Year 2 | Issue 1
February 2023

let's FACILITATE

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

In this issue

●●● Towards harmonization

We have just entered the second year of FACILITATE, and are ready to face the new challenges that the project poses and to work together to realize our goals. Collaboration, harmonization, and alignment will be the guiding words of our next efforts

This year has been extremely fruitful and has allowed us to grow as a collaborative consortium and lay the groundwork for the second year of the project, with more tangible output, as comes out from our first Annual Report, which has just been delivered to IMI/IHI.

It has been a great collaborative effort, which highlighted how the work of the different research groups is progressing towards the mutual definition of the ethical and legal frameworks, on which the subsequent FACILITATE activities are built.

Another important result of the first phase of the project, which is now coming to an end, is the establishment of use cases to be employed in the development of the prototype focusing on the needs and rights of the study participants, on the basis of which the FACILITATE platform can be designed in compliance with ethical, legal, technical, and regulatory requirements.

This is why in this second issue of let's FACILITATE we dedicate a special space to the research led by EURAC, a partner of our consortium contributing at defining use cases as a specific response to patients' needs and motivations identified through an in-depth qualitative analysis.

It only remains to wish you a good read and to discover the latest news and advances in FACILITATE!

Véronique Poinsot and Johanna Blom

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.

●●● Where we are

Starting from the patients' perspective

Eurac researchers present the FACILITATE research methodology for the definition of clinical studies ideal models, to provide patients with ethical and lawful access to their medical data

FACILITATE is an Innovative Medicines Initiative (IMI) project aimed at enabling clinical trial participants to access and utilize their personal health data collected during the study, and to allow the re-use of those data in future research.

EURAC Research contributes to defining realistic clinical trial models or use cases (go to Glossary, page 5) based on patient needs, to ensure a respectful experience for patients involved in clinical trials and to provide ethical and lawful access to control their medical data.

With this goal in mind, a qualitative background analysis based on online semi-structured interviews and focus groups has been conducted to better identify not only the views and claims of social actors, but also the deep motivations and feelings of patients towards these claims. The next step will be to construct use cases as a specific response to patients' needs, considering existing legal and regulatory constraints as well as the necessary ethical safeguards.

Putting the patient "at the centre" - a much abused slogan in the health sector - means nothing other than this: developing new processes using patient perspective at the core of reflection.

The exploratory phase

Between September and December 2022, five people were interviewed, each representing one of the five stakeholders' categories: rare disease patients, non-rare disease patients, clinicians, pharma industry representatives and regulators.

The interviewees were recruited by stakeholders' representatives working for FACILITATE as they had previously been involved in clinical trials either as participants or as professionals. The interviews sought to collect experiences and opinions with a focus on the return of data and results, and consent to the secondary use of these data in future research. The content of these interviews was used to prepare a semi-structured interview guide to lead a subsequent series of focus groups.

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The qualitative phase

The qualitative analysis was based on the discussions and debates held in four focus groups with 5-8 people from across Europe and the USA who belong to one of the five stakeholder categories. Overall, 32 people participated in the qualitative phase (Figure 1).

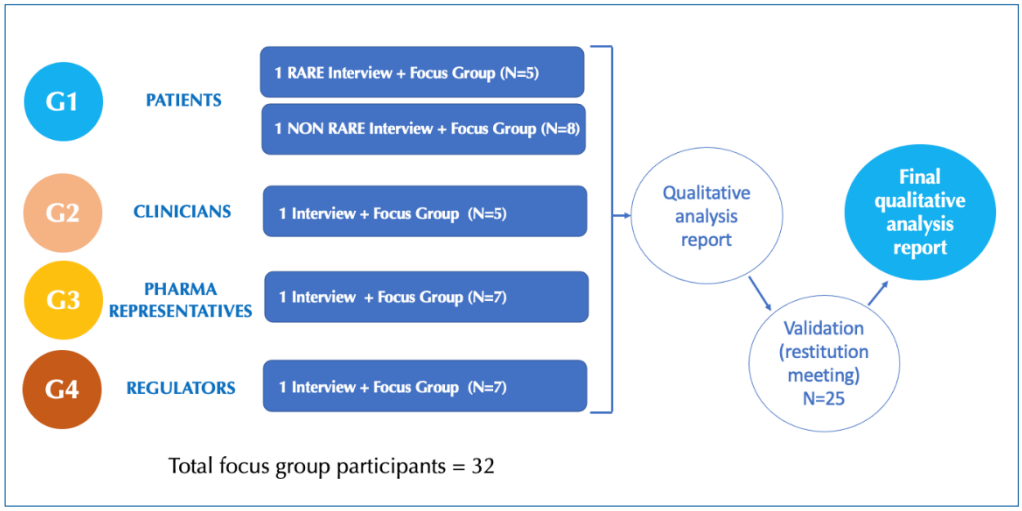

Figure 1. Methodological steps of the qualitative analysis

Both the interviews and the focus groups addressed the two main questions FACILITATE deals with: Return of Results and Secondary Use of Data. The resulting texts were transcribed verbatim and analysed by two researchers working separately. Each researcher followed the same sequence, starting by assigning thematic labels to relevant sections of the text.

Once the labelling phase was completed, the researchers worked together to select and group the labels that shared a common theme and internal coherence, creating categories. At the end of this process, the researchers selected a set of five categories relevant to FACILITATE:

1. quality of life
2. trust between patients and the clinical trial institution, process, and personnel
3. control over the data
4. patient participation and its implications
5. the (social-legal-communicative) informed consent form.

These five categories constitute the basis for identifying a set of open questions and discussion points to be addressed by FACILITATE and are currently under review.

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The validation process

After the completion of the qualitative analysis, a report with the main findings was produced. In parallel, all participants in the qualitative part of the research were invited to join a final online "restitution meeting" to validate the qualitative analysis. The restitution meeting served to reassure the researchers that the opinions and perspectives of the patients had been correctly included and explained.

Patient feedback was also collected by email so that participants who were unable to attend online could also take part in the discussion. The restitution meeting was well attended and overall the researchers received feedback from most of the patients and experts involved in the qualitative analysis.

The qualitative analysis report incorporated feedbacks from the restitution meeting as well as other forms of written feedback received by the researchers and was therefore shared in the final version.

Next steps

As already mentioned, the next goal for EURAC is the construction of use cases as a specific response to patient needs. These use cases will also consider the existing legal and regulatory constraints as well as the necessary ethical safeguards that need to be put in place. Within FACILITATE, the qualitative analysis will also constitute the basis for the second field research, the quantitative part, which aims to assess the generalisability of the findings of the qualitative research.

Virginia Romano and Carlo Calmasini, EURAC Research

FACILITATE glossary

Clinical Trial Use Case

According to FACILITATE final goal, a Clinical Trial Use Case is a model designed to identify the key pathways, criticalities and relative solutions associated with the need to return data and health information to clinical trial participants and to consult with them to express their will regarding potential secondary use of their data for future research purposes.

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●●● Focus on

Health-related data protection

In accordance with resolutions 75/282 and 76/552 of the UN's General Assembly, FACILITATE partner Privanova joined the expert panel of the Ad Hoc Committee tasked with drafting a Comprehensive International Convention on Combating the Use of Information and Communications Technologies for Criminal Purposes.

One of the main objectives of the contribution to the convention drafting was to highlight the possibility of exploiting EU-funded project results in a way that promotes the general understanding of cyber criminality to better counter it. In this context, Privanova included in the recommendations formulated for the Ad Hoc Committee, an acknowledgment of its portfolio projects.

Substantively, the negotiations aim to better combat cybercrime by first identifying and categorizing them efficiently, and then by reinforcing cooperation in the matter. To achieve this, the United Nations is following a multilateral methodology based on seeking consensus among the member states that will be invited to sign the convention. The convention drafting also aims to engage multiple stakeholders and emphasise the role of all actors in combatting cyber criminality.

Health-related data is at top priority in the European Union's data strategy. This explains Privanova engagement in FACILITATE in assisting policy-making that protects fundamental rights when processing this valuable data. Concerns regarding the health data usage and protection were thus mentioned during the panel's discussions.

Our recommendations were also based on the results of EU-funded projects in which Privanova is participating. These results encompass analyses of frameworks for the protection of fundamental rights such as the right to privacy as well as the importance of solid cooperation between involved entities.

In this regard, the delegation of the European Union at the United Nations praised the highlighting of EU initiatives that aim to reinforce the cybersecurity capabilities of the UN member states.

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●●● 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 two months:

A shared position on the EHDS proposal

VUB discusses the EHDS proposal with the LIBE committee of the European Parliament

On 9 January 2023, the Health and Aging Law Lab (HALL) at Vrije Universiteit Brussel (VUB), WP2 (legal) leader of the FACILITATE project, was invited to an informal meeting with the Committee on Civil Liberties, Justice and Home Affairs (LIBE) of the European Parliament to discuss the Proposal for the Regulation of the European Health Data Space (EHDS).

HALL members shared their positions on the EHDS Proposal and raised specific issues that require further consideration in the next versions of the legislative proposal. These issues included, among others, lack of clarity of several key definitions, the EHDS status as a lex specialist for certain provisions of the GDPR, individual rights in the secondary use of electronic health data, and the protection of health data of deceased persons. HALL members also provided written feedback with suggestions to amend the current proposal.

The establishment of the European Health Data Space will have a significant influence on the governance models of electronic health data in the EU and will provide enormous potential for facilitating the sharing of health data for scientific research. Therefore, it is closely linked to the objectives and activities of FACILITATE project.

HALL offered opinions in this meeting exclusively on its own behalf, but was able to benefit from the contributions of some other partners of the FACILITATE project.

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FACILITATE stakeholders' meet in Cape Town

On 21 February 2023, representatives of WP3 held a FACILITATE stakeholder workshop at Stellenbosch Medical School, Cape Town, South Africa

The workshop was hosted jointly with the Stellenbosch University Research Ethics Office and the Office of Research Integrity. The purpose of the meeting was to elect feedback from expert stakeholders on the developing ethical frameworks for secondary use of clinical trial data and the return of data to participants.

South Africa has a data protection regulation (Protection of Personal Information Act 2013) that is similar to the General Data Protection Regulation (GDPR). Moreover, the country is the site of numerous clinical trials, particularly in HIV and TB, and is collaborating with the international research community and thus cognizant of the issues related to data sharing. Therefore, the South African research community is ideally placed to provide expert feedback on the developing FACILITATE ethical frameworks.

In total of 22 participants with expertise in bioethics, law, clinical trials, policy, research ethics, research integrity, bioinformatics, and data management were present. The meeting was opened by outlining FACILITATE, its aims, objectives, ambition, and process of working. Next the qualitative research conducted so far and the results of the literature review were discussed with the participants. Finally, the participants were informed about the ethical frameworks, the principles guiding the frameworks and the preliminary outline of the implementing framework.

The subsequent two-hour discussions focused on the overall project, consent, the proposed governance model, and issues that may need to be addressed for non-EU partners who are collaborating with European partners. Overall, transparency and communication were seen as critical to the success of the proposed processes.

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Global perspectives on return of individual research results

On 23 February 2023, the development of guidelines for the return of clinical trial data has been discussed at the 14th International Congress on Human Genetics in Cape Town

The return of individual research results is fraught with ethical, legal, and social concerns, impacting patients' autonomy and their right not to know. Currently, there is a lack of consensus on how results should be returned, and amidst this ethical uncertainty, many local biobanks, consortia, professional bodies, and industry are developing policies for returning results.

In the Session "Global perspectives on return of individual research results to participants" chaired by Prof. Dr. Johanna Blom, FACILITATE deputy coordinator, researchers discussed different perspectives on policies on the return of data to patients applied in specific contexts.

Dr. Deborah Mascalzoni presented the recent revision of the return policy of the Cooperative Health Research in South Tyrol (CHRIS) study, a healthy cohort study that explores the genetic and molecular foundation of cardiovascular, metabolic, neurological, and psychiatric diseases in the general population of the middle and upper Vinschgau/Val Venosta in South Tyrol, Italy, including what prompted the change, the process it followed, and its guiding principles.

Using examples from some genomics studies in the African context, Dr. Nchangwi Syntia Munung highlighted how communitarian ethics offer an alternative approach to the development of practical guidelines and frameworks for the return of results in genetic research in Africa.

Dr. Calvin Ho discussed the ethical framework on return of research findings to participants in the Hong Kong Genome Project (HKGP), which is an initiative introduced by the government of Hong Kong to drive the local development of genomic medicine for more personalized healthcare and disease surveillance. Apart from the ethical framework, Dr Ho also highlighted some of the social and practical challenges, as well as measures that have been applied to enhance engagement and benefit sharing.

Finally, Dr. Ciara Staunton introduced the FACILITATE ethical framework and the role of patients, industry, researchers, and other stakeholders in developing it.

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Just happened

The first periodic technical and financial report, showing the progress of the FACILITATE IMI2_JU project from 1 January (month 1) to 31 December 2022 (month 12), was submitted to IHI at the end of February 2023.

The first webinar - Let's FACILITATE A Project to Facilitate the Access to Clinical Trial Data and to Manage its Reuse – was conducted on 27 January 2023. The recording can be viewed at the following link.

FACILITATE was represented at the Stakeholders' meeting in Cape Town, South Africa the 21 February 2023 and at the 14th Congress on Human Genetics on 23 February 2023, within the Session Global perspectives on return of individual research results to participants.

Will happen

On 1 March 2023, Prof. Dr. Johanna Blom has been invited to participate as a speaker at the 3rd International Conference on Rare Diseases: Greek Chapter, 2023, Athens in the Session "Flash Updates of RD Flagship Initiatives".

On 3 March 2023, Prof. Dr. Johanna Blom and Dr. Deborah Mascalzoni will present the FACILITATE project and its challenges in the Third Ethical Legal VALKYRIES Workshop "Dealing with ethical legal issues in technology development: the current approaches adopted in ongoing projects", at the School of Advanced Studies – Pisa, Italy.

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

On 15-16 March 2023, EURAC will host 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.

On 24-26 May 2023, FACILITATE will participate in two Expert Panels at the Computer Privacy and Data Protection (CPDP) meeting in Brussels: 1. Enabling the secondary use of clinical trial data for scientific research purposes; 2. The EHDS and secondary use of data: is it possible to balance individual interests with the ultimate need for data sharing to facilitate research? (Organized by VUB).

On 8-9 June 2023, SANOFI will host a semiannual face-to-face meeting in Chilly Mazarin, Paris.

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●●● Join the event, watch the webinar!

Our first webinar for stakeholders - Let's FACILITATE A Project to Facilitate the Access to Clinical Trial Data and to Manage its Reuse - has been conducted on 27 January 2023, with the support of the EDUNOVA inter-university centre (UNIMORE). The participation was good, with **466 registered and 166 attendees**, mostly patients or patient associations, pharma representatives and clinical researchers from different EU and extra-EU Countries.

Under the coordination of Nuala Ryan (WP6 leader, Takeda), Prof. Dr. Luca Pani (Project coordinator, UNIMORE) gave an introduction on the context in which the project was born and its importance in the current scenario. Véronique Poinsot (Project leader, Sanofi) and Prof. Dr. Johanna Blom (Project deputy-coordinator, UNIMORE) presented the project's objectives, its mission, architecture, benefits for stakeholders and challenges. Daniela Quaggia (WP6 leader, ACN) emphasized the patient and other stakeholders' role as the main beneficiaries. Pauline Granger (WP2 leader, Sanofi) analysed the legal and data privacy framework and associated challenges regarding the return of clinical trial data and their secondary use considering current European legislation, while Dr. Deborah Mascalzoni (WP8 leader, EURAC) discussed the two ethical contexts in which such data should be returned and reused to meet the needs of the patient.

To better understand FACILITATE's innovative approach to returning data to trial participants, **watch our webinar!**

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Website: https://facilitate-project.eu

Do you have any questions?

Please direct all the enquiries to

pmo@facilitate-project.eu

Save the date

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

March 2023

3rd International Conference on Rare Diseases: Greek Chapter
Session "Flash Updates of RD Flagship Initiatives"
28 February-1 March 2023, Athens, Greece

Third Ethical Legal VALKYRIES Workshop
Dealing with ethical legal issues in technology development the current approaches adopted in ongoing projects
3 March 2023, School of Advanced Studies – Pisa, Italy

4th Intersessional Consultation of the Ad Hoc Committee
6-7 March 2023, Vienna, Austria

Clinical R&T - 3rd World Congress
Advances in Clinical Research and Trials
20-21 March 2023, London, UK

Patients as Partners USA
20-22 March 2023, Washington, USA

EFPIA - TransCelerate Workshop
22 March 2023, Basel, Switzerland

DIA Europe 2023
22-24 March 2023, Basel, Switzerland

SCRS-Society for Clinical Research Site
Diversity Site Solutions Summit
30-31 March 2023, Austin, Texas, USA

April 2023

21st Clinical Trial Innovation Programme
18-19 April 2023, Düsseldorf, Germany

For a complete list of events go to FACILITATE website.

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