

IMI2 Project ID 101034366
FACILITATE

FrAmework for CLinical trlal participants daTA reutilization
for a fully Transparent and Ethical ecosystem

WP1 – Project Management
and Administration

D1.8 Scientific Advisory Board establishment and management rules

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Document History

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V0.3	04/09/2023	Approved version
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Abbreviations

ExCom: Executive Committee

GA: General Assembly

PMO: Project Management Office

SAB: Scientific Advisory Board

Summary

This deliverable, which is fundamentally based on the Consortium Agreement and the Grant Agreement, lays out the composition of the Scientific Advisory Board (SAB) and its working practises. The SAB has been established for the purpose of supporting the FACILITATE Project. This document may be updated as a working document should the composition of the SAB change.

1. Introduction

The Scientific Advisory Board (SAB) is a consultative body established to provide advice directly to the ExCom on specific areas related to the project. It is composed of 3 senior experts external to the consortium.

SAB follows the project development and provides necessary feedback in order to ensure that the scientific and technological evolution of the project is in the direction to fulfil its goals, and provides an external global viewpoint to ensure that the project's research and development targets and activities are appropriate for producing significant advancements beyond the state-of-the-art. In addition, the members will be invited to review any of the deliverables of interest to them during each year's reporting period and to offer their views, ideas, and solutions. The Board will participate at least once a year in a project meeting or review.

2. SAB scope and responsibilities

The Advisory Board is foreseen to consist of experts from other international initiatives and representatives or coordinators of related EU or international projects as well as experts from clinical or technical sciences.

Its main task is to give advice to the GA and/or to the ExCom. The advice is to be taken into account when preparing the deliverables or other relevant documents. It will be convened by the Project Coordinator and chaired by an elected Chair. SAB members can be invited to project meetings when relevant.

Annual meetings are foreseen, but the Advisory Board can meet more often per year if required.

The role of the Advisory Board is described in the Grant Agreement under Section 3.2 Management Structure.

3. Setting up the composition of the SAB

The SAB is composed of three members.

For the selection of the SAB candidates, the following criteria have been applied:

- Longstanding and specific experience
- Interest in FACILITATE topics
- Provides valuable input
- Ready to provide honest feedback
- Sounding board function
- Is available to attend meetings and keep up-to-date with the project

- Is reliable
- Broad knowledge across disciplines
- Organisation not associated to FACILITATE
- Helicopter view/bird's eye perspective on the programme

Any Partner had the rights to submit nominations for the SAB to the PMO. The PMO, ensured the composition of the SAB is appropriate to provide the guidance required to achieve Action goals.

Following the discussion within the PMO, and the preliminary agreement on the potential list of members, the Coordinator invited formally those persons, by sending them an official letter (Annex I).

4. FACILITATE Scientific Advisory Board

No.	Member	Expertise
1	Prof. Giovanna Zamboni (female) Organization: University of Modena and Reggio Emilia Country: Italy Email: giovanna.zamboni@unimore.it	Giobvanna Zamboni is Associate Professor of Neurology at the University of Modena and Reggio Emilia, Italy. She is also a practicing neurologist with expertise in cognitive disorders and dementia. Her research work has focussed on the use of MRI-based imaging techniques in combination with neuropsychology and subtle clinical and biomarker characterisation to study brain changes that occur in dementing neurodegenerative diseases, with the aim of identifying those that occur preclinically (i.e., before the onset of dementia) and those that may change in response to treatment. She is the grant fellow of the ERC STG, No. 101042625, UnaWireD “Anosognosia and delusions in the diseased brain”
2	Adv. Giorgia Masina (female) Organization: Studio Legale Masina Country: Italy Email: giorgia.masina@studiomasina.com	Giorgia Masina has been advising on data protection since 2003. She is the founder of Studio Legale Masina (2017), a boutique firm that is specialized manly in data protection in the health sector (electronic medical record, online reporting, customer satisfaction surveys, e-Health, mobile-Health, scientific research in the medical field and clinical trials, genetic data and biological samples for the creation of biobanks). Giorgia is also a leading advisor on data protection for public bodies (Universities), financial and insurance firms as well as for online and media providers.
3	Prof. Emanuele Di Angelantonio (male) Organization: Human Technopole Country: Italy	Emanuele Di Angelantonio is Head of the Health Data Science Centre at the Human Technopole and Professor of Clinical Epidemiology at the Department of Public Health and Primary Care of

Email: emanuele.diangelantonio@fht.org	the University of Cambridge. Emanuele deals with "big data" analyzes applied to the study of chronic diseases, blood donors, and cardiovascular risk prediction. After graduating in medicine and specializing in internal medicine in Italy and France, he obtained a master's degree in medical statistics from the London School of Hygiene and Tropical Medicine and a PhD in epidemiology from the University of Cambridge. Throughout his career he has held senior positions at the University of Cambridge, NHS Blood and Transplant, the European Society of Cardiology (ESC), and the World Health Organization (WHO).
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5. Governing rules

The following Governing rules have been approved by the PMO, agreed with other partners involved in T1.5.

5.1 Duties of the SAB

The SAB 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 decision making support.

5.2 Meetings of the SAB

Each SAB member will meet upon request of the Project Management Office but at least once every twelve (12) months during the Action. Meetings are organized in presence or via *ad hoc* teleconferences. All SAB meetings will be based on an agreed agenda to ensure efficient decision-making. Relevant documents should be circulated beforehand to allow for adequate preparation.

Meetings of the SAB will be attended by:

- SAB members
- Further invited participants (where appropriate)

Only SAB members have voting rights. Decisions will be taken by simple majority.

SAB members can be invited to attend the GA, or ExCom meeting, when appropriate.

5.3 Organization of the activities

The SAB uses 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.

5.4 Duties and rights of the SAB member

SAB members have to declare potential conflicts of interest. Where issues are discussed that may involve a conflict of interest, the affected member shall recuse herself/himself from the discussion. Conflicts of interest will be noted in the minutes of the relevant meeting.

Prior to their first participation in a meeting of an SAB 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.

Each member shall be entitled to reimbursement of travel expenses in accordance with the Financial Regulations of the Consortium.

6. General Management Roles

FACILITATE adopts a governance model that promotes the active participation of all involved stakeholders, including patients, academia and EFPIA partners as well as other stakeholders such as pharmaceutical companies, regulators, CROs, etc. with the objective to achieve maximum collaboration. The management structure of FACILITATE has been developed to respond to the needs of an international multistakeholder project. It is based on a traditional management structure adapted to the attributes of FACILITATE.

FACILITATE is a challenging project to manage due to its transformative ambition of a complex and heterogeneous legal, ethical and regulatory environment across Member States, and the variety of activities and their interdependencies. The project aims to harmonise the interests of the public and EFPIA partners with a specific focus on patients' needs and expectations, therefore a strong internal trust and communication interface is crucial to set the project up for success.

The project is composed of complementary, as well as parallel activities, with strong dependencies between critical work packages outputs. This implies a detailed time schedule for many of the tasks, which is closely monitored and communicated between team members to avoid bottlenecks and to allow effective completion of tasks, milestones and their subsequent deliverables.

The management structure is set up with the objective to provide a balance between the ability to address the complexity of the project and an efficient management structure that will avoid creating a high amount of bureaucracy that would consume resources outside of the key focuses of the project. As a conclusion, the management structure proposed for FACILITATE is based on a multi-level organisational structure that balances:

- The fulfilment of the work plan.
- The management of trade-offs affecting scope, quality, time and cost.
- The primary focus is needed on critical activities that aim to ensure the achievement of milestones and that contribute to strategic objectives.

- The relationships and trust among partners, including conflict resolution.
- The quality and efficiency with which the project activities are carried out.
- The appropriate implementation of the Consortium Agreement, with special attention to the governance procedures, intellectual property management and the related use of results.
- The implementation of the Grant Agreement, including administrative and financial elements.

7. Conclusions

In this deliverable the FACILITATE SAB is defined and the roles established. 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 of the workplan or of the planned research activities.

ANNEX I. Official invitation letter for the SAB members

To
Mail

Re: **FACILITATE PROJECT (H2020-IMI-2) – request for appointing a member of the Scientific Advisory Board**

Dear ...

we write to you on behalf of the Consortium FACILITATE (Framework for Clinical trial participants' data reutilization for a fully Transparent and Ethical ecosystem; <http://www.facilitate-project.eu/>). This project has been 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.

Considering your experience in the ... project, we would like to know if you or someone in your Consortium in your Consortium would be willing to become a member of the FACILITATE Scientific Advisory Board. The mission of this board, consisting of three to five members, is to provide feedback to ensure that the scientific and technological evolution of the project is in the direction to fulfil its goals. The board should also provide an external global viewpoint to ensure that the project's research and development targets and activities are appropriate for producing significant advancements beyond the state-of-the-art.

It would be great if you could support us.

If you need further details about the project and its aim, please contact the Project Management Office at pmo@facilitate-project.eu.

Looking forward to hearing from you

Best regards