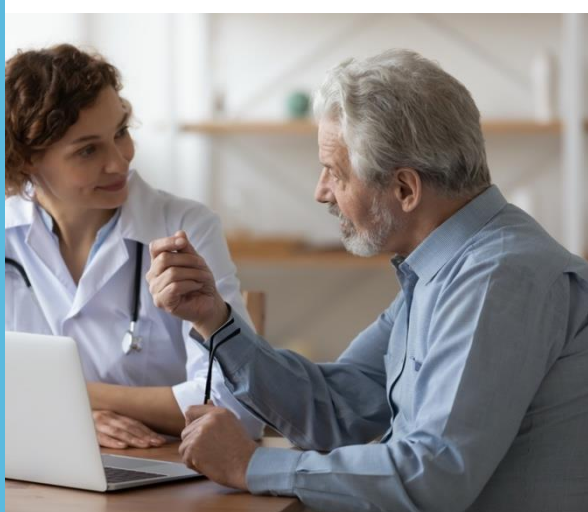Year 1 | Issue1
December 2022

let's FACILITATE

FACILITATE

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

In this issue

●●● One year in FACILITATE

Almost one year has passed since the project started in January 2022 and FACILITATE has remained true to its mission: to put patients at the center of the clinical trial process with regards to return and reuse of results after their involvement in a clinical trial.

A lot has happened this year: all the objectives have been reached and due deliverables sent to IHI, research activities are ongoing, legal, ethical, and regulatory studies are underway, internal meetings are held regularly, and expert decision-making committees have been set up.

All this progress was successfully discussed at the first General Assembly meeting, which has just been concluded in Modena, Italy, under the banner of optimism and awareness that the project is growing and making progress within all work packages.

We inaugurate this first number of let's FACILITATE with an overview of the General Assembly meeting and a focus on a topic of interest.
We wish to the consortium to work together taking concrete steps towards development and construction of real outcomes.

Véronique Poinsot, Johanna Blom

●●● Where we are

From the first FACILITATE
General Assembly meeting

On 17 and 18 November, the consortium's first annual meeting took place in Modena, in a hybrid format with 27 in-person and 28 online participants. Here are some of the key highlights of the two days.

Our hallmarks

Optimism, collaboration, and involvement

Welcome by Project leaders
Véronique Poinsot (Sanofi) and Johanna Blom (UNIMORE)

Véronique and Johanna welcomed all participants with a brief presentation about the core of the project, which will be mainly based on collaboration between partners, harmonization of objectives and alignment of activities.

One year in FACILITATE
by Philippe Bordes (Sanofi)

Philippe gave an overview of the project during the year: FACILITATE currently consists of 137 members from 18 European and non-European countries, with a balanced gender distribution (64 women and 73 men). All deliverables have been sent to IMI, 32% of IMI funds have been delivered to each partner, and the annual report will be prepared next January.

The presentation went on illustrating the governance of FACILITATE, from the work packages to the Steering Committee, the three Expert Decision Committees, the Scientific Advisory Board, and the Project Coordination Team, comprising the project leader, the coordinator, and the Project Management Office, with a special attention to tasks and responsibilities of the work package leaders, the real drivers of the project.

FACILITATE at work
During the two-day discussion, the ongoing activities and those planned for the next year were discussed. On the following pages you will find some of the most important progress made by the researchers in the work packages.

WP2. Legal and Data Privacy framework
by Pauline Granger (Sanofi) and Wenkai Li (VUB)

Building on the D2.1 Initial Report on Legal Requirements, which outlined the relevant legal and regulatory framework at the EU level, WP2 partners are now investigating the national legislation to identify the legal specificities of different Member States about the return of individual data to study participants and the secondary use of data.

This work will serve as a basis for the subsequent tasks and deliverables, including the development of the informed consent forms and the final guidance document for clinical studies. This will help to clarify the technical solution required for the FACILITATE project (WP4 and WP5).

Over the next 6 months, WP2 will prepare consultations with selected Data Protection Authorities (DPAs) and the Expert Decision Committee regarding the identified legal challenges.
Discussions and alignment will also be continued with WP3 to promote the synergy between legal and ethical research.

WP3. Ethics and regulatory framework
by Deborah Mascalzoni (EURAC)

The core question

How should a process for returning data be designed to respond to the needs of patients and at the same time be feasible within the clinical trial reality?

Deborah Mascalzoni
EURAC

On the one hand, WP3 researchers are currently developing two ethical frameworks: the ethical framework on the future use of clinical trial data for scientific research and the ethical framework on the return of clinical trial data to patients.
These patient-centered ethical frameworks aim to empower patients and protect their rights as well as the public interest in science when returning patient data as well as reusing patient data for future scientific research.

On the other hand, a qualitative analysis based on focus groups involving patients and other stakeholders engaged in the project (clinicians, pharmaceutical company representatives, regulators) is now in its final stages.

This analysis, together with a case studies report, has been set up to identify and provide the basis for creating the FACILITATE framework (clinical study use cases). Its aim is to classify a set of categories representing issues, key open questions, and discussion points to be addressed by stakeholders. This will be followed by a quantitative analysis based on a discrete choice model (DCM).

WP4. Platform architecture design and requirements
by Nenad Gligoric (Zentrix)

The first year of the FACILITATE project was focused on defining the Legal and Ethical requirements. The work in the WP4 will begin in 2023, and the major goal of the WP4 is to define the technical process with architecture and infrastructure, driven by the data reuse in different healthcare use cases, thus answering to the needs of the stakeholders, ethical and regulatory framework requirements.

Its methodology consists mainly in analyzing State-of-the-art (existing patient summary services), work in the domain of federated data sharing, and reference healthcare architectures, to create an overlay process compliant with the legal and ethical framework for data sharing and reuse.

WP5. Technology framework and interoperability solutions
by Sebastiaan van Sandijk (Odysseus Data Services)

WP5 activity will start as planned early next year in close collaboration with WP4.
Based on the priority use cases defined in WP2 and WP3, with the corresponding ethical and regulatory requirements and stakeholder expectations, the researchers will begin the work by inventorying and assessing available solutions and potential useful approaches for returning data to clinical trial participants and empowering them to share their data for further reuse. To facilitate a smooth collaboration, the partners involved in WP5 will be invited for a preparatory online meeting next month.

WP6. Communication and Dissemination
by Nuala Ryan (Takeda) and Daniela Quaggia (ACN)

A detailed communication and dissemination plan has been prepared for the project. The main communication tools are either prepared or in progress. The FACILITATE website is currently being updated with a newly designed newsroom. This will include different sections for news, newsletters, press releases, webinars, videos, details of congresses where FACILITATE is presented and podcasts.

It will also contain a glossary and a 'Questions and Answers' section for patients and healthcare professionals, as well as infographics to provide easy-to-understand information about the project and its main achievements to all stakeholders and interested parties.

Other communication and dissemination tools are being finalized (slide deck, flyer, poster and roll up). These will be useful for the Consortium to present FACILITATE with a clear and well-defined image at internal and external events.

In terms of stakeholders' engagement, stakeholders from the various stakeholder groups (patients, Pharma, Clinicians) were identified for interviews and focus groups (WP3) to discuss challenges or identify issues to be addressed as part of the project - a report was prepared based on the output of these events.

Terms of reference for the various expert stakeholder groups have been prepared and members recruited for each group. Quarterly meetings will be organized to ensure continuous engagement to collect patients, citizens, clinicians, and other relevant stakeholders' feedback. This will start in January 2023 with an overview meeting for all stakeholders on the project.

Other stakeholders can register through the FACILITATE website to either receive updates on the study or participate in engagement activities such as surveys as needed throughout the project.

The coordinators of the four stakeholder groups - patients, clinicians & healthcare professionals, pharma industry/sponsors, healthcare actors on a broader spectrum - will work together as an Engagement Coordination Team (ECT) to ensure that members of each individual group keep in regular contact to ensure consensus across the stakeholder groups, to ensure success of the process implementation and to have a process that satisfies the needs of all stakeholders collectively.

●●● Next steps

The first Amendment - Roche becoming a new partner - is going to be prepared and the deliverables timelines have been reviewed and updated

The first annual report, from 1 January 2022 to 31 December 2022, will be prepared, and is expected to be submitted to IHI at the end of February 2023

A webinar - Let's FACILITATE A Project to Facilitate the Access to Clinical Trial Data and to Manage its Reuse – has been scheduled for 27 January 2023, 4-5 pm CEST

EURAC will host a face-to-face meeting in Bolzano on 15-16 of March, to discuss both ethical frameworks that WP3 is developing (return of clinical trial data and secondary use of data)

FACILITATE will be presented at the Human Genetics congress in Cape Town, South Africa, in February 2023 (https://www.ichg2023.com) and at the Computer Privacy and Data Protection meeting in Brussels in May 2023 (https://www.cpdpconferences.org), where a symposium (Global perspectives on return of individual research results to participants) and expert panel (Proposal for a Health and Ageing Law Lab panel) have been proposed

SANOFI will host a semiannual meeting face-to-face in Paris on 8-9 of June 2023

Do you have any questions?

Please direct all the enquiries to:

pmo@facilitate-project.eu

● ● ● Focus on: The workshop

Societal impact and response to AI and data intensive research use of genomic data

The secondary use of clinical trial data has been discussed by Ciara Staunton and Deborah Mascalzoni (EURAC) in a workshop at the Brocher Foundation in Geneva on 9 and 10 August

Biobanks, databanks, and repositories provide a rich source of samples and data that can be used and reused in genomic research.
Artificial intelligence (AI) has the potential to exploit that data to develop new knowledge, algorithms, and tools to define and accurately predict diseases and recommend personalized treatments. The implementation of it requires the provision of genomic and other health related data, access to other medical records likely to be available in the local health system, and the linking of this data with other datasets.

On the one hand, this is fraught with legal, ethical, and social concerns that researchers are already trying to address in the context of genomic and biobank research. On the other hand, the use of these data, combined with the use of AI introduces a whole new level of complexity into the equation for many reasons: the opaque nature of machine learning, the currently largely unregulated use of technology in this sector, the bias that is inherent in these datasets, the potential impact of AI on the relationship and trust between patients and the health sector.

The delicate balance between solidarity public and private interest may be heavily impacted by the co-creation of technologies and a social landscape still to be imagined. The definition of the policy of AI development and of the use of data is a political exercise that reshapes the boundaries of proprietary use, access to the new "personalized medicine" and the same concept of justice in healthcare.

Patient groups, lawyers, ethicists, data scientists, social scientists, and industry brought together to discuss the impact of AI and data-intensive research use of genomic and biobank data from a societal perspective, to identify how best to enable a patient-centric approach to address these issues and ensure that the resulting benefits are global in nature.

●●● Save the date

FACILITATE members are invited to attend and present at numerous 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 events where FACILITATE could be present in the coming months:

6th Annual Conference Patients as Partners Europe
30-31 January 2023 London, UK
https://theconferenceforum.org/conferences/patients-as-partners-europe/overview/

14th International Congress on Human Genetics
22-26 February 2023, Cape Town, South Africa
FACILITATE Symposium: Global perspectives on return of individual research results to participants
https://www.ichg2023.com

Digital Healthcare Innovation Summit (DHIS)
1st February 2023
The Lodge at Torrey Pines, San Diego, USA
https://dhis.net/west

ICPHMPE-International Conference on Population Health Management and Patient Engagement
6-7 February 2023 Lisbon, Portugal
https://waset.org/population-health-management-and-patient-engagement-conference-in-february-2023-in-lisbon

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Join the event

Don't miss our webinar,

scheduled for 27 January 2023, 4-5 pm CEST

Let's FACILITATE

A Project to Facilitate the Access to Clinical Trial Data

and to Manage its Reuse

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