IMI2 Project ID 101034366
FACILITATE

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

WP1 – Project Management and Administration

D1.2 Expert Decision Committees establishment and management rules

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V1.0	30.06.2022	Submission
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Abbreviations

EDC: Expert Decision Committee
DPA: Data Protection Authority
EC: Ethical Committee
PCT: Project Coordination Team
PMO: Project Management Office

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Summary

FACILITATE will establish three project Expert Decision Committees (EDC) composed of internal and external members including experts nominated from different areas to represent user groups from patients' associations, national competent authorities, ethics committees, regulators and industry. The EDCs will have an enhanced mandate and a continuous opportunity to test, review, select and verify project outcomes.

The purpose of the Expert Decision Committees is to provide relevant feedback regarding the FACILITATE research and operational activities corresponding to their respective fields of expertise, and ensure respect of the end-user ethical, legal and regulatory requirements. The EDCs will validate project outcomes throughout the lifecycle of the project. In addition, these groups of stakeholders will be considered as additional platforms for communication and dissemination of the results of the project. To this end, the competencies of the consortium partners will be integrated with other relevant stakeholders including technical experts experienced in the anonymization of health data, healthcare professionals, experts in genetics counselling, data protection authorities' representatives, ethics committees responsible for follow up of the clinical trials, as well as patient associations and regulators.

This document may be updated as a working document should the composition of the EDCs change.

1. Introduction

Decision-making committees (topic-specific committee) draw on their specific expertise to develop recommendations in the areas defined by the scope of the project. Therefore, the establishment and organization of effective committees represents an important part of producing this deliverable which is based on the Consortium Agreement and the Grant Agreement in which the composition of the three Expert Decision Committees (EDCs) and their working practices are layed out. EDCs are designed so that a small group of experts may focus in detail on a particular realm of the project. The EDCs have been established for the purpose of supporting FACILITATE and therefore the composition of each of the committees is tailored to the different needs of FACILITATE. As far as possible, each committee will aim for diversity in participation, based on equality, a fundamental principle observed by FACILITATE. Equality and anti-discrimination considerations are reflected at every stage of recruitment. Also, all committee members have equal status, acknowledging the importance of the expertise and experience that each member brings to their respective committee.

2. EDCs scope

The Expert Decision Committees are advisory boards to the Action in general and the General Assembly and Executive Committee in particular. Efficiency, as well as economy, makes it necessary to limit the number of experts participating in discussions related to specific topics; on the other hand, it is difficult, in a small group of experts, to obtain adequate representation of the various branches of

knowledge which bear upon this project, and of the diversified forms of experience and trends of thought prevailing in the various fields of expertise and different parts of the world. Therefore, three different committees will be created. The final composition of a specific committee is agreed by the partners aiming at quality assurance and considering the deliverables of the project. Each committee will comprise between 7 and 15 members. This number allows members to contribute effectively to discussions while including a broad range of experience and knowledge.

2.1 The role and composition of the EDCs

The EDCs will support the project implementation and decision-making process **by formally reviewing the proposed standards and providing official feedback prior to submitting for formal endorsement by regulators**. The EDCs will formally validate standards derived from WP2, WP3, WP4 & WP5 and as such represent the conceptual and ethical architecture of FACILITATE.

According to Call no. 23 of IMI, Topic 1, the Consortium has three EDCs:

- The **Technical and Medical Expert Decision Committee (EDCa)** is responsible for providing advice to the Beneficiaries, the General Assembly and the Executive Committee on the reasonable needs, expectations and constraints from a technical and medical point of view from the medical community.
- The **Ethical and Legal Expert Decision Committee** (**EDCb**) is responsible for providing advice to the Beneficiaries, the General Assembly and the Executive Committee on the reasonable needs, expectations and constraints from a legal and/or ethical point of view from the medical community.
- The **Patients and Regulators Expert Decision Committee** (**EDCc**) is responsible for:
    - providing advice on the the proper application of the legal and ethical rules by the Beneficiaries;
    - providing advice to the Beneficiaries, the General Assembly and the Executive Committee on legal and ethical issues; and
    - providing advice on the compliance with European ethical laws and regulations and with different guidelines, laws and regulations of countries where studies are being performed.

EDCs will:

- Advise on the proposed legal and ethical standards and where appropriate propose alternative approaches
- Consider the evidence
- Develop the proposals for practice and research
- Consider regarding regulatory issues associated with implementing the project deliverables
- Consider factors that may help or hinder implementation ('levers and barriers')
- Advise on implementation support that may be needed.

The EDCs are involved during the project for the following further activities:

- Supporting the drafting of the aligned position papers including the proposed regulatory standards and guidance documents. They should include an official opinion of the regulators (e.g., of the European Data Protection Board (EDPB)), where possible;
- Participating in workshops organized with the aim to foster harmonization of the health data processing provisions across Member States (ie the workshop already planned in WP2, T2.3 - D2.7). Decision positions should, where possible, include an official opinion of the regulators (e.g., EDPB) at the end of the project.

2.2 Members of the EDCs

The Expert Decision Committees are composed of experts from Beneficiaries and Third Parties with detailed knowledge and will provide relevant feedback to the Action corresponding to their respective fields of expertise, ensuring the respect of the end-user ethical, legal and regulatory requirements. The resulting committees should, where possible, reflect the range of stakeholders and groups whose activities, services or care will be covered by FACILITATE. Therefore, the committees will have a multidisciplinary make-up.
Nominations for membership of the Expert Decision Committees may be submitted to the Project Coordination Team by any Beneficiary. The Project Coordination Team shall ensure that the composition of the EDCs is appropriate to provide the guidance required.

2.3 Principles

The EDCs must perform their tasks in compliance with the principles of

- Expertise: advisors need to have up-to-date clinical, scientific or technical expertise – MDR Article 106(3); and
- Independence, impartiality and objectivity: advisors must not have interests which could affect their impartiality (MDR Article 107) and must act objectively, i.e., solely on the basis of scientific, clinical or technical considerations; and
- Commitment: advisors need to commit to all principles and commit to provide their advice to the best of their ability; and
- Confidentiality: advisors must not divulge any information of confidential nature acquired as part of their work in the expert panels and not divulge any commercially confidential information and trade secrets.
- Transparency

2.3.1 Expertise

Expert panels consist of advisors appointed based on their up-to-date clinical, scientific or technical expertise in the field and with a geographical distribution that reflects the diversity of scientific and clinical approaches in the Union. The Commissions seeks to achieve gender balance when selecting and appointing advisors.

2.3.2 Independence, impartiality and objectivity

Committee members are selected for their knowledge and experience, and do not represent their organisation(s). Experts who make up the EDCs shall represent user groups from patients' associations, national competent authorities, ethics committees and industry involved in the Action.

1. Experts are appointed or assigned in their personal capacity. They must not delegate their responsibilities to any other person.
2. Advisors must not have financial or other interests or in a notified body or any other organisation or sector, which could affect their independence, impartiality and objectivity. They must make a declaration of interests indicating any interest, which may compromise or may reasonably be perceived to compromise their independence, impartiality and objectivity, including any relevant circumstances relating to their close family members.
3. Declarations of interests are submitted in writing and by using the appropriate declaration of interest (DOI) electronic form in accordance with the instructions for filling out the form provided by the PMO.
4. To this end, advisors must ensure that the PMO has up-to-date versions of their DOIs at any point in time during their term.

2.3.3 Commitment

- EDC members must act in the public interest and observe the principles outlined in the GA.
- EDC members must sign a declaration of commitment.
- Advisors must respond to requests and other communications from the PMO or the Chair of their respective expert panel or sub-group without undue delay.

2.3.4 Confidentiality

Prior to their first participation in a meeting of an EDC or their first receipt of Confidential Information, any Third-Party expert or qualified person shall first enter into a suitable Advisory Agreement pursuant to Clause 11.5.1.4.

The following principles will apply:

- EDC members must not divulge any information of confidential nature acquired as part of their work in the expert panels or as result of other activities governed by the Action.
- EDC members must sign a declaration of confidentiality.
- EDC members must comply with the rules on security regarding the protection of the European Union classified information (EUCI) and sensitive non-classified information.

2.3.5 Transparency

1. EDCs must provide relevant information on their actions and outcomes in agreement with transparency requirements and ensuring consideration of confidentiality in regard to personal data.

2. The PMO collects and processes personal data in compliance with Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies and agencies and on the free movement of such data.

3. Establishment of the EDCs: Selection, Appointment and Term of Office of Members

The establishment of the EDCs has been a concerted action by the partners involved in task 1.2. The Partners decised on the composition of the 3 committees, the number of experts to be invited to each expert committee, the duration, and when to convene the committees. It was decided that members of an expert committee would be invited based on the principles of equitable geographical representation, gender balance, representation of different trends of thought, approaches and practical experience, as well as an appropriate interdisciplinary balance. Nominations for membership of the Expert Decision Committees can be submitted to the PMO by any Beneficiary: the PMO shall ensure that the composition of the EDCs is appropriate to provide the guidance required.
Partners involved in the establishment of the EDCS

- UNIMORE, SANOFI, EURAC, VUB, IMR, INPECO, INPECO TPM: definition of a strategy to establish the three committees, timelines, general discussion;
- UNIMORE, SANOFI, IMR, INPECO, INPECO TPM: focus on EDCa, definition of the list of expertise needed, first list of potential technical members;
- UNIMORE, SANOFI, EURAC, VUB: focus on EDCb
- UNIMORE, SANOFI, EUPATI, EUPATI IT, EURORDIS, ACN: focus on EDCc, discussion of the different needs from patients perspective;

Following the preliminary agreement on the potential list of members, the Coordinator shall formally invite those experts, by sending them an official letter and a synopsis of the project (Annex I).
The PCT shall provide the final decision, after having received the commitment by identified members. Prior to their first participation in a meeting of an EDC or their first receipt of Confidential Information, any EDC member shall first enter into a suitable Advisory Agreement pursuant to the CA, signed by the Project Leader and the Project Coordinator. A copy of the Governing rules, as set at point 4 of this deliverable, will be shown to each member, and signed for approval of the conditions.

4. Governing rules

The following Governing rules have been approved by the PCT, in agreement with other partners involved in T1.2.

4.1 Purpose of the EDCs

The purpose of the Expert Decision Committees is to provide relevant feedback regarding the FACILITATE research and operational activities corresponding to their respective fields of expertise and ensure that the end-user ethical, legal and regulatory requirements are respected. Each EDC is asked to focus in detail on a particular set of issue. The EDCs will also validate project outcomes throughout the lifecycle of the project. In addition, these groups of stakeholders will be considered as additional platforms for communication and dissemination of the results of the project. To this end, we will integrate the competencies of the consortium partners with other relevant stakeholders including: technical experts knowledgeable regarding the anonymisation of health data, healthcare

professionals, experts in genetics counselling, data protection authority representatives, ethics committees responsible for follow up of clinical trials, as well as patient associations and regulators.

4.2 Duties of the EDCs

The Expert Decision Committees will advise the General Assembly and the Executive Committee upon request of the Project Leader together with the coordinator and provide non-binding advice to the General Assembly and the Executive Committee as integral support of the decision-making process. Each EDC will have clear terms of reference that clarify the role, purpose and responsibilities given to a committee. A reporting mechanism will be put in place so that the main managing bodies are kept informed and updated regarding proposals and considerations raised by the EDCs.

4.3 Chairs of the EDCs

Each EDC has a Chair and a Vice-Chair. The EDC will elect its Chairs from among its members. The tenure of the chairs is two years, renewable for a further two years. The Chairs have the following roles:

- Organising the working structure of the EDC if needed (e.g.thematic groups)
- Communicating relevant information to the EDC members
- Working with the FACILITATE partners and/or the PMO in planning and carrying out meetings, agendas etc.

EDC Chairs will be invited to attend the GA, SC, ExCom meeting, when appropriate.

4.4 Meetings of the EDCs

4.4.1 General principles

Committees are multidisciplinary and their members bring with them different beliefs, values and experience. All these perspectives are valued by FACILTATE. Each member should have an equal opportunity to contribute to the issue at hand. The chair should ensure that there is sufficient discussion to allow a range of possible approaches to be considered, while keeping the group focused on the problem at hand and the evidence being reviewed. Each EDC will meet upon request of the Project Coordination Team but at least once every twelve (12) months during the Action. Meetings are organized in presence or via *ad hoc* teleconferences. All EDC meetings will be based on an agreed agenda to ensure efficient decision-making.
Meetings of the EDC will be attended by:

- EDC members
- FACILITATE project partners devoted to supporting each EDC
- FACILITATE Project Management Office members (where appropriate)
- Further invited participants (where appropriate)

Only EDC members have voting rights.

4.4.2 Meeting timelines

EDC members are expected to dedicate the necessary effort in order to complete the advice/opinion asked for to the best of their ability and within of the timelines outlined by the consortium.
Advice in response to a Consultation must be delivered within 21 calendar days from when the EDC receives the documents from the PMO via the electronic platform for document exchange (TEAMS).

4.4.3 Meeting documentation

Relevant documents should be circulated beforehand to allow for adequate preparation. Meeting documentation is usually sent to committee members at least 5 working days before a committee meeting.

The EDC takes formal minutes during committee meetings and these are reviewed and approved at the next meeting. The approved minutes of each meeting are posted on the teams portal. Information to be included in the minutes:

- date, time and where(how: in person or telematic) the meeting took place
- who attended
- declarations of interests of those attending, including any conflicts of interest
- a list of the subjects to be discussed.

Decisions will be taken by simple majority. The Chair shall have a casting vote.

4.5 Organization of the activities

The EDCs will use an electronic mailing list to communicate relevant information to all of its members. All members should be kept up to date electronically and should receive FACILITATE dissemination materials.

4.6 Code of conduct and declaration of interests: duties and rights of the ECD members

4.6.1 Declaring interests

All EDCs members, including the chairs must declare any potential conflicts of interest. For committee members, including the chair, this happens on acceptance of committee membership. Any relevant interests, or changes to interests, should also be declared publicly at the start of each committee meeting. Where issues are discussed that may involve a conflict of interest, the affected member shall recuse herself/himself from the discussion. Before each meeting, any potential conflicts of interest are considered by the committee chair and at least one other member of the committee. Any decisions to exclude a person from all or part of a meeting should be documented. Any changes to a member's declaration of interests should be recorded in the minutes of the meeting.

4.6.2 Code of conduct and confidentiality (see section 2)

The EDCs work is based on the principles of transparency and confidentiality.

Prior to their first participation in a meeting of an EDC meeting or their first receipt of Confidential Information, any member shall first enter into a suitable Advisory Agreement provided by the Project Leader and Project Coordinator.

4.6.3 Rights

Each member has the right to be refunded for travel costs, accordingly to the Consortium financial rules for further details see the Consortium Handbook).

5. EDCa – Technical and Medical Expert Decision Committee

The EDCa is composed of 15 members, who represents a wide range of expertise
The final list of EDCa members, is included below (alphabetical order):

Table 1. EDCa composition

No.	Member	Expertise
1.	**Dr Kenneth Shane Baldwin (M)** North Carolina State University Raleigh-Durham-Chapel Hill (USA) pbs3456@gmail.com	Expert in Quality Assurance and Compliance
2.	**Dr Angelico Carta (M)** WorldWide Clinical Trial (USA) angelico.carta@worldwide.com	CT expert - Neuropsychopharmacology
3.	**Dr Francesca Frexia (F)** CRS4 (Italy)	Expert in Healthcare standards - Interoperability, Traceability, Telemedicine and Modelling of data and processes in the clinical context
4.	**Prof Vesna Garovic (F)** Mayo Clinic Rochester (USA) Garovic.Vesna@mayo.edu	CT expert - Obstetric nephrology
5.	**Dr Rosa Gini (F)** Agenzia regionale di sanità della Toscana (Italy) rosa.gini@ars.toscana.it	Data standardization (e.g., IMI-ConcePTION) and Data science (secondary use of electronic health records)

6.	**Prof Jozef Glasa (M)** Slovak Medical University Bratislava, Institute of Medical Ethics and Bioethics (Slovakia) jozef.glasa@szu.sk	CT expert- Clinical pharmacology and therapeutics
7.	**Dr Asieh Golozar (M)** Odysseus Data Services (USA) asieh.golozar@odysseusinc.com	Expert in Medical research, Data science and RWE - Epidemiology, Biostatistics, Data Science, Medicine (Oncology)
8.	**Prof Juan Ramon Gutierrez Villar (M)** GrupoBC (Spain) jrgutierrezv@grupobc.com juraguvi@gmail.com	Expert in Business Processes Transformation Management, Technical solution design
9.	**Dr. Nicole Mather (F)** IBM United Kingdom LTD 76/78 Upper Ground South Bank London SE1 9PZ Nicole.Mather@ibm.com	Expert in Digital strategy, Analytics, cognitive technologies and Cloud technology solutions
10.	**Dr Pierandrea Muglia (M)** GRIN Therapeutics (Belgium) pierandrea.muglia@gmail.com	CNS Drug Developer - Child Neurologist and Psychiatrist
11.	**Dr Begonya Nafría Escalera (F)** Sant Joan de Deu Hospital, Barcellona (Spain) begonya.nafria@sjd.es	CT expert - Patient Engagement in Research
12.	**Dr Florence Robert-Gangneux (F)** University of Rennes 1 (France) florence.robert-gangneux@univ-rennes1.fr	CT expert - Parasitology and Mycology and Health Innovation Technology
13.	**Dr Tim Schuckman (M)** WCG Princeton, NJ (USA) tschuckman@wcgclinical.com	CT expert - Quality and Efficiency of clinical trials
14.	**Dr Sabine Straus (F)** Netherlands Medicines Evaluation Board (Netherlands)	CT and RWD expert - PRAC Chair

15.	**Dr Alessandro Sulis (M)** CRS4 (Research Centre) (Italy)	Expert in interoperability between clinical systems (main standards and best practices)

Publication of the e-mail address was authorised by each member via e-mail.
The activities of the EDCa are supported by the project partners: INPECO, IMR, UNIMORE and SANOFI.

6. EDCb – Ethical and Legal Expert Decision Committee

The EDCb is ideally composed of 15 members, who represents a wide range of expertise. The current list of EDCb members (11), is included below (alphabetical order).

Table 2. EDCb composition

No.	Member	Expertise
1.	**Dr Cristina Avendano Sola** Research Ethic committee of the NorthWest region in Madrid (Chair) (Spain)	Expert in Ethics in Health data
2.	**Dr Veronique Ciminà** EDPS - European Data Protection Supervisor ciminav@hotmail.it	Data protection expert - Health and scientific research
3.	**Dr Jean Herveg (M)** CRIDS, Univeristy of Namur (Belgium) jean.herveg@unamur.be	Data Protection expert - IT law (privacy and eCommerce) and Health law (eHealth products and services)
4.	**Dr Calvin WL Ho (M)** University of Hong Kong Faculty of Law cwlho@hku.hk	Expert in Biomedical Law & Ethics, Regulatory Governance, Artificial Intelligence, Data Science
5.	**Dr Klaus Høyer (M)** University of Copenhagen (Denmark) klho@sund.ku.dk	Expert in Ethics in Health data - Research biobanking, Stem cells, Property issues, Public-private partnerships and public perceptions of genetics
6.	**Prof Jane Kaye (F)** Centre for Law, Health, and Emerging Technologies (HeLEX), Oxford (UK) jane.kaye@law.ox.ac.uk	Expert in Digital innovation - Digital privacy and dynamic consent, Public involvement and engagement in research, Biobanks, Genomics, Data-sharing framework
7.	**Dr Dorota Krekora Zajac (F)**	EC expert - Biobanks

	University of Warsaw | UW · Institute of Civil Law (Poland) d.krekora@wpia.uw.edu.pl	
8.	**Dr Max Polano (M)** Netherlands Medicines Evaluation Board (Netherlands)	EC expert
9.	**Dr Emmanuelle Rial-Sebbag (F)** French Institute of Health and Medical Research | Inserm (France) emmanuelle.rial@univ-tlse3.fr	Expert in Law and Bioethics - Biobanking, Personal health data protection, Big Data
10.	**Prof. Georg Schmidt (F)** German Association of Medical Ethics Committees (Germany) gschmidt@tum.de	EC expert
11.	**Prof. Joop M. A. Van Gerven** CCMO-Central Committee on Research Involving Human Subjects (Chairman) (Netherland)	EC expert

Publication of the e-mail address was authorised by each member via e-mail.
The activities of the EDCb are supported by the project partners: VUB, EURAC and SANOFI.

7. EDCc – Patients and Regulators Expert Decision Committee

The EDCc is ideally composed of 15 members, who represents a wide range of expertise
The current list of EDCb members (8), is included below (alphabetical order):

Table 3. EDCc composition

No.	Member	Expertise
1	**Dr Martin Černák** AOPP - Association for the Protection of the Rights of Patients (Slovakia) cernak.mato@gmail.com	Expert in Patients' Rights
2	**Dr Penka Georgieva** POWY - Patients Organizations With You (Bulgaria) pdimgeorgieva@gmail.com	Expert in Patients' Rights
3	**Dr Audun Hågå**	Expert in Medicines Regulatory Affairs

	Norwegian Medicines Agency - NoMA (Norway) Audun.Haga@legemiddelverket.no	
4	**Dr Jasna Karacic** Croatian Association for the Promotion of Patients' Rights (Croatia)	Expert in Patients' Rights
5	**Dr Jo Maes** Epecs Foundation (Netherlands) jo.maes@epecs.eu	Expert in Patients' Rights
6	**Dr Eleftherios Pallis** National Organization for Medicines (Greece) vicepresident@eof.gr	Expert in Medicines Regulatory Affairs
7	**Prof Pierluigi Russo** Agenzia Italiana del Farmaco-AIFA (Italy)	Expert in Medicines Regulatory Affairs
8	**Prof Anthony Serracino-Inglott** Medicines Authority (MALTA) anthony.serracino-inglott@gov.mt	Expert in Medicines Regulatory Affairs

Publication of the e-mail address was authorised by each member via e-mail.
The activities of the EDCc will be supported by the project partners: SANOFI, EUPATI, EUPATI IT, EURORDIS, ACN.

8. Conclusions

This document, relative to deliverable D1.2 Expert Decision Committees establishment and management rules of FACILITATE outlined and defined the responsibilities of the three EDCs. Complying with the described actions will lead to an efficient execution of the project, avoiding misunderstandings and, as a consequence, saving time.

The document is to be updated during the project implementation, according to any modification in the workplan or of the planned research activities.

9. Repository for primary data

All the data acquired will be stored according to the Data management Plan (D1.7).
The repository for each EDC is organized in Teams: only EDC members are entitled to enter this protected space.

Annexes

ANNEX I. Invitation letter to EDCa members

To **Dr/Prof**
Institution (Country)
Mail …

Re: **FACILITATE PROJECT (H2020-IMI 2) – request for appointing a member of the Expert Decision Committee**

Dear Dr/Prof…
we write you on behalf of the Consortium FACILITATE[1] (Framework for ClinicaL trial participants' data reutilization for a fully Transparent and Ethical ecosystem). This project was recently awarded by the Horizon2020 – Innovative Medicine Initiative 2 on the topic "*Returning Clinical Trial Data to study participants within a GDPR compliant and approved ethical framework*". The project started last January the 1st, 2022, and will last for 4 years. The University of Modena and Reggio Emilia is the Project Coordinator, while SANOFI-AVENTIS RECHERCHE & DEVELOPPEMENT is the Project Leader.

FACILITATE is a project built on a patient-centred, data-driven, technological platform where an innovative data sharing and re-use process allows the returning of clinical trial data to study participants within a GDPR compliant and approved ethical framework. FACILITATE starts-off by providing clear rules in a trusted ethical, legal, and regulatory ecosystem before engaging patients as data generators. This avoids the current situation where clinical data are siloed in separate repositories without any possibility to be used beyond their original single-sided purpose.

FACILITATE will provide the technological solutions to comply with GDPR in medical research by building on the empowered stakeholders' willingness to share and re-use their data. The FACILITATE Consortium was constituted by drawing from a broad range of capacities to tackle the ambitious challenges related to future clinical trials, such as preventive, long-term, and real-world evidence trials. The Consortium took an innovative approach to the data return to study participants by asking them what they needed to be implemented to feel in a trusted ecosystem. This required all Consortium participants to leverage on their existing networks to bring together stakeholders at all levels in the decision-making chain, including patients, healthcare professionals, software designers, clinical trials repositories processors and controllers, ethicists,

[1] http://www.facilitate-project.eu/

lawyers, and other active regulators. Having obtained a consent on the data portability FACILITATE will re-use and cross-reference them with those contained in other repositories including RWE data captured across multiple settings and devices.

Its strategy represents a unique and innovative opportunity for medicines drug development and regulation to better understand the clinics of diseases, and to evaluate the effectiveness of products in the healthcare system.

Within the project activities, three Expert Decision Committees (EDCs) are established. The EDCs will support the project implementation and decision-making process by reviewing the proposed standards and providing official feedback prior to submitting for formal endorsement by regulators. The EDCs will meet at least once a year, with ad-hoc meetings for validation of standards derived from the other project activities where the Consortium will create the conceptual and ethical architecture of FACILITATE. All your expenses for travelling lodgings and meals will be covered by us.

By considering your expertise, we would like to invite you to become a member of the "Technical and Medical Expert Decision Committee". The role of the experts in clinical trials, interoperability, healthcare standards, anonymization/pseudo-anonymization, data analysis, encryption, is essential in the definition of the FACILITATE Working Prototype.

We are really counting on your support and would much appreciate your positive feedback, looking forward to hearing from you.

Best regards

Prof. Luca Pani, MD
Coordinator of FACILITATE

Dr Véronique Poinsot
Leader of FACILITATE

ANNEX II. Invitation letter to EDCb members

To **Dr/Prof**
Institution (Country)

Mail

Re: **FACILITATE PROJECT (H2020-IMI 2) – request for appointing a member of the Expert Decision Committee**

Dear Dr/Prof…,

we write you on behalf of the Consortium FACILITATE[2] (Framework for ClinicaL trial participants' data reutilization for a fully Transparent and Ethical ecosystem). This project was recently awarded by the Horizon2020 – Innovative Medicine Initiative 2 on the topic "*Returning Clinical Trial Data to study participants within a GDPR compliant and approved ethical framework*". The project started last January the 1st, 2022, and will last for 4 years. The University of Modena and Reggio Emilia is the Project Coordinator, while SANOFI-AVENTIS RECHERCHE & DEVELOPPEMENT is the Project Leader.

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We would like to invite you, to become a member of the "Ethical and Legal Expert Decision Committee". The role of the experts from the Ethical Committees is essential in the definition of the FACILITATE Working Prototype, to give feedback on the project legal and ethical standards concerning the reuse of clinical data by patients and study participants within a legal and ethical framework in compliance with the GDPR and the CTR[3] (Clinical Trial Regulations).

We are really counting on your support and would much appreciate your positive feedback, looking forward to hearing from you. If you need further details about the project and its aim, please contact the Project Management Office at pmo@facilitate-project.eu .

Best regards

Prof. Luca Pani, MD
Coordinator of FACILITATE

Dr Véronique Poinsot
Leader of FACILITATE

3 Regulation (EU) No 536/2014

ANNEX III. Invitation letter to EDCc members (Regulators)

To **Mr/Mrs/Dr/Prof**
Institution
(Country)
e-mail

Re: **FACILITATE PROJECT (H2020-IMI 2) – request for appointing a member of the Expert Decision Committee**

Dear Mr/Mrs/Dr/Prof,

we write you on behalf of the Consortium FACILITATE[4] (Framework for ClinicaL trial participants' data reutilization for a fully Transparent and Ethical ecosystem). This project was recently awarded by the Horizon2020 – Innovative Medicine Initiative 2 on the topic "*Returning Clinical Trial Data to study participants within a GDPR compliant and approved ethical framework*". The project started last January the 1st, 2022, and will last for 4 years. The University of Modena and Reggio Emilia is the Project Coordinator, while SANOFI-AVENTIS RECHERCHE & DEVELOPPEMENT is the Project Leader.
FACILITATE is a project built on a patient-centred, data-driven, technological platform where an innovative data sharing and re-use process allows the returning of clinical trial data to study participants within a GDPR compliant and approved ethical framework. FACILITATE starts-off by providing clear rules in a trusted ethical, legal and regulatory ecosystem before engaging patients as data generators. This avoids the current situation where clinical data are siloed in separate repositories without any possibility to be used beyond their original single-sided purpose.

FACILITATE will provide the technological solutions to comply with GDPR in medical research by building on the empowered stakeholders' willingness to share and re-use their data. The FACILITATE Consortium was constituted by drawing from a broad range of capacities to tackle the ambitious challenges related to future clinical trials, such as preventive, long-term and real-world evidence trials. The Consortium took an innovative approach to the data return to study participants by asking them what they needed to be implemented to feel in a trusted ecosystem. This required all Consortium participants to leverage on their existing networks to bring together stakeholders at all levels in the decision-making chain, including patients, healthcare

[4] http://www.facilitate-project.eu/

professionals, software designers, clinical trials repositories processors and controllers, ethicists, lawyers and other active regulators. Having obtained a consent on the data portability FACILITATE will re-use and cross-reference them with those contained in other repositories including RWE data captured across multiple settings and devices.

Its strategy represents a unique and innovative opportunity for medicines drug development and regulation to better understand the clinics of diseases, and to evaluate the effectiveness of products in the healthcare system.

Within the project activities, three Expert Decision Committees (EDCs) are established. The EDCs will support the project implementation and decision-making process by reviewing the proposed standards and providing official feedback prior to submitting for formal endorsement by regulators. The EDCs will meet at least once a year, with ad-hoc meetings for validation of standards derived from the other project activities where the Consortium will create the conceptual and ethical architecture of FACILITATE. All your expenses for travelling, lodgings and meals will be covered by us.

Following your previous letter of support, we would like to invite you, or any of your delegate, to become a member of the "Patients and Regulators Expert Decision Committee". The role of the Regulators is absolutely essential in the definition of the FACILITATE Working Prototype, in order to give feedback on the project legal and ethical standards concerning the reuse of clinical data by Patients and study participants before the approval of the other Authorities involved in the project, such as the Data Protection Agency.

We are really counting on your support and would much appreciate your positive feedback, looking forward to hearing from you,

Best regards

Prof. Luca Pani, MD
Coordinator of FACILITATE

Dr Véronique Poinsot
Leader of FACILITATE

ANNEX IV. Invitation letter to EDCc members (Patients)

To **Mr/Mrs/Dr/Prof**
affiliation
Mail

Re: **FACILITATE PROJECT (H2020-IMI 2) – request for appointing a member of the Expert Decision Committee**

Dear Mr/Mrs/Dr/Prof ….
we write you on behalf of the Consortium FACILITATE[5] (Framework for ClinicaL trial participants' data reutilization for a fully Transparent and Ethical ecosystem). This project was recently awarded by the Horizon2020 – Innovative Medicine Initiative 2 on the topic "*Returning Clinical Trial Data to study participants within a GDPR compliant and approved ethical framework*". The project started last January the 1st, 2022, and will last for 4 years. The University of Modena and Reggio Emilia is the Project Coordinator, while SANOFI-AVENTIS RECHERCHE & DEVELOPPEMENT is the Project Leader.

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Its strategy represents a unique and innovative opportunity for medicines drug development and regulation to better understand the clinics of diseases, and to evaluate the effectiveness of products in the healthcare system.

[5] http://www.facilitate-project.eu/

Within the project activities, three Expert Decision Committees (EDCs) are established. The EDCs will support the project implementation and decision-making process by reviewing the proposed standards and providing official feedback prior to submitting for formal endorsement by regulators. The EDCs will meet at least once a year, with ad-hoc meetings for validation of standards derived from the other project activities where the Consortium will create the conceptual and ethical architecture of FACILITATE. All your expenses for travelling, lodgings and meals will be covered by us.

Following your previous letter of support, we would like to invite you, or any of your delegate, to become a member of the "Patients and Regulators Expert Decision Committee". The role of the Regulators is absolutely essential in the definition of the FACILITATE Working Prototype, in order to give feedback on the project legal and ethical standards concerning the reuse of clinical data by Patients and study participants before the approval of the other Authorities involved in the project, such as the Data Protection Agency.

We are really counting on your support and would much appreciate your positive feedback, looking forward to hearing from you,

Best regards

Prof. Luca Pani, MD
Coordinator of FACILITATE

Dr Véronique Poinsot
Leader of FACILITATE