



Dreams

DREAMS project

[D.8.5.] Creation of the Ethical Board

Project Founded by the European Commission

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Contributors	Organization	Reviewers	Organization
Laura Brullé-Soumaré	CECS	Segolene Martin	Kantify
		Alexandre Mejat	AFM
		Xavier Nissan	CECS
		Ane Garcia	Zabala
		Marina Ruilope	Zabala
		Juliette Peterka	AFM

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List of Abbreviations

TERM	DEFINITION
EU	European Union
EB	Ethical Board
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
PC	Project Coordinator

1 Organisation of the Ethical Board (EB)

1.1 Chairmanship & membership

The Ethical Board (EB) will be led by the Coordinator CECS together with AFM and Kantify and will be responsible of key ethical aspects of the DREAMS project such as: scientific, technical, patients and AI tools. The Project Coordinator (PC), CECS, will chair the EB.

The EB will be formed by at least one representative of CECS, AFM and Kantify and an independent external expert, according to the rules provided in section 1.2.

1.2 Members and participation

Participation to the EB is voluntary and only applies to Consortium Members whose project contribution is related to ethics. It is not mandatory for Consortium Members to participate in the activities of the EB unless their tasks are directly associated with ethical considerations.

The following rules apply:

- One Consortium Member, if it considers to be involved in the EB, will be entitled to propose 2 participants: one official EB member and one EB observer.
- One external expert from Ecole Nationale Veterinaire Alfort (ENVA), Geneviève Marignac, for animal welfare aspects.
- Only the official EB members and the external expert will have a voice in case of a consensus discussion or a vote.
- Depending on the topic, one or several members can request the participation of an expert who will participate in the specific agenda item discussion for which he/she has been asked to join. The member requesting the participation of the expert will ensure that this person is bound to the same confidentiality rules as the requesting member itself.

Table 1. DREAMS Ethical Board members

DREAMS Partner Organization	EB member	EB observer (not compulsory)
CECS	Xavier NISSAN	Laura BRULLE-SOUMARE
KANTIFY (Meetsies SA)	Segolene MARTIN	Nik SUBRAMANIAN
AFM (Association Française Contre Les Myopathies)	Alexandre MEJAT	Wael KHAZEN

Geneviève Marignac, the EB's external ethics expert, is a senior lecturer, with over 20 years expertise in the field of veterinary Dermatology. After specializations in Health Ethics, she is now in charge of lecturing in Ethics and Law at Alfort Veterinary School (Ecole Nationale Veterinaire Alfort (ENVA), France).

1.3 Meeting frequency

All members of the consortium via the coordinator can solicit the EB by email if any issue regarding ethics occurs during the course of the project. If necessary and after consultation between Members of the board (CECS, AFM and Kantify), the EB will be scheduled by the project Coordinator (PC).

- Meetings can be held in person or via teleconference, depending on the circumstances.

- Meetings will be convened at least within 7 calendar days.

1.4 Decision making

Decisions are made on a consensus basis. In the absence of consensus, the Chair may call a vote, requiring a majority to pass.

1.5 Minutes

Minutes of the Ethical Board meetings, once accepted, shall be sent by the Coordinator to the General Assembly for information and/or validation.

2 Missions and obligations of the Ethical Board members

2.1 Missions

The Ethical Board will be mainly a consultation board and its mission will be to guide, assist and provide advice to the Consortium, especially the technical partners in key ethical issues related to the project, like the pre-clinical studies, patient related aspects and AI tools.

2.2 Key obligations of EB members

2.2.1 Transparency and Accountability

EB Members are responsible for ensuring transparency and accountability in the review process. This includes maintaining accurate records of review activities, decisions, and communications, as well as providing clear explanations of decisions to researchers and participants.

2.2.2 Responsibility of EB Members

By appointing a representative to the EB, each Consortium Member ensures that its representative will respect and adhere to the confidentiality obligations applicable to all members of the consortium. These obligations, as described in the projects Consortium Agreement include:

- Maintaining the confidentiality of discussions, decisions, and documents related to the EB meetings.
- Ensuring that any confidential information obtained through participation in the EB is not disclosed to unauthorized individuals or used for any purpose outside the scope of the project.

Mrs. Geneviève Marignac, appointed by Ecole Nationale Veterinaire Alfort (ENVA), as external expert of the EB undertakes to sign the confidentiality agreement in the same terms as described in the Consortium Agreement and in this section.