the return and secondary use of data

FACILITATE was not conceptualised or initiated in a vacuum. Rather, it builds on the groundwork of other projects, ethical frameworks, regulations, guidelines, empirical research, and published conceptual analyses. This forgoing work has served as the basis for the development of FACILITATE's ethical frameworks, but what is novel about our project is the person-centric approach in the return of clinical trial data and their secondary use (Figure 1). It is this approach that serves as our starting point for the processes to be developed as part of the project, including the ethical frameworks. Processes will need to give control to the extent possible to participants in decisions on return of clinical trial data and secondary use of data.



**Figure 1.** The FACILITATE person-centric approach in the return of clinical trial data and their secondary use.



Equally, the methodology of reflective equilibrium, that follows the path of reflection, discussion, and revision to reach a conclusion, is important as it mirrors the co-creation approach that is central to the work of FACILITATE. Ongoing consultation is therefore a key feature of the developing ethical frameworks, with regular consultative discussions within WP3 researchers, project members and stakeholders.

### Methodology at a glance

As a first step, we sought to identify the ethical principles that should guide our ethical frameworks. Key legal and ethical frameworks that relate to the return of clinical trial data and the secondary use of clinical trial data were analysed and principles identified (Table 1). These principles and their meaning were revised through a process of discussions within WP3 and amongst all partners in the consortium.

### From theory to practice

The next stage of the process concentrated on implementing these principles into practice to develop an ethical process for the return of clinical trial data and the secondary use of clinical trial data. The processes to implement these ethical principles were identified in part through a literature review that looked in particular at empirical research that

**Table 1.** Principles guiding the ethical framework on the return of clinical trial data (A) and on the secondary use of clinical trial data for scientific research (B)

A	B
Respect for persons and communities	Rights and respect of individuals
Beneficence	Privacy
Non-maleficence	Data custodianship
Privacy	Non-maleficence
Utility	Trustworthiness
Empowerment	Transparency
Public value	Accountability
Data custodianship	Empowerment
Justice	Legitimacy
Transparency	
Accountability	

reported on patient views and other stakeholders and also the empirical work conducted as part of WP3.

This is to ensure that our ethical frameworks are rooted in public preferences. For the return of clinical trial data, the discussions to date have focused on when to return what data, by whom, what data can be returned directly to a participant, and patient control. For the secondary use of clinical trial data for research, discussions have focused on the role and form of consent, when research ethics committee (REC) approval is needed, the criteria to determine access for secondary use, the need for independent oversight, and patient control.

Maria Francesca Serra and Ciara Staunton,  
on behalf of WP2 and WP3 researchers





## ● ● ● Focus on

### Pfizer's strategy on return of clinical trial data

On April 25, 2023 David Leventhal from Pfizer, one of our EFPIA partner companies with a strong commitment to health equity, gave an interesting overview of a return of clinical trial data strategy designed to empower patients to make more healthcare decisions and optimize their adherence to trial experience over time.

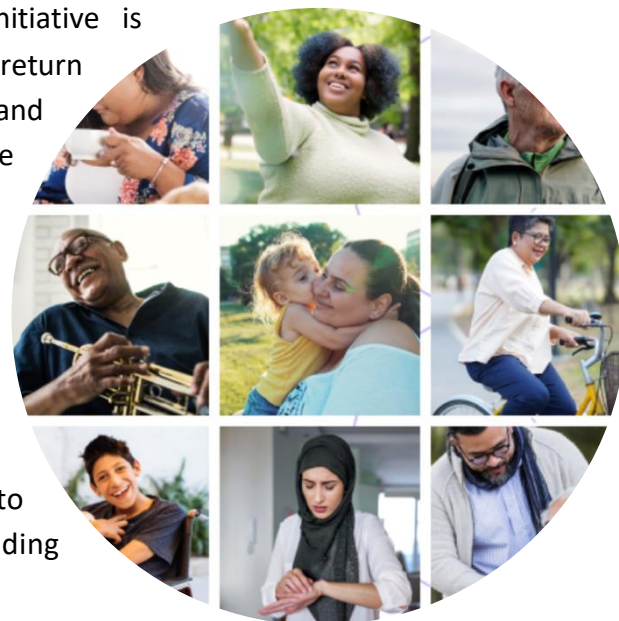
*Clinical trial participants have demanded the ability to access, visualize and share their data, and clinical researchers have a responsibility to provide more transparency and engagement with participants.*

Pfizer is working at building a robust and scalable data return solution with the objective to fulfill its social contract with participants by enabling response to any data requests and allowing patients to opt-in to data return. The main objective is to empower participants to make more informed healthcare decisions by providing necessary context to their clinical trial data and facilitate continued care beyond trial. The maintenance of the engagement with patients will improve trial experience and will optimize trial adherence and retention.

Pfizer's participant data return program purpose is based on trust, to make trials more patient-centric. The goal is to establish industry best practices for health information exchange and sharing. How? Designing a digital data return capability that allows patients to securely access individual clinical trial data in various formats to influence other industry initiatives for participants data return.

Pfizer Participant Data Return Initiative is enabling and scaling an end of trial return solution that is meaningful and contextualized, while respecting the scientific integrity of the trial.

Since 2015, Pfizer has been providing an opt-in website ([Pfizer Clinical trial Alumni](#)) that helps clinical trial participants stay connected with their study and find information and resources related to the study or their condition, including aggregate and individual data.



## Almirall presents the basics of data standardization

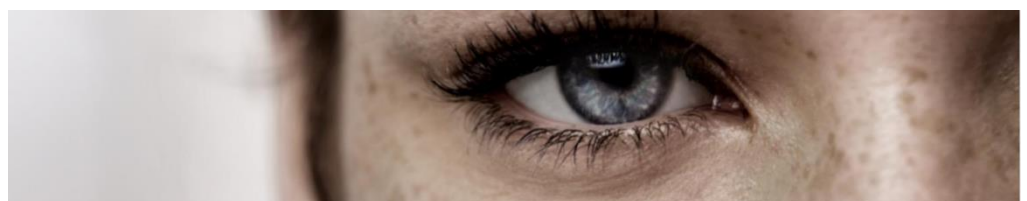
On May 5, 2023 Diego Herrera, from Almirall one of our EFPIA partner highly committed in health data sharing and reuse, gave us an interesting presentation on the basics of data standardization, allowing efficient review of the dossiers submitted to Health Authorities for market authorization.

Clinical Trials have a long and lively history. Since the 1990's, the efforts were focused on defining some standard modules to collect data (CDASH), and structure data into standardized datasets (SDTM), and define some derivation rules to analyze the data (ADAM). The standardization uses some codification for laboratory tests or adverse events. The domains - very stable - are now about 160 and some new domains are in progress (for example, biomarkers).

Diego Herrera presented an overview on CDISC (Clinical Data Interchange Standards Consortium), a global not-for-profit organization that actively develops data standards with the collective knowledge and experience of volunteers within the pharmaceutical industry. CDISC creates and communicates standards that support acquisition, exchange, submission and archive of data for medical and biopharmaceutical product development. The consortium works in tandem/collaboration with global agencies to develop guidelines and requirements that influence the standards for both clinical and nonclinical data

Implementation of CDISC standards can decrease timelines and costs during drug development by expediting the regulatory processes, leading to a faster marketing authorization. CDISC standards reduce the amount of time FDA reviewers spend on data review and allows them to spend more time on the science of drug development. When CDISC data standards are implemented, high quality, interpretable data can be exchanged easily and efficiently between CROs, Sponsors and Regulatory Agencies.

You can find direct resources from CDISC at the link <https://www.cdisc.org/>



## ●●● From the world

FACILITATE members are present at conferences and meetings in Europe and across the world to provide their perspective on clinical trial issues and new technologies for data sharing and reuse. Here are some of the main events FACILITATE has participated in the last four months.

### FACILITATE at the Rare Disease Day in Greece

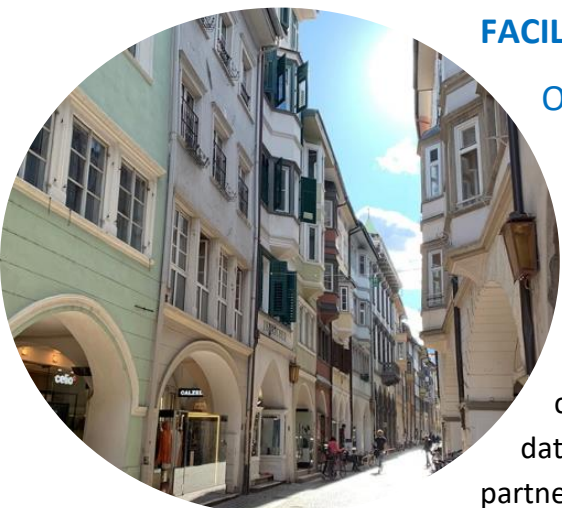
On March 1, 2023, Prof. Johanna Blom has been invited to present the FACILITATE project and its challenges at the [3<sup>rd</sup> International Conference on Rare Diseases: Greek Chapter 2023](#), Athens, in the Session “Flash Updates of RD Flagship Initiatives”.

The conference focused on the theme: “Leveraging momentum for a comprehensive rare disease strategy”, with the goal to raise awareness and promote policies aimed at improving the “diagnostic odyssey”, treatment and equal access of rare patients to quality health services.

The central themes of FACILITATE - the return of clinical trial data to the patient and the secondary use of these data in an ethical ecosystem – and the architecture of the project, its mission and ambition have been presented to participants. The belief is that they fully integrate with highly topical issues discussed at conference, such as policy landscape on rare diseases, regulatory ecosystem evolution, research, clinical trials as part of the care, patient data and real-world evidence, supporting education for patients and healthcare professionals.

The Conference was under the auspices of the European Organization for Rare Diseases (EURORDIS - Rare Diseases Europe), while it has been held with the support of the Hellenic Ministry of Health, the European Federation of Pharmaceutical Industries and Associations (EFPIA), the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), the Greek Patients’ Association (EAE), Greek Branch of the European Patients’ Academy (EUPATI Greece), the Institute of Pharmaceutical Research and Technology (IFET), the Hellenic Association of Pharmaceutical Companies (SFEE) and the PhRMA Innovation Forum (PIF).





## FACILITATE workshop on developing ethical frameworks

On March 15 and 16, 2023, the leaders of WP3 held a meeting with partners at EURAC Research, Bolzano (Italy) to discuss key elements of the ethical frameworks on return of clinical trial data and on their secondary use in scientific research.

The goal of the discussion was to reach agreement on the components critical to implementing ethical processes on the return of clinical trial data to patients and their secondary use. In advance of the meeting, all partners submitted detailed feedback on the current draft ethical frameworks, that was analyzed by WP3 leaders and formed the basis of the discussions at the meeting.

The meeting opened with Prof. Johanna Blom, Deputy coordinator of the FACILITATE project, reminding about the aims and objectives of FACILITATE and the importance of a person-centered approach to achieving our aims. Dr. Deborah Mascalon provided a background to legal and ethical policies and guidelines, empirical work, literature as well as previous projects and consortium that have informed and influenced FACILITATE's developing ethical frameworks. All participants individually spoke about what they considered to be an essential component that might be included in the developing ethical frameworks. Over the 2 days, partners agreed on certain key points:

- transparent and accountable processes that detail roles and responsibilities of key individuals in the decision-making process but also provide clear, transparent, and ongoing information to participants are essential;
- informed consent is a process and study participants should be approached as early as possible in the clinical trial to discuss the use of their clinical trial data for secondary research. This consent should be followed up again before the end of the clinical trial;
- as part of this consent process, study participants should be afforded with the opportunity to opt-out of any research projects;
- to ensure transparency, study participants should be notified of the use of their clinical trial data in research;
- finally, notification, opt-out and changes to consent preferences should be managed through a participant information and decision platform.

Following these 2 days of rich and engaged discussion, WP3 is revising the ethical frameworks before starting its next stage of engagement.





## TransCelerate and FACILITATE at work to set synergies

On March 21, 2023, in Basel, Switzerland, the [TransCelerate project](#) co-hosted a workshop with [EFPIA - European Federation of Pharmaceutical Industries and Associations](#) to collaborate on modernizing clinical trials and preclinical research while maximizing impact.

The workshop was the opportunity to raise the need to set robust and simple mechanism to exchange some contents between TransCelerate and IMI projects. For example, IMI-FACILITATE and TransCelerate Participant Data Return or Privacy Methodology have common interests.

For the TransCelerate project, participant data return is focused on the development of pragmatic resources to enable sponsors' return of meaningful individual data to clinical trial participants who opt-in to receive it and building trust in the research enterprise by enabling access to an individual's data for their personal care. FACILITATE, taking a broader angle on legal and ethical frameworks based on trust and with patient needs at its core, would make the exchange a win-win scenario.

Waiting for a formal agreement and bridge between the TransCelerate and FACILITATE initiatives to leverage work already done from both parts public materials can be consulted. Material publicly available here: [Participant Data Return - TransCelerate \(transceleratebiopharmainc.com\)](https://transceleratebiopharmainc.com)

The workshop was a true moment of open and trustful exchanges, looking for synergy between IMI-FACILITATE and TransCelerate projects, and paving the road to a full complementary articulation between the organizations, eventually, for the benefit of patients.





## Health data sharing: challenges in an interconnected society

On April 26, 2023, the Health & Ageing Law Lab (HALL) of Vrije Universiteit Brussel (VUB) hosted FACILITATE its successful inaugural [Health, Law and Technology \(HELT\) symposium in Brussels](#).

The symposium aimed to explore the challenges and impacts of the European Health Data Space (EHDS), the first sectorial legislation proposal for data governance in the EU, with a central theme of health data sharing in an interconnected society. The event brought together experts from various fields, including academics, policymakers, industry, healthcare professionals, scientific researchers, data subjects and NGO representatives, resulting in insightful discussions and interactions.

In the panel centered on EHDS and interoperability of health data Sebastiaan van Sandijk, from the FACILITATE partner Odysseus Data Services, discussed with other experts how AI and other technologies not just benefit from standardization and improved interoperability of health data but also can help improve the quality and reusability of these data, which is essential both for healthcare delivery and research. Other topics presented during the day included a 'standard health consent' proposal for data generated in health and wellness apps, sensor technologies and wearables and an approach to introduce fairness of data usage and individual priorities and values into secondary use practices.

In the panel focused on the EHDS and the secondary use of health data for scientific research, the Deputy coordinator of the FACILITATE project, Prof. Johanna Blom, explored how FACILITATE could contribute to advancing participatory clinical research. Prof. Blom underlined how a substantial volume of health data is generated daily, which remains isolated and underutilized beyond the primary clinical trial due to existing ethical, legal, and technical challenges. Integrating data protection regulations, ethical standards, and advanced technology can lead to a harmonized approach to clinical research, benefiting patients and participants involved in CTs as well as the scientific community and public health.

The role of FACILITATE is to shuttle data to actionable information, through GDPR compliant processes embedded in ethical principles, respecting participants rights, meeting the needs of all stakeholders involved in the healthcare ecosystem. It's a journey towards a more ethical, person-centric, and efficient data-driven future for CTs and data management.



## Striking a balance on good governance

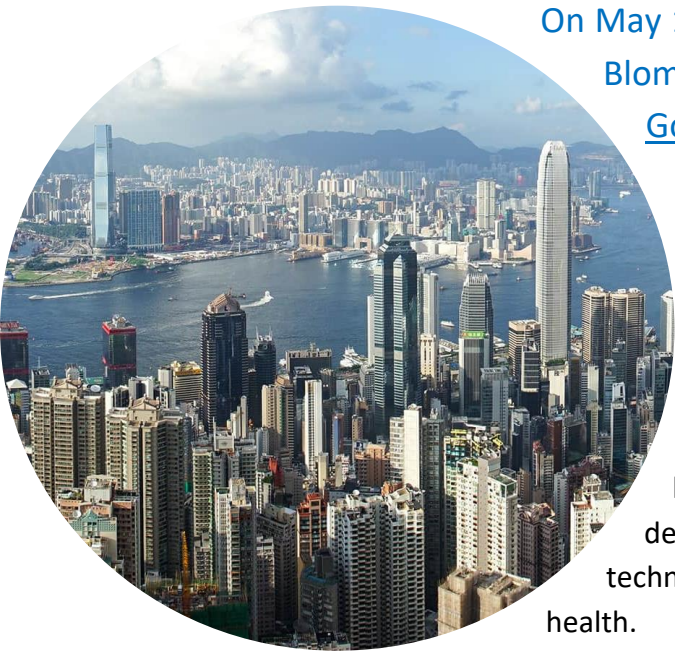
On May 10, 2023, FACILITATE was presented by Prof. Johanna Blom, Deputy coordinator of the FACILITATE project, at the [Governance of Medical AI Conference](#) in Hong Kong (9-11 May) organized by the Centre for Medical Ethics and Law (CMEL).

CMEL develops new ideas and solutions in response to the big ethical, legal and policy questions of medicine and health, bringing together bioethicists, academic lawyers, medical scientists, and other scholars to conduct cutting edge bioethical and legal research and contribute to policy development in flagship areas like digital health and emergent technologies, mental health and capacity, and population and global health.

The central theme of the conference was the regulatory governance of medical devices with machine learning/artificial intelligence capabilities and related application in genomic medicine given that they are becoming increasingly risk-based, context-specific, case-sensitive, decentralized, collaborative, and - in terms of its epistemic constituents - pluralistic. With focus on governance policies of the National Medical Products Administration of China, the European Medicines Agency and the US Food & Drug Administration, this international conference considered regulatory and ethical challenges for developers and users operating within the architecture of the Internet of Medical Things.

Topics ranged from Trends in Medical AI Governance and Medical AI and Data Governance to Collaboration and Participation in Ethical Governance. FACILITATE was present in that it represents an innovative approach to governance of the return of clinical trial data and the reuse of clinical trial data for future research purposes.

Prof. Blom stressed that within this context an important challenge is capturing the dynamic interaction among various values, characteristics, and principles adhered to by the various stakeholders as well as by the quality of relationships among the stakeholders, both at the start, during, and after the clinical trial. If participants, physicians, and sponsors collectively agree that decisions are consistently made with accountability and transparency, while accounting for values such fairness, adherence to standards, and justice, then it means that a context of transparency and trust has been created.



## ●●● Happened

**March 1, 2023** Prof. Johanna Blom - FACILITATE Deputy Coordinator - participated as a speaker at the [3<sup>rd</sup> International Conference on Rare Diseases: Greek Chapter, 2023](#), Athens in the Session “Flash Updates of RD Flagship Initiatives”.

**March 6-7, 2023** Privanova participated as a panellist in the fourth intersessional consultation of the Ad Hoc Committee to be held in Vienna, Austria, using this opportunity to disseminate the efforts done in FACILITATE.

**March 15-16, 2023** Eurac Research hosted a face-to-face meeting in Bolzano to discuss the two ethical frameworks that WP3 is developing for the return of clinical trial data and for the secondary use of data.

**March 21, 2023** The [TransCelerate project](#) co-hosted a workshop with [EFPIA - European Federation of Pharmaceutical Industries and Associations](#) in Basel, Switzerland, to collaborate on modernizing clinical trials and preclinical research while maximizing impact.

**April 26, 2023** The Health & Ageing Law Lab (HALL) of Vrije Universiteit Brussel successfully hosted its inaugural [Health, Law and Technology \(HELT\) Symposium](#) in Brussels. Deputy coordinator of the FACILITATE project, Prof. Johanna Blom, presented the FACILITATE and its relevance to the EHDS regarding the secondary use of health data for scientific research. Sebastiaan van Sandijk, from Odyssey Services, provided his expert insight regarding the interoperability of health data.

**May 2, 2023** The MRCT (Multi-Regional Clinical Trials) Center of Brigham and Women's Hospital and Harvard held a [webinar](#) this week on returning individual research results and data to participants experience from the field

**May 10, 2023** FACILITATE was present at the Medical AI and Data Governance, with Focus on Genomics hosted at the [Governance of Medical AI Conference in Hong Kong](#) (9-10 May) Invited speakers: Dr. Deborah Mascalzoni, Uppsala University/EURAC Research, Prof. Johanna Blom, University of Modena and Ciara Staunton, EURAC Research

**May 20, 2023** EUPATI-Portugal marked the [International Day of Clinical Trials](#) with a face-to-face event dedicated to the theme: “Space for Health Data”. Among the Invited speakers, [Ana Vieira](#), one of the expert patients involved





and consulted in FACILITATE, shared the project and the importance of return of individual clinical studies data.

**June 8-9, 2023** SANOFI hosted a Semi-annual face-to-face and online meeting in Le Campus Gentilly, 82 avenue Raspail, 94 255 Gentilly Cedex

**June 12-13, 2023** [The 7th annual European Patients as Partners in Clinical Research Conference](#) was back in person.

**June 13-15, 2023** The [Patient Engagement Open Forum \(PEOF\)](#), a patient engagement community throughout the year with virtual and in-person events, promoted an in-person event which could be of interest for FACILITATE interactions with patients

**June 25-29, 2023** The [DIA 2023 Global Annual Meeting ILLUMINATE](#) has been host in Boston industry, regulatory government, academics, and patients to network, problem-solve, and discuss global and local challenges facing the life sciences community. FACILITATE participated in a joint panel on Data Return and Secondary Use for a dialogue on this topic with IMI/IHI, MRCT and TransCelerate

## ●●● Join the event, watch the MRCT webinar!

### Returning individual research results and data to participants: experience from the field



The MRCT (Multi-Regional Clinical Trials) Center of Brigham and Women's Hospital and Harvard held a webinar on returning individual research results and data to participants experience from the field

Since the updated Individual Return of Results toolkit was released last year, the MRCT Center has continued collaborating with leaders from academia, patient advocacy groups, and industry to create a series of case studies. These cases detailed the experiences of 5 organizations planning and implementing procedures to return individual research results and data to participants, highlighting ethical, scientific, operational, regulatory, and technical considerations that should be considered.

Click here [to watch the webinar](#) and [Related Resources](#)



## Save the date

Do not miss next FACILITATE meetings and events of interest. Sign your calendar!

### September 2023

#### [Clinical Research as a Care Option](#)

September 20, 2023, Boston, MA, USA

### October 2023

#### [Scope EU](#)

October 17-18, 2023, Barcelona  
TransCelerate-FACILITATE Panel

### November 2023

#### [ICPHMPE-International Conference on Population Health Management and Patient Engagement](#)

November 11-12, 2023, Venice Italy

### December 2023

#### [DIA Global CT disclosure and Data Transparency Conference](#)

Virtual December 5-8, 2023

For a complete list of events go to FACILITATE [website](#).

## Coming soon

A series of podcasts on FACILITATE will be published on our website every fortnight, starting in September. We will update you!

The image shows a podcast cover titled "Striking a Balance: Good Governance". It features a circular portrait of BLOM Johanna Maria Catharina, identified as the "Coordinator of Business Project". The cover includes a diagram with a central circle labeled "Co-create" and "Align", surrounded by "Govern". To the right, there are five horizontal bars representing key principles: "Anticipation of change" (Critical assessment of change affect on trust and governance), "Co-creation" (Respect for patient and participants perspectives), "Accountability" (Safeguards and adequate security measures), "Validity" (Valid alternatives to governance rules no longer adequate), and "Adaptation" (New rules to fit needs in a dynamic flexible way). Logos for efpia, imi, and UNIMORE are visible at the bottom.

## Keep Up with Us!

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<https://www.linkedin.com/company/imi-facilitate>

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Website: <https://facilitate-project.eu>

## Do you have any questions?

Please direct all the enquiries to

[pmo@facilitate-project.eu](mailto:pmo@facilitate-project.eu)



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