Dreams

Drug REpurposing with Artificial intelligence for Muscular disorderS

[D8.1] Quality Report

Project Founded by the European Commission		
DISSEMINATION LEVEL		
PU	Public	☒
SEN	Sensitive	☐

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Contributing partners	Zabala
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List of Abbreviations

TERM	DEFINITION
AP	Associated partners
BEN	Beneficiary
CFS	Certificate on the Final Statement
D	Deliverable
DMP	Data Management Plan

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DoA	Description of the action
EB	Ethical Board
EC	European Commission
EU	European Union
GA	Grant Agreement
IEB	Innovation & Exploitation Board
IPR	Intellectual Properties Rights
NDA	Non-Disclosure Agreement
PAB	Patient Advisory Board
PC	Project Coordinator
PTC	Project Technical Committee
QA	Quality Assurance
RP	Reporting Period
WP	Work Package

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1 INTRODUCTION

1.1 Purpose

The aim of DREAMS' quality report Handbook is to set quality assurance (QA) guidelines and procedures for supervising the technical implementation of the project, ensuring not only efficient and timely implementation of tasks, but also that high quality standards are met.
This document summarises all the required knowledge for the good management of the documentation of the project and contains all information related to the management strategy, structure of the consortium, reporting issues, templates to be used, publication procedures, etc. Furthermore, the purpose of this guide is to clarify legal and financial aspects of the Grant Agreement and Consortium Agreement that may need further explanations to beneficiaries.
This Handbook is a 'living' document and can be modified according to the project needs. This document will be updated and extended, if needed, through the lifecycle of DREAMS project, including relevant issues and changes in the project or procedures. Every time the document is updated, all the partners will be duly informed about the updates and the changes made with respect to the previous version.

1.2 Relation to other project documents

In the event of discrepancy between documents, this Handbook is overruled by the Grant Agreement (GA) including its Annexes and the Consortium Agreement.

2 PROJECT BASIS

2.1 Participants

The beneficiaries or Project Participants of DREAMS are listed in the GA, in the Consortium Agreement, and presented in the next list:

Table 1. List of participants

Number	Role	Short Name	Legal Name	Country
1	COO	CECS	CENTRE D'ETUDE DES CELLULES SOUCHES	FR
2	BEN	KANTIFY	MEETSIES SA	BE
3	BEN	UC	UNIVERSIDADE DE COIMBRA	PT
4	BEN	INSERM	INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE	FR
5	BEN	APHP	ASSISTANCE PUBLIQUE HOPITAUX DE PARIS	FR
6	BEN	TECHNION	TECHNION - ISRAEL INSTITUTE OF TECHNOLOGY	IL
7	BEN	AFM	ASS FRANCAISE CONTRE LES MYOPATHIES	FR
8	BEN	ZABALA	ZABALA INNOVATION CONSULTING SA	ES
9	AP	SAMSARA	SAMSARA THERAPEUTICS LTD	UK

An updated list of contacts is available in DREAMS MS Teams Repository, under the *WP8.Project Management* folder. New contacts, changes and / or corrections to the list of contacts should be addressed to ZABALA in order to keep updated the contact details of beneficiaries involved.

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2.2 Grant agreement

Grant Agreement No. 101080229– DREAMS and the following annexes form an integral part of the Grant Agreement (GA):

- Annex 1 Description of the action (DoA)
- Annex 2 Estimated budget for the action
- Annex 2a Additional information on unit costs and contributions
- Annex 3 Accession Form
- Annex 4 Model for the financial statements
- Annex 5 Specific rules

The Grant Agreement and its annexes are available in the DREAMS MS Teams Repository under folder named "*WP8.Project Management*".

3 PROJECT STRUCTURE

The overall plan of the DREAM project follows the tasks, activities, schedule and budget as laid down in the Description of the Action - DoA. The guiding point of reference of all work and planning are the deliverables due to the EC along the 4 Reporting Periods (RP) of DREAMS.

3.1 Work packages list/overview

DREAMS is a 60-month project organized in 8 Work packages, with the structure and relations between Work Packages described in DoA and the Figure below:

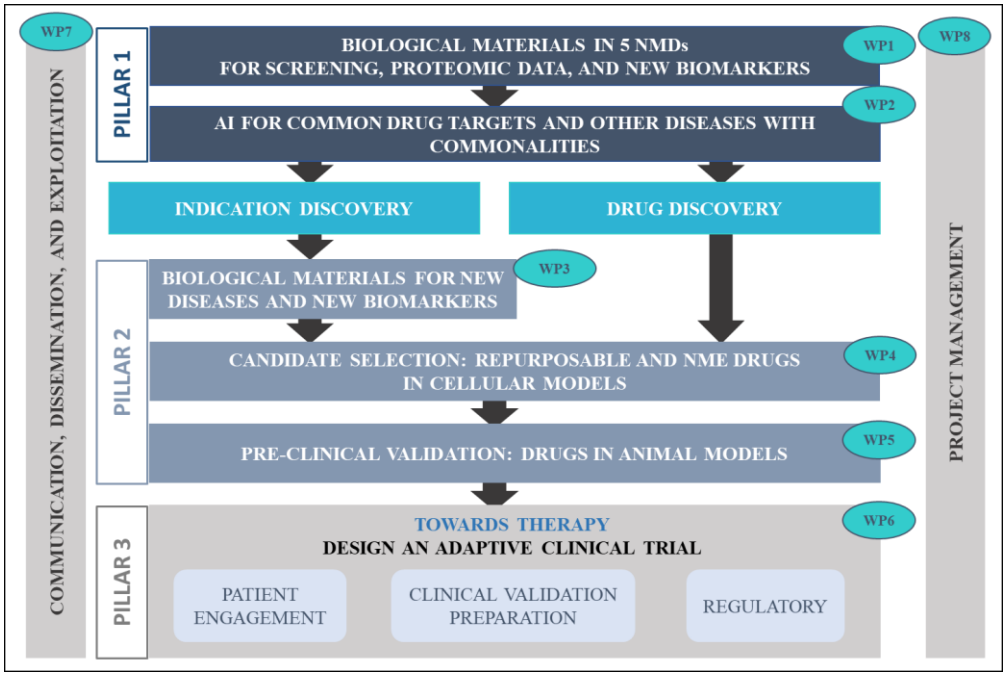

Figure 1. Structure of DREAMS WPs

The main characteristic of each of the 8 Work Packages in which the project is structured are the following:

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Table 2. Characteristics of the WPs

Num.	Title	Lead Beneficiary	Effort (Person-months)	Start Month	End Month
WP1	Biological Materials in 5 NMDs for Screening, Proteomic Data, and New Biomarkers	1-CECS	237.00	1	36
WP2	AI for Common Drug Targets and Other Diseases with Commonalities	2-KANTIFY	124.00	1	36
WP3	Biological Materials for New Diseases and New Biomarkers	3-UC	93.00	36	48
WP4	Candidate Selection: Repurposable and NME Drugs in Cellular Models	2-KANTIFY	173.00	36	48
WP5	Pre-Clinical Validation: Drugs in Animal Models	4-INSERM	87.5	37	60
WP6	Towards Therapy: Design an Adaptive Clinical Trial	7-AFM	78.25	1	60
WP7	Communication, Dissemination, and Exploitation	8-ZABALA	72.00	1	60
WP8	Project Management	1-CECS	62.00	1	60
TOTAL			926.75	1	60

Each Work Package has its own WP leader whose responsibility is the completion of the work described for his/her Work Package in Annex I of the Description of the Action (DoA).

Table 3. Participants on each WP (Leaders and other participants).

Num.	Title	Lead Beneficiary	Other participants
WP1	Biological Materials in 5 NMDs for Screening, Proteomic Data, and New Biomarkers	1-CECS	INSERM, UC, SAMSARA, TECHNION, APHP,
WP2	AI for Common Drug Targets and Other Diseases with Commonalities	2-KANTIFY	ALL PARTNERS
WP3	Biological Materials for New Diseases and New Biomarkers	3-UC	CECS,
WP4	Candidate Selection: Repurposable and NME Drugs in Cellular Models	2-KANTIFY	UC, TECHNION, CECS, INSERM, SAMSARA
WP5	Pre-Clinical Validation: Drugs in Animal Models	4-INSERM	TECHNION,
WP6	Towards Therapy: Design an Adaptive Clinical Trial	7-AFM	APHP, KANTIFY
WP7	Communication, Dissemination, and Exploitation	8-ZABALA	ALL PARTNERS
WP8	Project Management	1-CECS	ALL PARTNERS

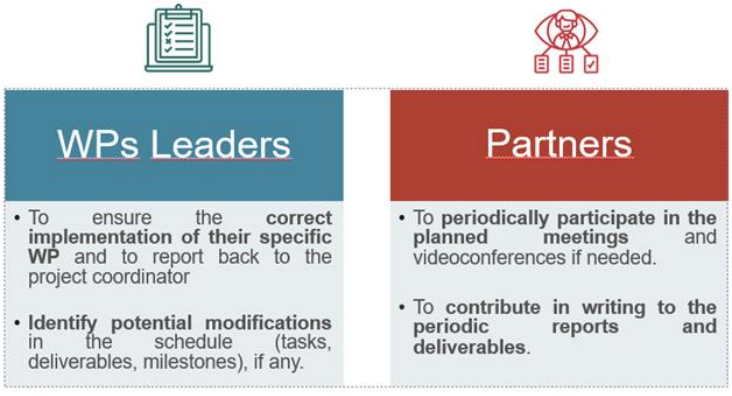

Figure 2. Requirements for partners according to their role in the project.

3.2 Project duration

The effective start of the DREAM project is 01/11/2023, and the project ends 60 months later, on 31/10/2028.

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3.3 Budget

The estimated budget for the action is **6.952.110,00€** and the maximum grant amount for the project is 6.952.110,00€, as set out in Annex 2 to the Grant Agreement. The budget distribution per partner per cost for the implementation of the project is also detailed in Annex 2.

4 PROJECT REPORTING OBLIGATION

Monitoring the project implementation is a continuous task that takes place at any moment during the active period and beyond. There are contractual tasks that make the project monitoring most relevant at certain periods in project´s life, in particular after each RP at the time of payments and concerning the submission of the deliverables.

4.1 Periodic Reports

After the end of each interim period, a Periodic Report shall be submitted to the EC. In DREAMS, four Periodic Reports shall be submitted, as detailed in the table below:

Table 4. Periodic report dates and deadlines.

Periodic report	From	To	Report submission deadline
1	M1 (01/11/2023)	M18 (30/04/2025)	End Jun 2025
2	M19 (01/05/2025)	M36 (31/10/2026)	End Dec 2026
3	M37 (01/11/2026)	M48 (31/10/2027)	End Dec 2027
4 (Final)	M49 (01/11/2027)	M60 (31/10/2028)	End Dec 2028

The three Periodic Reports and the Final report shall be submitted to the EC by the Project Coordinator (PC) within **60 days after** the end of the RP. The Periodic Report should be prepared by the consortium participants together and submitted by the PC (see section 4.2).

At the end of each RP, the EC shall evaluate and approve project reports and deliverables and distribute the corresponding **payments within 90 days** of their receipt. In the case that the EC requests any further information, clarification or documentation on the Periodic Report, the time of 90 days will be stopped from the EC side restarting the count-down upon reception of requested information.

4.2 Content of Periodic Reports

The content of the Periodic Reports is compulsory and determined by the EC in accordance Article 21.2 of the Grant Agreement. A template of the **Periodic Report** will be available at DREAMS MS Teams Repository before the reporting period starts (see folder “Project Templates and Logo<Project Templates<Reporting templates”).

The **structure of the Periodic Report** contains the technical and financial report:

Technical report, containing:

- An explanation of the work carried out by the beneficiaries.
- And overview of the progress towards the objectives of the action, including milestones, and deliverables identified in Annex 1, Part B.
- A summary for publication by the EC.

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- Questionnaire covering issues related to the action implementation and the economic and societal impact.

Regarding the Technical Report, on the one hand, **Part A** comprises a summary with project information and will be filled direct in the F&T portal. On the other hand, **Part B or Report Core** comprises the narrative that includes explanations of the work carried out by the beneficiaries during the reporting period and will be upload as PDF by electronic submission.

Financial Report, containing:

- An "individual financial statement" from each beneficiary
- An explanation of the use of the resources and the information on subcontracting and in-kind contributions provided by third parties (if applicable) from each beneficiary.
- A "periodic summary financial statement" (see Annex 4 of the Grant Agreement), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and the request for interim payment.
- Detailed cost reporting table.

The content of the different parts of the Periodic Reports is detailed below in the following figure:

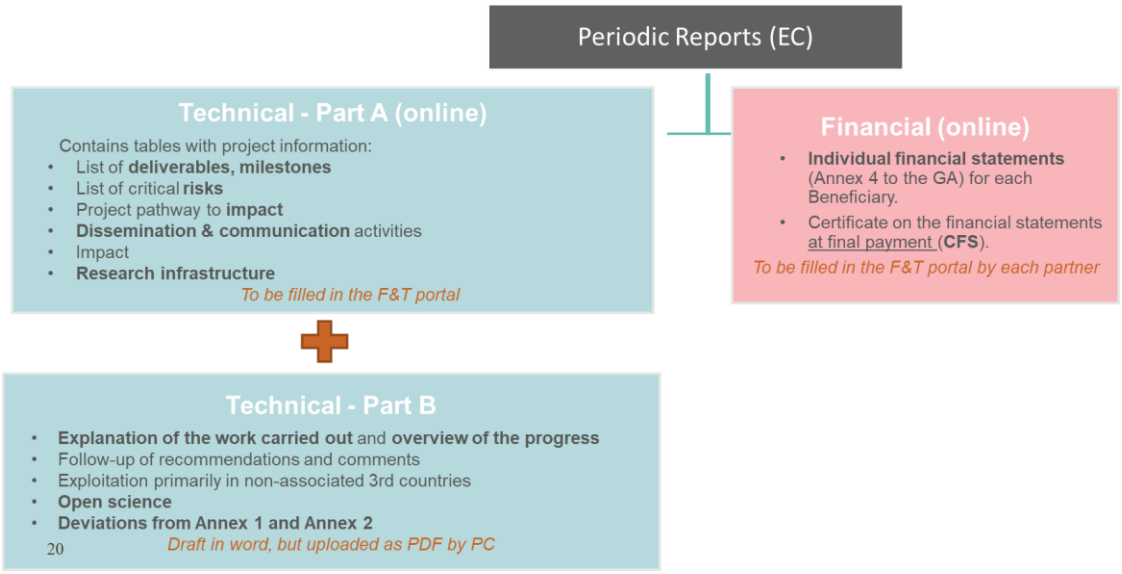

Figure 3. Content of the Periodic Report (Technical Part A & Part B, and Financial)

4.3 Electronic submission of Periodic Report

All participants should contribute to the technical part of the Periodic Report, but it is the Project Coordinator (PC), supported by Zabala, who will have to submit it as a single report. The PC will use the electronic exchange system according to Article 36.1 of the Grant Agreement.

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4.4 Data collection from beneficiaries and roles

For the preparation of the Periodic Reports technical and financial inputs are necessary from beneficiaries.

Technical Information

The process for collecting and preparing this information is detailed bellow:

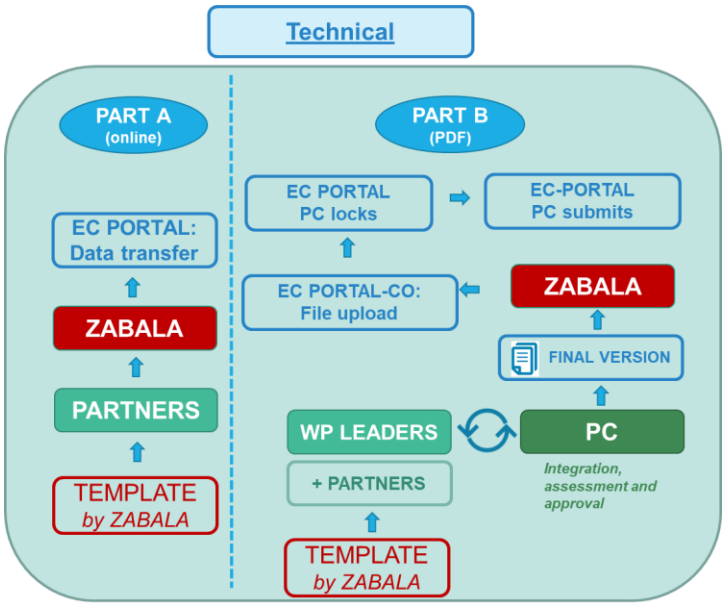

Figure 4. Technical information – workflow

The PC of DREAMS is Dr. Xavier Nissan from CECS and together with ZABALA will launch the process of **collecting technical inputs** for the technical report at the **end of M18** (30/04/2025), **M36** (31/10/2026), **M48** (31/10/2027) and **M60** (31/10/2028). All the process for collecting and preparing this information will be supervised by Zabala.

On the one hand, each beneficiary will fill in the technical Part A template provided by Zabala. Then, Zabala will check that the data provided is correct and duly explained.

On the other hand, each WP leaders, in collaboration of the partners participating in that WP, will fill in the technical Part B template provided by Zabala with a narrative description of the work carried out in each WP during the reporting period. Afterwards, Zabala will review and bring together all the narrative descriptions of each WP in a single report, **that should be assessed and approved** by both the PC and WP leaders.

Finally, once a Final version of the Part B report is available, **Zabala will be responsible for the upload submission of the complete Periodic Report.**

Financial Information

The process for collecting and preparing these inputs will be supervised by Zabala and is detailed bellow:

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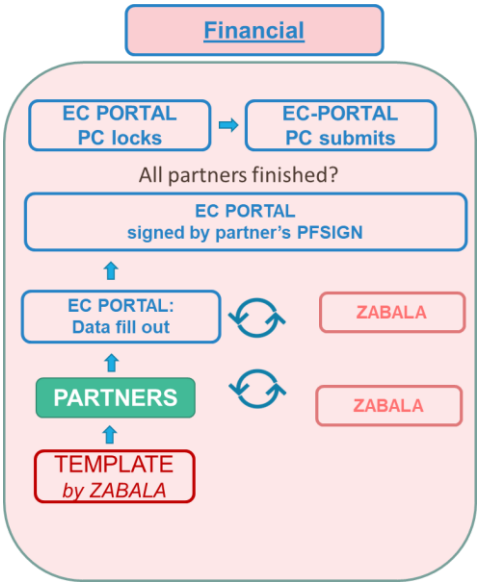

Figure 5. Financial information – workflow

The PC/ Zabala will launch the process of **collecting technical inputs** for the Technical Report at the **end of M18** (30/04/2025), **M36** (31/10/2026), **M48** (31/10/2027) and **M60** (31/10/2028) for verification.

Each beneficiary will fill in the financial template provided by Zabala, and the explanation of the costs and deviations incurred during the period. Then, Zabala will check that all costs declared are correct and duly explained.

Afterwards, each beneficiary will fill in the online application, comprising the individual financial statement and an explanation of use of resources. A beneficiary may request the PC to fill the financial statement on his behalf and the required information will be filled in by Zabala.

Only at the end of the project, **In the FINAL** report, and if it is required, the beneficiary should prepare the Certificate on the Final Statement (CFS) (further detail in Section 8.5). In this stage, Zabala will check that CFS are aligned with EC requirements.

Later, **the Individual Financial Statements of each beneficiary shall be signed** electronically by the corresponding **Project Financial Signatories (PFSIGN)** appointed by each organization.

Finally, once all individual Financial Statements are signed by all the beneficiaries, **the PC will be responsible for the submission of the complete Periodic Report.**

As a summary, the liabilities of the beneficiaries regarding the Periodic Technical and Financial Reports are the following:

Table 5. Summary of inputs and deadlines for the periodic reports.

REPORT	WHO	WHAT	WHEN (to PC)
TECHNICAL REPORT	Work Package Leader	WP Progress report within the period	▫ **M18** (30/04/2025) ▫ **M36** (31/10/2026) ▫ **M48** (31/10/2027) ▫ **M60** (31/10/2028)

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TECHNICAL REPORT	All the partners	Estimation of resources	▫ **M18** (30/04/2025) ▫ **M36** (31/10/2026) ▫ **M48** (31/10/2027) ▫ **M60** (31/10/2028)
FINANCIAL REPORT	Beneficiaries	Cost statement	▫ **M18** (30/04/2025) ▫ **M36** (31/10/2026) ▫ **M48** (31/10/2027) ▫ **M60** (31/10/2028)
FINANCIAL REPORT	Beneficiaries	Model for the financial Statements	▫ **M18** (30/04/2025) ▫ **M36** (31/10/2026) ▫ **M48** (31/10/2027) ▫ **M60** (31/10/2028)
		Certificate on Financial Statements (if required)	▫ **M60** (31/10/2028)

4.5 Deliverables

The list of deliverables for the DREAMS project is included in the table below, ordered by work package:

Table 6. List of deliverables.

WP No.	D No.	Deliverable Name	Lead beneficiary	Type	Dissemination level	Due month	Due date
WP1	D1.1	Characterization and Quality control of iPSC lines and myogenic derivatives. I	1 - CECS	R	PU	8	30 Jun 2024
WP1	D1.2	Characterization and Quality control of iPSC lines and myogenic derivatives. II	1 - CECS	R	PU	18	30 Apr 2025
WP1	D1.3	Bioassays and SOPs to assess autophagy dysregulation	9 - SAMSARA	R	PU	24	31 Oct 2025
WP1	D1.4	Bioassays and SOPs to measure additional pathological phenotypes	4 - INSERM	R	PU	36	31 Oct 2026
WP1	D1.5	Genes and proteins dysregulated	1 - CECS	R	PU	36	31 Oct 2026
WP1	D1.6	Drug doses for phenotype rescuing	1 - CECS	R	PU	36	31 Oct 2026
WP2	D2.1	Report on the collection of public and private data	2 - KANTIFY	R	SEN	18	30 Apr 2025
WP2	D2.2	AI algorithm improvements	2 - KANTIFY	OTHER	SEN	24	31 Oct 2025
WP2	D2.3	Target analysis	2 - KANTIFY	R	SEN	36	31 Oct 2026
WP2	D2.4	Extended indications	2 - KANTIFY	R	SEN	36	31 Oct 2026
WP3	D3.1	Report on extra indications cellular models	3-UC	R	SEN	44	30 Jun 2027
WP3	D3.2	Drugs rescue in extra indications	3-UC	R	SEN	48	31 Oct 2027
WP4	D4.1	List of Therapy and NME Candidates	2 - KANTIFY	R	SEN	42	30 Apr 2027
WP4	D4.2	Characterization of a selected list of drugs and their predicted MOA	1 - CECS	R	SEN	48	31 Oct 2027
WP5	D5.1	In vivo safety assessment of the drug candidates	4 - INSERM	R	SEN	56	30 Jun 2028
WP5	D5.2	Preclinical evaluation of the drug candidates on autophagy function	4 - INSERM	R	SEN	60	31 Oct 2028

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		and functional dysregulated phenotypes					
WP6	D6.1	Consent form preparation involving patients	7 - AFM	R	PU	3	31 Jan 2024
WP6	D6.2	Innovative clinical trial design	7 - AFM	R	PU	24	31 Oct 2025
WP6	D6.3	European Medicines Agency (EMA) validation	7 - AFM	R	PU	54	30 Apr 2028
WP6	D6.4	Regulatory and ethics approval for blood sample collection	7 - AFM	R	PU	3	31 Jan 2024
WP7	D7.1	Plan for the Exploitation, Communication and Dissemination of Results	8 - ZABALA	R	PU	3	31 Jan 2024
WP7	D7.2	Report on communication and dissemination activities. I	8 - ZABALA	R	PU	18	30 Apr 2025
WP7	D7.3	Report on communication and dissemination activities. II	8 - ZABALA	R	PU	36	31 Oct 2026
WP7	D7.4	Report on communication and dissemination activities. III	8 - ZABALA	R	PU	48	31 Oct 2027
WP7	D7.5	Report on communication and dissemination activities. IV	8 - ZABALA	R	PU	60	31 Oct 2028
WP7	D7.6	Articles and Guidelines	7 - AFM	R	PU	54	30 Apr 2028
WP7	D7.7	Dossier for exploitation, business, and future plans	8 - ZABALA	R	PU	60	31 Oct 2028
WP7	D7.8	Project Website	8 - ZABALA	OTHER	PU	3	31 Jan 2024
WP8	D8.1	Quality Report	1 - CECS	DMP	PU	6	30 Apr 2024
WP8	D8.2	Data Management Plan (DMP) and updated version at each RP.	1 - CECS	OTHER	PU	6	30 Apr 2024
WP8	D8.3	Creation of the EAB	1 - CECS	OTHER	PU	3	31 Jan 2024
WP8	D8.4	Creation of The Patient Advisory Board	7 - AFM	OTHER	PU	6	30 Apr 2024
WP8	D8.5	Creation of the Ethical Board	1- CECS	OTHER	PU	6	30 Apr 2024
WP8	D8.6	Creation of the Innovation and Exploitation Board	2 - KANTIFY	OTHER	PU	6	30 Apr 2024

TYPE codes: R = Document, report // OTHER // DMP = Data Management Plan.
DISSEMINATION LEVEL codes: PU = Public // SEN = Sensitive.
DUE DATE: Month in which the deliverables will be available, understanding that the deadline for submission is the last day of the month indicated.

Each deliverable has usually a main contributor (Lead Beneficiary on the table above), which is also the person responsible for the deliverable. This responsibility is always shared with the WP leader who is responsible for the work in the Work package (including the deliverables).

In order to have the best quality in the deliverables to be prepared, the inputs to the report have to be original (whenever possible), not extracted or copied from other sources of information. Nevertheless, information taken from other sources could be valid and valuable for some deliverables, but in these cases, it is necessary to explicitly refer to the source from which the information has been taken.

Regarding the role of the responsible of each deliverable, it is important to take into account that its responsibility goes beyond to a simple coordination of the process and/or gathering inputs from other participants in the task. In this sense, the responsible of each deliverable is expected to be very active in contributing to the deliverable as well as in giving the necessary coherence for a good quality level. WP

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leaders are also expected to have a leading role in the elaboration of each deliverable, as each WP leader is the first responsible for the quality of the deliverables generated within each WP.

4.6 Submission of deliverables

During the course of the project, the deliverables identified in Annex I to the Grant Agreement have to be submitted according to the timetable specified in the deliverables list (in Section 4.5).

All deliverables have to be submitted electronically to the Commission through the SyGMA electronic system in the Participant Portal and the PC, supported by Zabala will be the person responsible for this uploading.

4.7 Deliverable data collection from beneficiaries and roles

For the preparation of the deliverables, technical information and main resources are necessary from beneficiaries. The process for collecting these inputs is detailed bellow:

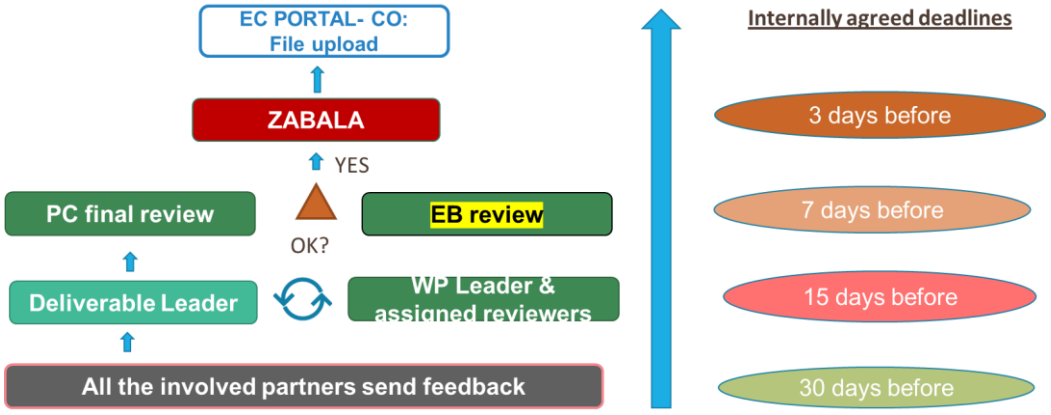

Figure 6. Deliverable data collection - workflow

Initially, Zabala, in representation of the PC, will remind for internal technical reporting to all beneficiaries involved in the deliverable, 30 days before the deliverable submission deadline.
Each beneficiary will provide its individual internal inputs corresponding to the deliverable leader at least 15 days in advance of the submission date of the deliverable to the Commission.

Then, the deliverable leader will prepare the deliverable report bringing together all the individual inputs in a single draft document. This draft document should be sent to the PC for review, at least 7 days prior to the submission deadline and later to Zabala, at least 3 days prior to the submission deadline. (further detail in section 8.3). The Ethical Board (EB) will also be consulted at least 7 days prior to the deadline, if necessary.

It is important that deadlines are respected. In case of delay, the partner responsible for the delivery will inform the PC as soon as possible in order to find a solution.

4.8 Continuous reporting

Apart from the project reporting obligations, the EC activates a Continuous reporting module via the electronic exchange system (SyGMA) at the time the project starts.

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This module makes available the electronic submission of Deliverables plus Periodic Reporting information that can be optionally entered at any time during the life of the project such as:

- Publishable summary
- Submit deliverables
- Report progress in achieving milestones
- Follow up critical risks
- Questionnaire on horizontal issues
- Publications
- Communications activities
- Rest of questionnaire on horizontal issues

The PC, supported by Zabala, will be responsible for completing the continuous reporting via the exchange tool system (SyGMA) with the Commission via the Participant Portal.

5 GOVERNANCE STRUCTURE

The DREAMS consortium will follow the organisational structure is shown in the following figure:

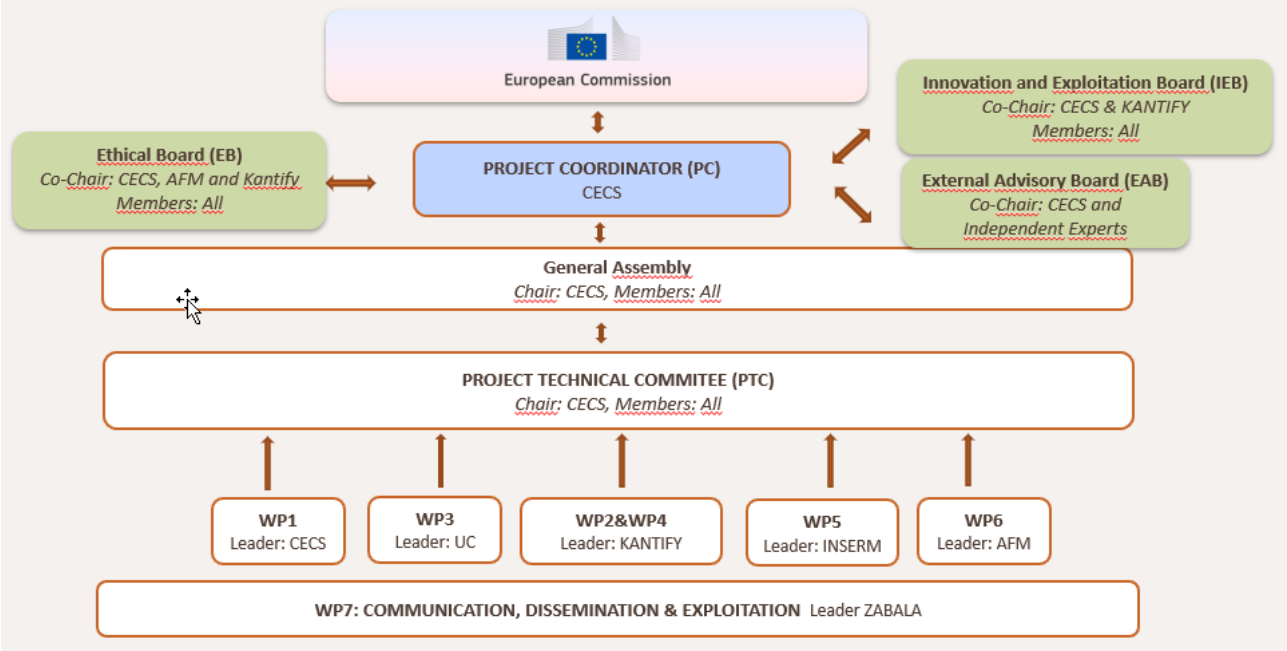

Figure 7. Governance structure

DREAMS' Governance structure comprises the following **Consortium Bodies:**

- General Assembly
- Project Technical Committee (PTC)
- External Advisory Board (EAB)
- Innovation & Exploitation Board (IEB)
- Patient Advisory Board (PAB)
- Ethical Board (EB)

And the following **figures:**

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- Project Coordinator (PC)
- Work Package Leaders (WP)

5.1 General Assembly

The General Assembly will be formed by an empowered representative of each of the members of the consortium and chaired by the PC (Dr. Xavier Nissan from CECS).

The General Assembly will be responsible for the "major decisions" affecting the implementation and success of the project such as finances and intellectual property rights, evolution of the consortium… etc. The following decisions shall be taken in the General Assembly:

- Any major change in the nature of the project including starting or stopping it to conduct a particular part of the project.
- Making proposals for the review or amendment of the terms of the Grant Agreement.
- General assessment and approval of the periodic activity and management reports that the EC might request.
- The preparation of the Budget and any proposed amendments therein.
- The preparation and adoption of the annual budgets and any proposed amendments therein.
- The approval of any exceptional expenditure not agreed upon in the Budget.
- Decisions and agreements on the ownership access rights of the results and exploitation plans.

The above list is not exhaustive.

The General Assembly will meet **at least once every 12 months in face-to-face, if possible as consortium meetings** and whenever it may be necessary upon request.

As a general rule, the meeting must be called 45 calendar days in advance and the General Assembly can only vote about items that are on the agenda, published 21 days in advance. Extraordinary meetings could be called 15 calendar days in advance with a published agenda 10 days in advance, upon request of 1/3 of the Members of the General Assembly

The General Assembly will take its decisions preferably by consensus. If consensus is not reached, the decision will be under the rule of **one party - one vote**. Decisions will be taken **unanimously, or if consensus is not reached, with 2/3 of the votes** cast with the participation of 2/3 of its members present.

5.2 Project Technical Committee (PTC)

The 5.2 Project Technical Committee (PTC) will be in charge of **supervising the implementation of the work programme and taking all decisions related to the technical execution and operational management of the project.** The PTC will act as "glue" between Work Packages, in order to create homogenous project outcomes and guarantee smooth interaction between Work Packages. In this context, the EC will:

- Provide an environment of discussion, interaction and collaboration between WP leaders on the advancement and results of each WP and their effects and interaction with other WPs.
- Advice and support the decisions of the PC on project operational issues.
- Decide on particular managerial issues related to the work plan and tasks.
- Report on the technical progress of the project.
- Decide on the update of the implementation plan if necessary.

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The PTC will be constituted by the **PC and one representative appointed by the partners.** The PTC has established to meet online in a regular basis **at least quarterly.** Special issues, like WP meetings, may be discussed deeply to meet the project requirements; for these cases, additional online or face to face meetings will be arranged.

5.3 External Advisory Board (EAB)

The consortium has set up an External Advisory Board (EAB) (D8.3 submitted 30 of January 2024), as the supervisory body for the execution of the Project, which shall report to and be accountable to the General Assembly providing scientific, technical and exploitation guidance to achieve the project objectives. The EAB will be co-chaired by Dr. Xavier Nissan from CECS and is formed by the following independent experts:

Table 7. DREAMS EAB members.

Representative	Entity	Expertise
Prof Volker Straub	Newcastle University	Neuromuscular Disorders
Prof Nicolas Levy	Pharmaceutical Group Servier	Human and medical genetics in Rare Diseases
Prof Laurent Servais	Oxford University	Paediatric Neuromuscular Disease
Prof Hugues Bersini	FARI | AI Institute for the Common Good	AI, computational sciences, bioinformatics and industrial design

The PC will ensure that a non-disclosure agreement (NDA) is executed between all project partners and each EAB member.

5.4 Innovation & Exploitation Board (IEB)

The Innovation & Exploitation Board (IEB) will be co-chaired by the PC and **Kantify and** formed by representatives of each other partner in the DREAMS project, appointed by the partners, and validated by the General Assembly.

The IEB is responsible to ensure during the whole duration of DREAMS that the project and its results are disseminated and exploited according to the exploitation plan set up in WP7. The IEB will ensure that the expected impact will be achieved as indicated. In order to ensure this, the IEB will convene **at least annually**, **with additional meetings scheduled as necessary upon request by the PC**.

During these meetings they will always have an agenda item reserved in order to give an update on the current activities and discuss further upcoming actions and events. During these meetings tasks could be assigned to the responsible project partners. The following individuals are appointed by the respective consortium partners. **Each partner will be entitled to 2 participants (1 IEB member and 1 IEB observer).** However, only the official IEB member will have voice.

Table 8. DREAMS IEB members and observers.

DREAMS Partner Organization	IEB member	IEB observer (if applicable)
CECS	Xavier Nissan (XNISSAN@istem.fr)	Imen Mestri (imestiri@genethon.fr)
KANTIFY (Meetsies SA)	Segolene Martin CEO (segolene@kantify.com)	Nik Subramanian CTO (nik@kantify.com)
ZABALA	Javier Uranga (juranga@zabala.es)	-

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INSERM (Institut National de la Santé et de la Recherché Médicale)	Stéphane Vassilopoulos (s.vassilopoulos@institut-myologie.org)	Antoine Muchir (a.muchir@institut-myologie.org)
UC (Universidade De Coimbra)	Lino Ferreira (lino.ferreira@uc.pt)	Catarina Santos (anacunhasantos@cnc.uc.pt)
APHP (Assistance Publique - Hopitaux de Paris)	Teresinha Evangelista (t.evangelista@institut-myologie.org)	-
TECHNION (Technion - Israel Institute of Technology)	Shenhav Shemer (Cohen) (shenhavc@technion.ac.il)	-
AFM (Association Française Contre Les Myopathies)	Alexandre Mejat (amejat@afm-telethon.fr)	Juliette Peterka (jpeterka@afm-telethon.fr)
SAMSARA (Samsara Therapeutics Ltd)	John Blackwood (john@samsaratherapeutics.com)	-

The IEB will oversee optimization of the exploitation possibilities of the project results and to cover the aspects related to future exploitation and Intellectual Properties Rights (IPR). In this context, IEB will:

- Identifying the exploitation potential of project results, following up all exploitation tracks and promoting contacts with potential end users.
- Validation of the exploitation plans.
- Validation of the exploitation risk assessment and the mitigation actions.
- Coordinating the exploitation activities and related IP protection and management.

5.5 Patient Advisory Board (PAB)

The Patient Advisory Board (PAB) will be chaired by AFM (Wael Khazen) and formed by 10 patients from various European countries representing the five neuromuscular diseases that will be initially studies in the DREAMS project: Duchenne Muscular Dystrophy (DMD), Emery-Dreyfuss Muscular Dystrophy (EDMD2), Centronuclear Myopathy linked to DNM2 gene mutations, Danon Disease, and Pompe Disease.

Table 9. DREAMS PAB patient members.

Patient member's initials	Country	Pathology
DA	Greece	Duchenne Muscular Dystrophy (DMD)
JB	Portugal	Duchenne Muscular Dystrophy (DMD)
IT	Romania	Duchenne Muscular Dystrophy (DMD)
FM	France	Danon Disease
VL	France	Danon Disease
OL	Ireland	Centronuclear Myopathy linked to DNM2 gene mutations
NH	France	Emery-Dreyfuss Muscular Dystrophy (EDMD2)
EC	Italy	Emery-Dreyfuss Muscular Dystrophy (EDMD2)
CE	France	Pompe Disease
OC	France	Pompe Disease

DREAMS Patient Advisory Board (PAB) will be created to ensure that Patients will be involved in all activities of the project. The PAB enables patient voices to be heard throughout the research and development process of the DREAMS PROJECT. It is designed to contribute to defining the project's priorities by facilitating the exchange of information between representatives of the DREAMS consortium and patients, as well as their relatives. PAB will meet at least every 6 months to follow the project development and dedicated meetings will be organized every time it is useful to collect patients' opinions, meetings can be adjusted depending on the progress of the project.

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The PC will ensure that a NDA is executed between all project partners and each PAB member.

5.6 Ethical Board (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 the "Creation of Ethical Board" deliverable D8.5 and will be responsible to assess all key ethical aspects of the project DREAMS such as: scientific, technical, patients and AI tools. The Project Coordinator (PC), CECS, will chair the EB.

Table 10. DREAMS EB members and observers.

DREAMS Partner Organization	IEB member	IEB observer (if applicable)
CECS	Xavier Nissan (XNISSAN@istem.fr)	Laura BRULLE-SOUMARE
KANTIFY (Meetsies SA)	Segolene Martin CEO (segolene@kantify.com)	Nik Subramanian CTO (nik@kantify.com)
AFM (Association Française Contre Les Myopathies)	Alexandre Mejat (amejat@afm-telethon.fr)	Wael KHAZEN

External EB ethics expert: Genevieve Marignac 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). The PC will ensure that a NDA is executed between all project partners and the External ethics expert.

5.7 Project Coordinator (PC)

The Project Coordinator (PC) is the legal entity acting representing the Consortium towards EC and is the Point of contact with the EC. The PC shall, in addition to its responsibilities as a Party, perform the tasks assigned to it as described in the Grant Agreement and the Consortium Agreement. In particular, the PC shall be responsible for:

- Monitoring compliance by the Parties with their obligations under this Consortium Agreement and the Grant Agreement
- Keeping the address list of Members and other contact persons updated and available in the DREAMS MS Teams Repository.
- Collecting, reviewing to verify consistency and submitting reports, other deliverables (including financial statements and related certifications) and specific requested documents to the Granting Authority
- Review the final content and timing of press releases and joint publications by the consortium or proposed by the Granting Authority
- Transmitting documents and information connected with the Project to any other Parties concerned
- Administering the financial contribution of the Granting Authority and fulfilling the financial tasks
- Preparing the meetings, decisions and agenda of the General Assembly meetings with the support of the Executive Committee
- Providing, upon request, the Parties with official copies or originals of documents that are in the sole possession of the coordinator when such copies or originals are necessary for the Parties to present claims.
- Providing a copy of the Grant Agreement and its Annexes to the Associated Partners.

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- Monitoring the compliance from all parties to their obligations, so that the project is carried out according to the agreed timing & estimated costs.
- Coordinating the payments to the consortium.

The Project coordination is done by CECS and the designated PC is Dr. Xavier Nissan. He will be the main project authority and the primary contact with the EC. He is responsible for the day-to-day management, supervising the project progress and deciding on any actions necessary to correct potential deviations from the project plan, from an operational or financial perspective. Dr. Xavier Nissan has a broad experience in coordinating collaborative projects and actions at international level. The PC will be supported by Zabala.

Additionally, the PC will host meetings for each WP with all the partners participating in the WP for the duration of the WP, to monitor the progress of the activities.

5.8 Work Package Leaders (WP)

Each WP has a leader in charge of the coordination of the tasks. WP Leaders will coordinate partner interaction within the WP and tasks and will call for internal WP meetings if required. Project progress will be critically reviewed at each milestone point.

Each organization have appointed a WP Leader, who is responsible for operational decisions and will guarantee that the partial and total objectives of the WP are accomplished, elaborating the reports of the WP and organizing the presentation of results.

Table 11. WP Leaders.

WP	DREAMS Partner	WP Leader Name
WP1	CECS	Xavier NISSAN
WP2	Kantify	Nik Subramanian
WP3	UC	Lino Ferreira
WP4	Kantify	Nik Subramanian
WP5	Inserm	Antoine Muchir
WP6	AFM	Alexandre Mejat
WP7	Zabala	Monica Perez (MONICAPEREZ@zabala.es)
WP8	CECS	

The designated people acting as WP Leaders could be changed by Partners they belong to if a situation derived from the business operative of these Parties requires so and it is notified to the PC and Zabala.

The role of the Work Package Leaders will be to:

- Define, in coordination with all partners involved in each task, the detailed planning of the subtasks and activities identified.
- Coordinate the work performed within the work package or task according to the time schedule.
- Monitor the technical quality of the work, in order to achieve the expected results.
- Coordinate with other work package or task leaders the information flow required by the various interdependencies.
- Prepare the progress reports summarizing the work performed.
- Inform the PC on the progress achieved, results obtained, problems encountered, before every PTC meeting.
- Coordinate, approve (preliminarily) and forward the deliverables prepared in the work package or task.
- Participate in the preparation of the review meetings with the Commission.

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6 PROCEDURES

6.1 Conflict Resolution

Having a good working relationship among the project team members will be a pre-requisite for a quick resolution of problems and issues. The partners shall always try to reach an agreement on conflicts based on. However, if this is not possible, the resolution of problems and conflicts must be handled systematically.

Conflicts will be solved at the lowest level possible, and preferably amicably. If an agreement cannot be reached at a task or WP level, then the PC will mediate. If that is not satisfactory, then the General Assembly will take a decision, and if necessary, it will ask for the authorisation of the EC.

Definitive conflict resolution procedures are laid down in the Consortium Agreement. This document formalizes the rights, obligations, relationships and procedures within the consortium, as well as any other relevant issues such as the use of background material, IPR, etc. In case of conflict between participants on access rights, the PC should advise the General Assembly for arbitration (in correlation with EC rules).

6.2 Project Meetings

The chairperson of a Body shall produce **written Minutes of each meeting** which shall be the formal record of all decisions taken. The chairperson shall send the draft to all its members **within ten (10) calendar days from the day of the meeting**. All meeting minutes will be available in the DREAMS MS Teams Repository in the folder **"WP8.Project Management<Meetings Minutes".**

The Minutes shall be **considered as accepted if, within fifteen (15) calendar days from sending** and confirmed receipt, no member has objected in writing to the chairperson concerning the accuracy of the draft Minutes.

The accepted Minutes shall be uploaded to the DREAMS MS Teams Repository and all members of the body notified. If requested, the PC shall provide authenticated duplicates to the partners.

As a summary, the following meetings are scheduled during the project duration:

Table 12. Meetings scheduled

Meetings	Periodicity	On line – Face to face
General Assembly	At least once a year	Face-to-face, if possible
Project Technical Committee (PTC)	At least quarterly	On-line, Hybrid or face-to-face
Innovation & Exploitation Board (IEB)	At least once a year	On-line, Hybrid or face-to-face
External Advisory Board (EAB)	When requested by PC	On-line, Hybrid or face-to-face
Ethical Board (EB)	When requested by PC	On-line, Hybrid or face-to-face

Additionally, each WP will arrange online meetings whenever it would be necessary in order to guarantee good communications between partners and progress of the activities being implemented.

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6.3 Risk Management

All project partners will identify and monitor, during project implementation, internal and external risks as well as any other issues that might affect the Project progress towards its objectives, in order to carry out mitigation actions as early as possible. Risks and contingency plans have been identified in DoA. Each Partner has the responsibility to report immediately to their respective WP Leader and to the PC, any risky situation that may arise and may affect the Project objectives or their successful completion.

Any change in time scheduled for deliverables or in the allocated budget must be reported to the corresponding WP Leader or to the PC.

In case of problems or delays, the WP leader will be consulted, and he/she may install task forces to take the necessary/corrective actions.

In case no resolution is reached, the different committees will be consulted and will establish mitigation plans to reduce the impact of risk occurring.

The DoA, included as part of the Grant Agreement includes a **list of the critical risks and proposed mitigation measures envisaged for the project.**

6.4 Voting rights and quorum

Only partners of the consortium have the right to vote under the rule of **one party - one vote**. Each Member of a Consortium Body present or represented in the meeting shall have one vote.

Decisions of a General Assembly are only valid if at least two-thirds (2/3) of its members are present or represented (quorum). If the quorum is not reached, the chairperson of the Consortium Body shall convene another ordinary meeting within 15 calendar days. If in this meeting the quorum is still not reached, the chairperson shall convene an extraordinary meeting which shall be entitled to decide even if less than the quorum of Members are present or represented.

Defaulting Parties may not vote.

All decisions shall be taken unanimously, or if consensus is not reached, with 2/3 of the votes.

6.5 Dissemination of results – open access – visibility of EU funding

6.5.1 Project Identity

For the internal and external communication, the following issues have already been defined:

- **Design and implementation of the DREAMS brand:** The DREAMS project has a distinct visual identity, featuring a professional logo and comprehensive visual guidelines, along with project templates for presentations and deliverables in Powerpoint and Word formats. All communication and dissemination material originating from the project will prominently showcase the DREAMS identity, accompanied by the EU emblem and funding statement. Partners have access to DREAMS brand identity materials,

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including logos, templates, typography, and brand assets, along with the brand application manual, through the shared folder: DREAMS > Project Templates and Logo.

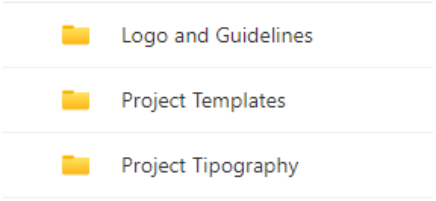

Figure 8. Content of the folder "Project Templates and Logo" in the Repository

- **Communication materials package:** In addition to DREAMS brand identity, partners will have access to a variety of communication and dissemination materials. These resources aim to inform and promote the project and results whether through events or other engagements. They encompass digital assets such as the project website and social media channels, as well as informative materials such as brochures, leaflets, posters, roll-ups, and press releases. To further support partner dissemination and communication efforts, some of these materials will be developed in the project's initial year and expanded upon as necessary throughout its duration. These materials will be available in the DREAMS Teams Repository: 04 Work Packages / WP7 Dissemination, Exploitation and Communication / Communication materials. The default language for all materials is English; however, partners will have the option to translate these materials into their respective languages by providing them with editable versions.

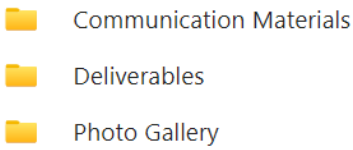

Figure 9. Content of the subfile WP7 in DREAMS MS Teams Repository

- **Website**: DREAMS has an official project website located at https://dreamshorizon.eu/, as detailed in section 2.2.4 of the DoA. The project website deliverable (D 7.8) for WP7 was submitted in month 3, dated January 31, 2024, when the website was searchable on the internet.

6.5.2 Dissemination of Results

Dissemination activities and publications will be governed by the Grant Agreement (Article 17) and the Consortium Agreement. As stated, any communication activities of the beneficiaries related to the action (including media relations, conferences, seminars, information material, such as brochures, leaflets, posters, presentations, etc., in electronic form, via traditional or social media, etc.), dissemination activities and any infrastructure, equipment, vehicles, supplies or major result funded by the grant must acknowledge EU support and display the European flag (emblem) and funding statement (translated into local languages, where appropriate).

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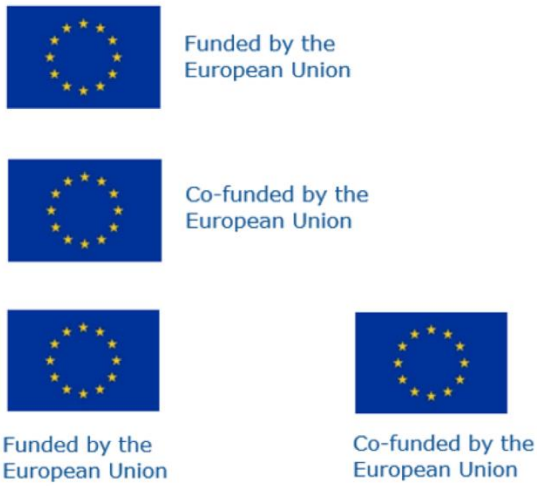

Figure 10. Display the EU logo.

The EU logo must remain distinct and separate and cannot be modified by adding other visual marks, brands or text. Apart from the emblem, no other visual identity or logo may be used to highlight the EU support. When displayed in association with other logos (e.g. of beneficiaries or sponsors), the emblem must be displayed at least as prominently and visibly as the other logos.

Beside the logo, the following text should be included: *"Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them."*

Any dissemination of results must indicate that it reflects only the author's view and that the EC is not responsible for any use that may be made of the information it contains.

A complete procedure for the dissemination of the activities and publications will be available in D7.1 - D7.5 and in the DREAMS MS Teams Repository in folder "WP7. Communication, Dissemination and Exploitation."

6.5.3 Open Access

Open access can be defined as the practice of providing on-line access to scientific information that is free of charge to the end-user. OA will be following Article 17 and Annex 5 of the GA. The consortium will be encouraged to publish in the Open Research Europe platform.

The partners will provide open access (OA) to peer reviewed scientific publications that are related to their project results. In particular, they must ensure that:

- at the latest at the time of publication, a machine-readable electronic copy of the published version or the final peer-reviewed manuscript accepted for publication, is deposited in a trusted repository for scientific publications.
- immediate open access is provided to the deposited publication via the repository, under the latest available version of the Creative Commons Attribution International Public Licence (CC BY) or a licence with equivalent rights; for monographs and other long-text formats, the licence may exclude commercial uses and derivative works (e.g. CC BY-NC, CC BY-ND).

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- For data designated for public release, the project leverages trusted repositories like NCBI's GEO and ProteomeXchange. These platforms, familiar within the bioinformatics community, provide long-term preservation and accessibility, including the assignment of Digital Object Identifiers (DOIs) to datasets.
- information is given via the repository about any research output or any other tools and instruments needed to validate the conclusions of the scientific publication.

Beneficiaries (or authors) must retain sufficient intellectual property rights to comply with the open access requirements.

The Data Management Plan (DMP) deliverable (D8.2) is under preparation and will be submitted by the 30 April 2024. The DMP will cover: Types of data/research outputs: definition of dataset units to be produced during the project life span. Each data set will contain, at least the work package to which it belongs and data typology, with a short description. It will be ensured that data produced in the context of the project and not subject to commercial exploitation or access restrictions will be made available as open data, following the FAIR principles.

Metadata of deposited data must be open under a Creative Common Public Domain Dedication (CC 0) or equivalent (to the extent legitimate interests or constraints are safeguarded), in line with the FAIR principles (in particular machine-actionable) and provide information at least about the following: datasets (description, date of deposit, author(s), venue and embargo); Horizon Europe or Euratom funding; grant project name, acronym and number; licensing terms; persistent identifiers for the dataset, the authors involved in the action, and, if possible, for their organisations and the grant. Where applicable, the metadata must include persistent identifiers for related publications and other research outputs. Metadata of deposited data will be open under a Creative Common Public Domain Dedication (CC 0); Reusability of data/research outputs: the right to access and reuse digital research data under the terms set out in the Grant Agreement will be ensured.

Possible patents in the case of the invention of new methods to bring together AI and iPSC; Trademark for the platform name and Copyrights on the database; Confidentiality of the dataset until 3 years after Project completion (will be open Access afterwards to promote open Access and open science).

7 PARTICIPANT PORTAL ROLES

The Funding & Tenders Portal (Funding & tenders (europa.eu)) is your entry point for electronic administration of EU-funded research and innovation projects and hosts the services for managing your proposals and projects throughout their lifecycle.

The Participant Portal offers flexibility in the management of access rights and roles in the projects. The roles of a user can be checked after logging in to the ECAS account on the Participant Portal under the "My Roles" button (under the button bearing the name of the user).

7.1 Main roles and access rights

- The Primary Coordinator Contact (PaCo) of a project is a unique role, set/modified by the Commission/Agency. All Primary Coordinator Contacts have full, read/write access to their own and the consortium's common e-forms, and can submit to the Commission/Agency via the Participant Portal.

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- Coordinator Contacts (CoCo) can be nominated by the Primary Coordinator Contact. All Coordinator Contacts have full, read/write access to their own and the common e-forms, and can submit to the Commission/Agency via the Participant Portal.
- Participant Contacts (PaCo) can be nominated either by the Primary Coordinator Contact or by Participant Contacts. All Participant Contacts can submit e-forms to the Coordinator Contacts via the Participant Portal. They have read/write access to their own forms and read-only rights to certain common forms.
- Task Managers (TaMa) can read, modify and save their own entity's forms.
- Team Members (TeMe) have read-only rights to the entity's own forms.
- The Financial Statement Authorised Signatory (FSIGN) is the person authorised to sign Forms C for their organisation. The FSIGN is nominated by the LEAR or an Account Administrator under the "My Organisations" tab > "RO" icon (consequently the nomination of LEARs is now mandatory). An unlimited number of FSIGNs can be nominated for an organisation. Then it's up to the Primary Coordinator Contacts, the Coordinator Contacts and Participant Contacts to assign FSIGNs to specific projects, becoming at this moment Project Financial Signatories (PFSIGNs). An unlimited number of FSIGNs can be assigned to a project.
- The Legal Statement Authorised Signatory (LSIGN). To appoint LSIGNs, the procedure is the same as for FSIGNs. The LSIGN has to be nominated by someone having an organisation role (LEAR, Account Administrators). The LSIGN must then be appointed to one or several project(s) by someone having a project role (Primary Coordinator Contact, Coordinator Contacts or Participant Contacts) in said project(s). At this moment, the Project Legal Signatories (PLSIGNS) will be appointed.

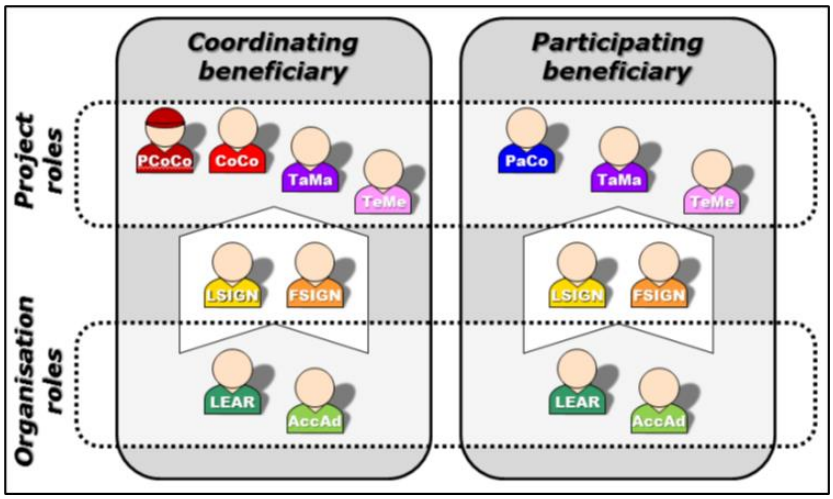

Figure 11. Scheme summarizing Participant portal roles

7.2 How to add or revoke roles in the Participant Portal

Except for the Primary Coordinator Contact (PCoCo) and the LEAR, every role must be modified by the Participants.

Each user can be nominated or revoked by another user, as follows:

- The Primary Coordinator Contact can nominate/revoke Coordinator Contacts, Task Managers and Team Members of the coordinating entity, Participant Contacts of other participating organisations, and assign LSIGNs and FSIGNs to a project.

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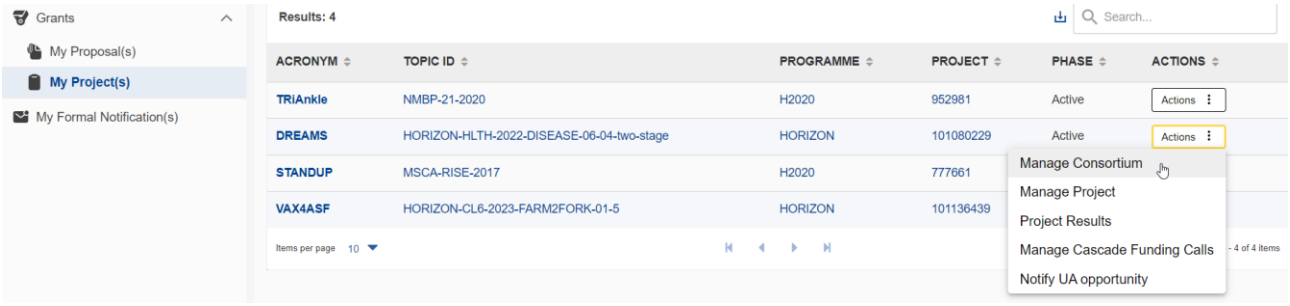
- Coordinator Contacts can nominate/revoke other Coordinator Contacts, Task Managers and Team Members of the coordinating entity, and assign LSIGNs and FSIGNs to a project.
- Participant Contacts can nominate/revoke other Participant Contacts, Task Managers and Team Members of their own entity, and assign LSIGNs and FSIGNs to a project.
- The Legal Entity Appointed Representative (LEAR) can nominate Account Administrators, LSIGNs and FSIGNs for his/her own entity.
- Account Administrators can nominate LSIGNs and FSIGNs for his/her own entity.

7.3 Roles defined in DREAMS

Roles appointed by each beneficiary can be checked via the Funding & Tenders Portal under “My Projects” (menu on the left), by choosing the option “Manage Consortium" under DREAMS actions.



The roles for each beneficiary can be checked by clicking on the arrow on the right and edited (if you have the right) by clicking on "Edit Role".

Current roles and persons appointed in DREAMS Funding and Tenders portal are also available in the contact list of participants uploaded in the **repository**. See label “Roles Participant Portal”. If you wish to change, add or revoke roles, you can always contact all the Zabala Team members: Ane García (anegarcia@zabala.es), Laura Sesma (lsesma@zabala.es) and Marina Ruilope (mruilope@zabala.es) via email and they will indicate how to manage with it.

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8 INFORMATION MANAGEMENT

8.1 Information flow chart

All the project related issues (problems, delays, etc.) must be communicated from each partner to the WP Leader and the PC. The Work Package Leader, with the support of the PC, will be the responsible for dealing with the issue raised and solve it. If needed, the problem will be transmitted to the corresponding Committee and ultimately to the General Assembly.

All relevant issues with an impact on the work and planning of the project will be discussed with the corresponding committee without unduly delays.

The PC will resolve the issues put up by the WP Leaders or will transmit them to the Commission if necessary.

8.2 Periodic and Final Reports

After the finalisation of the reporting periods specified in the Grant Agreement, Zabala, in name of CECS, will submit a Periodic Report prepared with the collaboration of all the partners via the SyGMA electronic submission system in the participant portal. In addition, at the end of the project a final report together with a report on the distribution of the financial contribution between beneficiaries will be submitted. For more detailed information, please see section 4.1 of this document.

8.3 Submission of deliverables

All the deliverables must be submitted within the deadlines defined in Annex I to the Grant Agreement. For more detailed information, please see section 4.2 of this document. **All Deliverables Leaders are responsible for the quality and adequacy of the deliverable**. Besides, the PC and Zabala are assigned as reviewers and responsible for the delivery date in accordance with the associated deadline as stated in the DoA document. During the deliverable definition the Deliverable Leader will review the deliverables based on the following aspects:

- Completeness:
  - is it according to the original proposal?
  - does it contain all required chapters?
- Correctness:
  - does it contain correct information?
  - language check.
  - lay-out / template check.
- Consistency:
  - Are the chapters consistent with each other?
  - Is it consistent with other deliverables?
  - is it according to the requirements of other WP's?

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At least one month in advance of the planned delivery date for each deliverable, the PC and/or Zabala will contact the lead partner in charge of a deliverable in order to check whether it will be submitted as planned or whether there is any unexpected problem that may cause a substantial delay. In case of expected delay, the PC will agree with the lead partner in charge of the deliverable and the corresponding WP leader on how to address the problem and on a new date for submission of the deliverable as soon as possible. If this happens, the PC will be in charge of informing the EC project officer as soon as possible.

RULES:

- Quality Assurance activities have to be implemented throughout the entire project by the entire consortium. This means that every project partner shall review his own results before transmitting them to someone else.
- The WP Leader will be the first instance to perform a quality control of deliverables. Further, all project deliverables will undergo a quality control of the Responsible Committee.

For a completes list of the project deliverables, including the lead beneficiary responsible for each deliverable and the due date, see Table 5.

8.4 Financial reporting

For each reporting period, all beneficiaries will have to submit the following documents to the PC/Zabala using the provided templates:

- **Cost statement** duly completes and explanation of the use of covering the specific period on the template to be provided. It will be uploaded in the Teams Repository and notified by email to PC and Zabala.
- **Financial Statement completed in SyGMA** duly signed electronically by the Project Financial Signatory (PFSIGN).

For more information on the information collection procedure for reporting periods, see section 4.1. For reporting period deadlines, see Table 3.

8.4.1 Cost statement completion

Each beneficiary shall provide to the PC/Zabala the Cost Statement of the period duly completed in order to check and verify costs to be claimed.

The timely receipt of the cost statement duly filled out is of primary importance for reporting issues as well as for providing a proper explanation of the use of the resources within the period in accordance with the EC requirements.

To support this process, a Cost Statement template will be created for DREAMS partners and will be available at the Teams Repository, under the WP8 folder, before the RP starts. The cost statement is aimed at collecting from all partners costs incurred in the period and the explanation of the use of the resources required by the Commission in the Periodic Report. Costs shall be detailed at WP level.

Costs declared must be set out in Annex 2 (estimated budget for the action). Costs not foreseen might be reported and claimed but they will have to be duly explained if we expect that the EC would accept them.

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Once the cost statement has been reviewed by Zabala and the PC, costs shall be completed in SyGMA by each partner, creating *Financial Statements* per beneficiary. The tool will automatically create the Financial Statements in accordance with Annex 4 of the Grant Agreement.

A beneficiary may request the PC/Zabala to fill the financial statement on his behalf and the required information will be filled in SyGMA by Zabala. Zabala will always verify the financial statement with the partners concerned before the electronic signature.

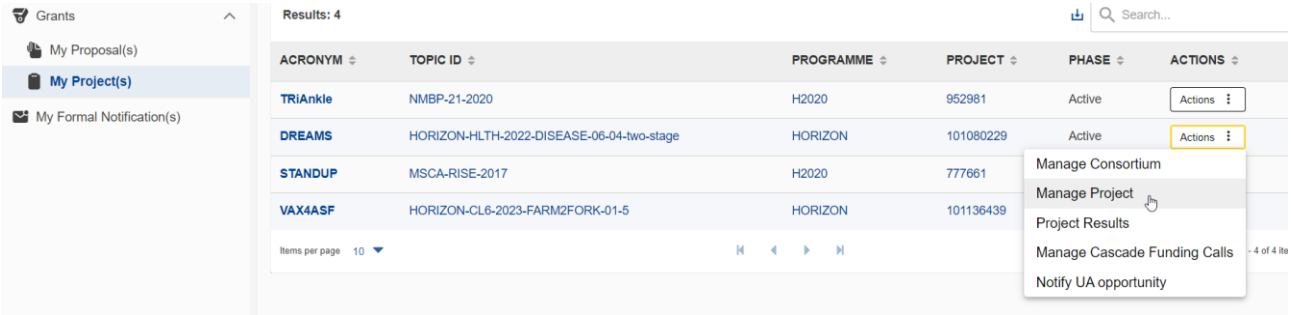
Individual Financial Statements of each beneficiary shall be signed electronically by the corresponding Project Financial Signatories (PFSIGN) appointed by each organization (see next section).

8.4.2 Electronic signature of the financial statement

All beneficiaries shall appoint a Project Financial Signatory (PFSIGN) in order to submit a Financial Statement and the request for reimbursement to the Commission. Each PFSIGN will have to sign in SyGMA using her/his ECAS account.
PFSIGNs appointed in DREAMs will also be available in the contact list of participants uploaded in the repository. See label “PFSIGN”. If any beneficiary wishes to change the PFSIGN in DREAMS they should send an e-mail to all the Zabala Team members: Ane García (anegarcia@zabala.es), Laura Sesma (lsesma@zabala.es) and Marina Ruilope (mruilope@zabala.es) and they will help you in the process.

Instructions for the electronic signature for the PFSIGN

- The Project Financial signatory (PFSIGN) shall log in the Participant Portal with your ECAS account at the following link: Funding & tenders (europa.eu)
- Once logged in, please go to “My project” tab on the left, and then click “Manage project" button of DREAMS Actions:



- Then the SyGMA portal will open, in which you will visualize the active processes of the DREAMS project (see an example for another project below).

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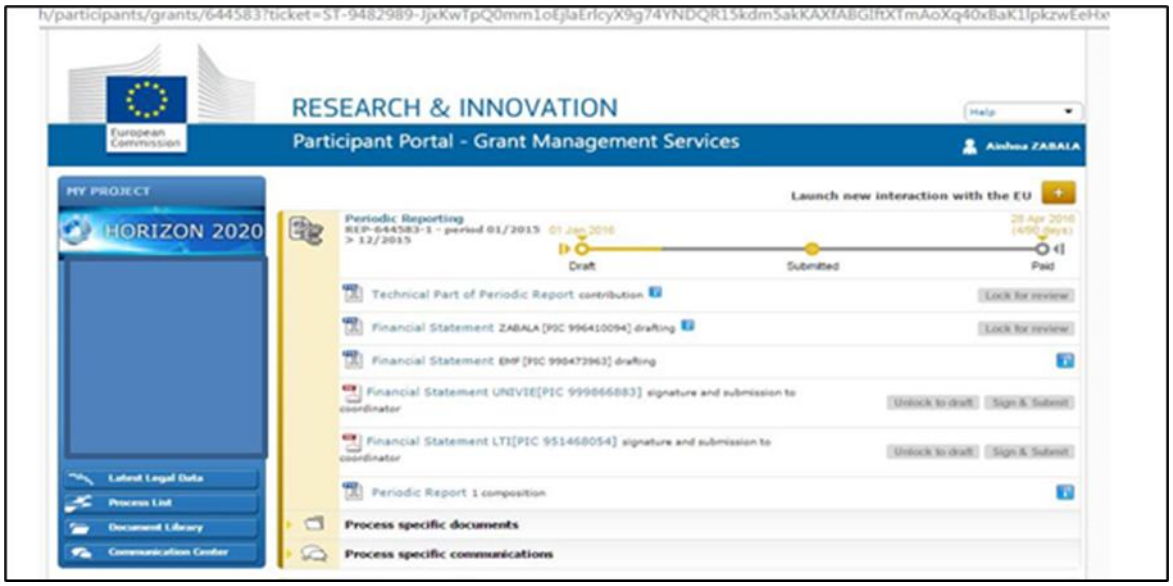
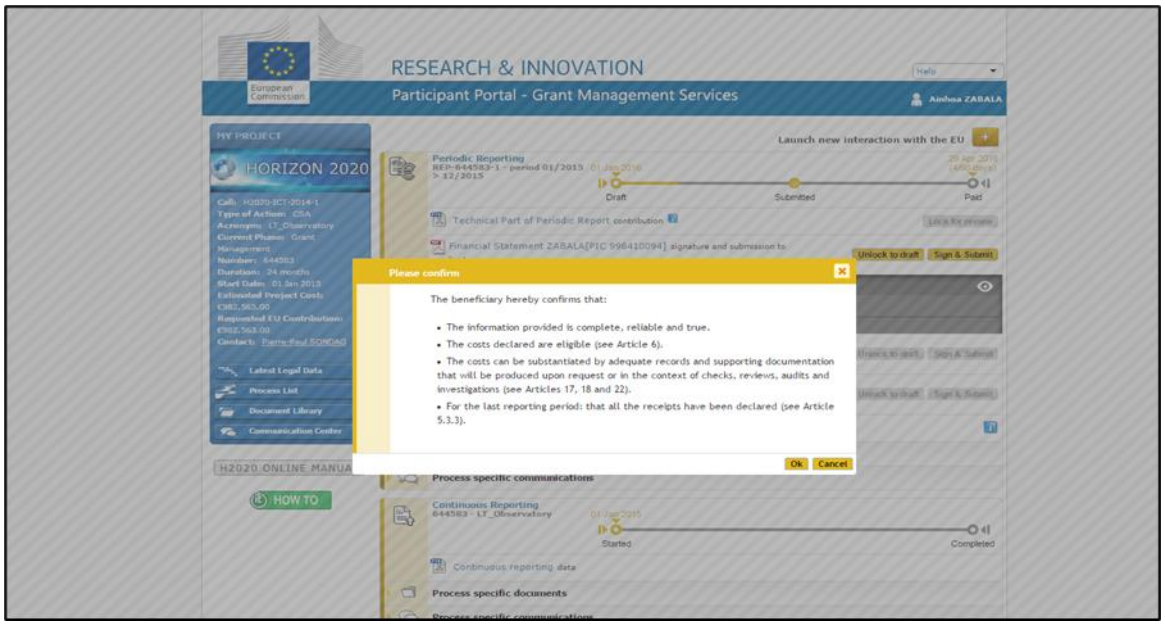


- Under the Periodic Reporting process, the PFSIGN will have in the beneficiary´s Financial Statement the option “Sign and Submit” Available. Please check that everything is correct and click “Sign and Submit”.



- The tool will ask you to enter again the PFSIGN´s ECAS password in order to sign electronically.

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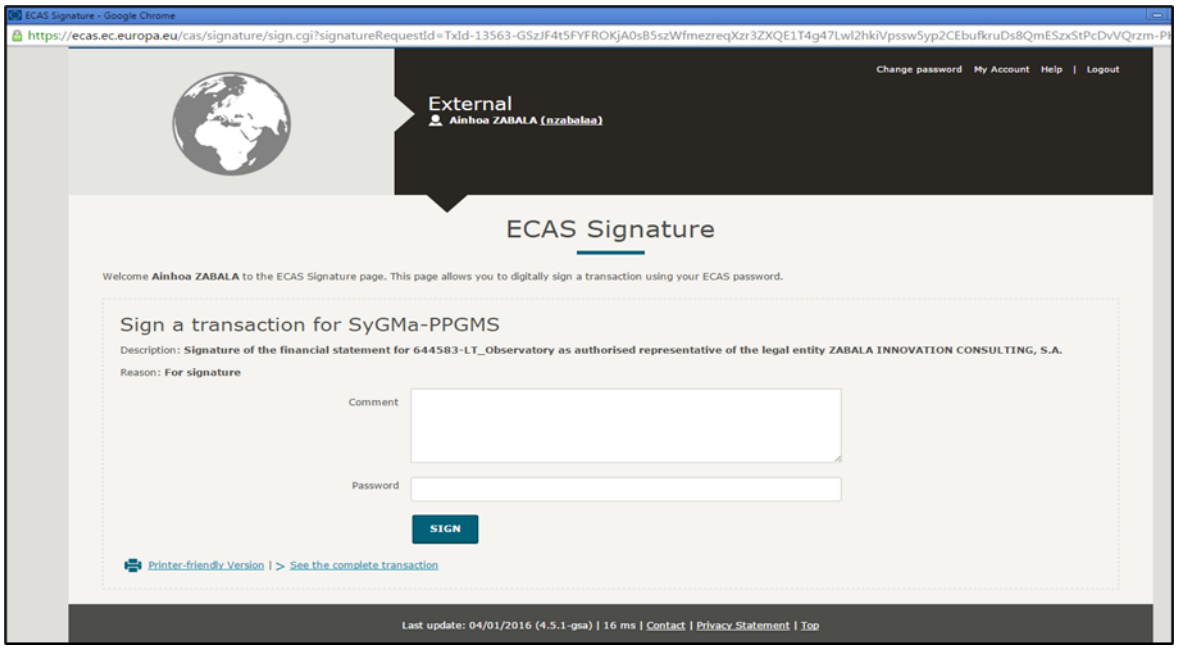

- Once the PFSIGN introduces his/her password and clicks “SIGN” the process will be completed, and the Financial Statement signed electronically.

8.4.3 Eligible costs and cost categories

Partners should report costs defined as eligible according to Article 6 in the Grant Agreement and structured as follows:

- Direct costs:
  - Personnel costs (Article 6.2 A)
  - Subcontracting costs (Article 6.2 B)
  - Purchase costs (Article 6.2 C)
    - Travel costs and related subsistence allowances
    - Equipment costs
    - Other goods, works and services
  - Other cost categories (Article 6.2 D)
- Indirect costs (Article 6.2 E)

Details about the nature of costs to submit

Find enclosed the levels of detail expected in the course of a sound financial management:

- **Personnel costs** (amounts, name, function, statute (additional or permanent), monthly rate or hourly rate (A) and working time spent on which WP (in month if monthly rate given in A or in hours if hourly rate is given in A),

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- **Travel costs** (amount by travel and by participants, name of travellers, exact dates (dd/mm/yyyy), origin/destination (from/to), and detailed purpose of the travel),
- **Depreciation costs of equipment** (amount claimed, nature of the equipment, price by equipment (VAT excluded), depreciation system (in years or month), % of use in the project)
- **Consumables** (amount by class of consumables, nature, list (when applicable), precise purpose and use of these consumables),
- **Subcontracting** (amount by subcontract, agreement EC (either technical annex or specific agreement (if so, please provide a copy of the agreement), nature of the tasks, name of subcontractor and link of these with the project),
- **Other costs** (class covering costs not covered by previous class – amounts by cost, very precise details about the nature of each cost),
- **Indirect costs** (25% flat rate). Indirect costs are calculated on the basis of the flat rate of 25% of the eligible direct costs (Article 6.2E of the GA) from which subcontracting and in-kind contributions are excluded.

According to the procedures and information to be provided to the Commission, it is mandatory for the Consortium to deliver in due time the Cost Statement Template per period. Without the delivery of this cost statement, the PC may not accept costs declared in the Model for the financial statement.
The Cost Statement Template will cover all requested information in order to allow the Project Officer the acceptance of costs declared as eligible costs of the project.

8.5 Certificate on the Financial Statements (CFS)

In accordance with the Grant Agreement, certificate on the financial statements' for each beneficiary are compulsory, if said beneficiary requests a total contribution to costs **≥ EUR 430.000 or more (indirect costs not considered)** (see Article 4.3 in the GA).
Special threshold for beneficiaries with a systems and process audit: financial statement: requested EU contribution to costs ≥ EUR 430 000.00.

The certificates must be drawn up using the template published on the Portal, cover the costs declared on the basis of actual costs and costs according to usual cost accounting practices. Please ask your auditors to follow strictly the model requested by the Commission. The PC must submit the CFS at final payment.

According to the estimated budget for the action (GA Annex 2), the following partners are expected to provide a CFS in DREAMS (as their expected EC contribution in their budget planned exceeds the threshold of EUR 430.000.):

- CECS: requested EU contribution 1 665 500.00€
- KANTIFY: requested EU contribution 1 568 125.00€
- UC: requested EU contribution 940 185.00€
- INSERM: requested EU contribution 895 000.00€
- TECHNION: requested EU contribution 804 550.00 €
- AFM: requested EU contribution 452 500.00€

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Without prejudice to the paragraph above, the Commission may request, on the basis of an analysis of risks, the submission of a certificate on financial statements from any beneficiary at any time until the agreement completion date.

Public bodies and international organisations referred to in Article 43 of Commission Regulation (EC, Euratom) No 2342/2002 of 23 December 2002 laying down detailed rules for the implementation of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities are not required to provide certificate on financial statements, unless the Commission requests the submission of such certificate on financial statements on the basis of an analysis of risks.

8.6 Record keeping – supporting documents of costs claimed

As mentioned in the previous section, the submission of a Certificate on the Financial Statements (CFS) does NOT waive the right of the Commission to carry out its own audit which may be launched at any time and up to 5 years after the end of the project. Therefore, all beneficiaries have to keep DREAMS supporting documentation up to 5 years after payment of the balance.

This list summarises all supporting documents (per cost category) that may be requested by an auditor:

Table 13. Supporting documents needed for audit of CFS.

Cost type	Supporting documents needed for audit of CFS
Personnel Costs	▫ Employment contracts (or other independent/legal justification of personnel costs claimed) ▫ Ledgers/ accounts, payroll records ▫ Time Sheets ▫ Detailed breakdown and justification of the productive hours denominator used for calculation of hourly rates
Subcontracting	▫ Invoices ▫ Proof of payment ▫ Original deliverables from the subcontractors ▫ Evidence of own internal management and supervision procedures to confirm completion of work required to specifications needed and reasonableness costs claimed in connection therewith.
Consumables	▫ Invoices ▫ Proof of payment ▫ In case of rented equipment: Rental contract, inventory list of the rented equipment; proof of the investment values of the rented equipment ▫ - Records concerning computer usage, if applicable.
Travel Expenses	▫ Transport tickets, including boarding passes, hotel bills… ▫ Invoices ▫ Mission approval forms ▫ A report, records, minutes etc. indicating purpose and participants of the meetings.
Indirect costs	▫ Full documentation concerning the calculation of the overhead costs and back-up documentation such as disaggregated balance sheet.

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	▫ Analysis, reconciliation and summary of final breakdown of overhead (by category of expense) charged to the project.
Bank statements (for PC)	▫ Relating to the payments of the EC contributions and the distribution among partners.
General ledger / Management Accounts	▫ Salient extracts and reconciliations of costs claimed to underlying accounting records/general ledger to facilitate easy verification of costs claimed and their eligibility.
Certificate on Financial Statement (CFS)	▫ Copies of any auditor certification statements issued with a claim for cost reimbursement.

8.7 Payments

Article 22 to the Grant Agreement establishes the payments to be made from the EC to the PC.

All the costs approved by the EC will be reimbursed by the PC to each party under the procedures defined in the Consortium Agreement. There will be up to 5 payments of contribution from the PC to the beneficiaries: an initial prefinancing, 3 interim payments and the final payment. The following table summarizes the payments and related RP for the project:

Table 14. Project Payments

Payment		Amount	Deadline
Initial prefinancing	35%	1st payment of 50% (1,216,619.25€)	M1 (Novembre 2023)
		2nd payment of 50% (1,216,619.25€)	M10 (August 2024)
Interim payment after RP1		Max. 50% of total grant between the 3 payments	90 days after receiving report
Interim payment after RP2			90 days after receiving report
Interim payment after RP3			90 days after receiving report
Final payment after RP4		10% (+5% EC guarantee fund retained)	90 days after receiving report

The pre-financing amount established for the DREAMS project is 2 780 844.00€. Before the RP4 (final payment), never more than 85% of total grant will be received.

9 DOCUMENT HANDLING

A Collaborative workspace for DREAMS on Microsoft Teams Tool has been set up to handle effectively the documentation of the project. This tool is aimed at both working on collaborative documents and sharing final documents of common interest on a document Repository and provide a chat for discussions among project partners. Two channels have been set up, one for discussion and document sharing among all the partners, and another with restricted access only for the coordination team.

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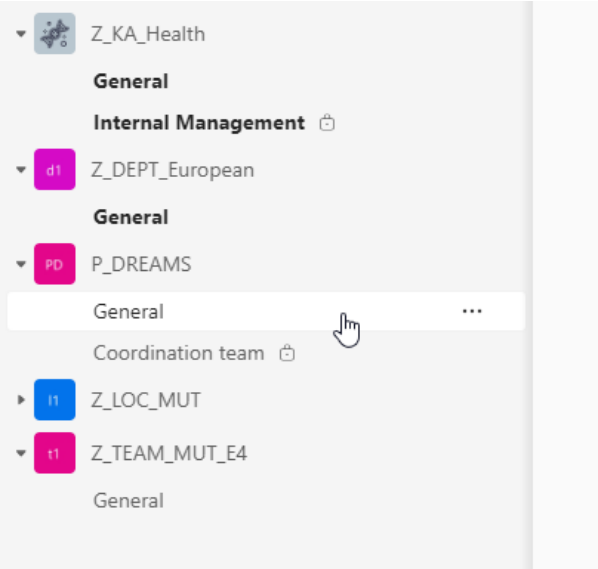

Figure 12. DREAMS collaborative MS Teams channels.

9.1 Access to the DREAMS MS Teams

All persons wishing to have access to the tool need a **personal account** to the system. ZABALA is in charge of granting access permissions to whoever needs them. If one person needs access to the system, he/she should send an e-mail requesting the access to all the Zabala Team members: Ane García (anegarcia@zabala.es), Laura Sesma (lsesma@zabala.es) and Marina Ruilope (mruilope@zabala.es).
They will grant access to the system and give any support in any question related to the functioning of the system.

9.2 Document repository

Linked to the DREAMS MS TEAMS channels is a MS SharePoint, that will be used as document repository. The link to access the SharePoint is the following: P_DREAMS - Home (sharepoint.com). The Repository will be updated by the PC/Zabala according to the needs of the project, creating new folders or sub-folders in accordance with the needs. The idea is having a full repository of working documents, final documents, legal docs, templates and any ready-to-use doc generated by the project team members. At this moment the files library it is organised in 9 main folders, 1 per WP and 1 with all the project templates and logo, although new folders might be created in accordance with the needs of the project.

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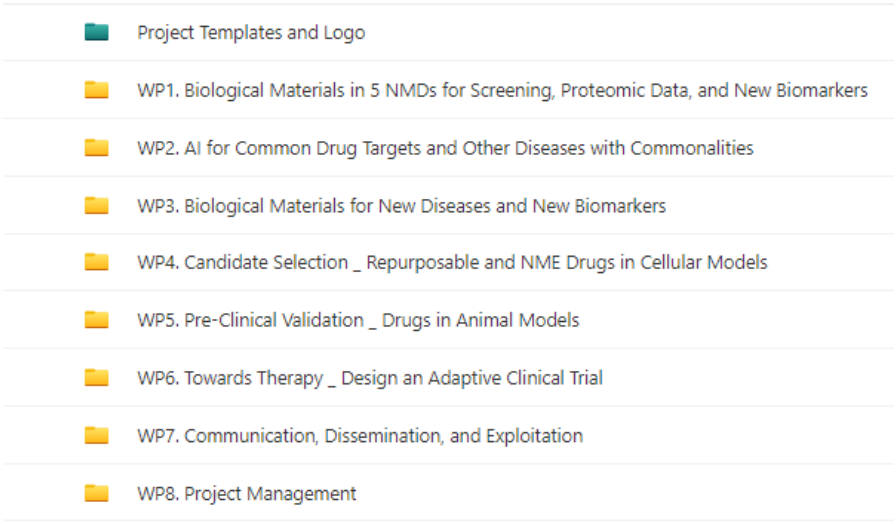

Figure 13. DREAMS MS Teams Repository folders

Each WP Leader is responsible for the contents of each WP subfolder in the Work Packages folders. The main recommendation is creating collaborative documents within each folder to foster the team working.
Final versions or stable drafts will be shared in the Repository. The idea is having a full repository of final documents, legal docs, templates and any ready-to-use doc generated by the project team members.

Additionally, project deliverable drafts will be shared under the WP8 folder<Deliverables and Zabala will include the final submitted versions in the "Final versions" folder.

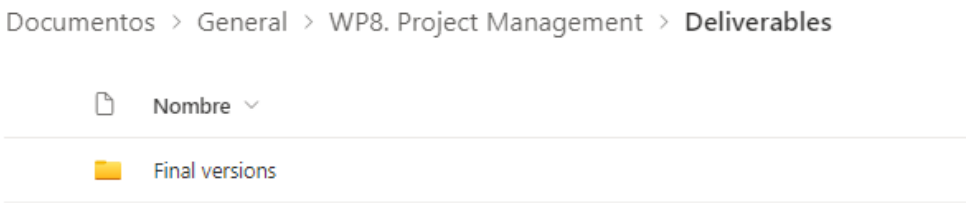

Figure 14. Deliverables organization folders.

9.2.1 File naming and numbering: deliverables

All the deliverables must follow the deliverable template available in the Template folder. The deliverable documents shared in the document repository will follow the name scheme proposed below:
DREAMS_Dx.y. name of the deliverable_Vz_partner

- X: WP number
- X.y. deliverable number
- Z: version number
- Partner: partners that created the version

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9.2.2 Language

According to the Grant Agreement, any report and deliverable shall be in **English**. Minutes of project meetings, project deliverables and periodic progress reports must be prepared in English. Meetings with attendance from abroad must be in **English**.

9.3 Document templates

It is compulsory to use the templates and logos available for all the documentation generated within DREAMS project. As mentioned in the previous section, all the templates are available at the project repository SharePoint, under the "Project Templates and logos" folder.

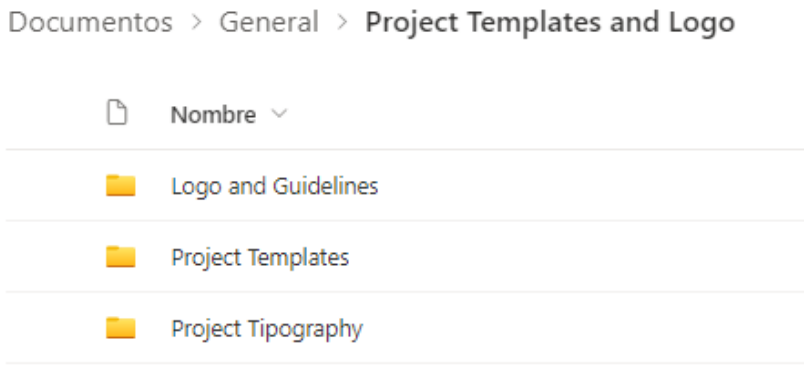

Figure 15. Project Templates and Logos folder distribution.

Templates available:

- DREAMS presentation templates
- DREAMS deliverable templates
- DREAMS press release template.

Additional templates will be creates/included in the folder as the project advances, if needed.
The folder also contains a Brand Identity Guideline document under the "Logo and Guidelines" folder, for partners to follow, and the DREAMS typography (DM-Sans).

10 PROJECT CHANGES AND POTENTIAL PROBLEM AREAS

10.1 Changes in the project: Amendments / information letters

The basic principle of the project is to carry out the tasks and activities within the time scheduled and resources foreseen as described in the Annex I (DoA) to the Grant Agreement (GA).

Any changes in the status of a beneficiary shall be communicated to the PC as soon as possible. The PC shall resolve queries and advise the beneficiaries. If required, the PC will contact the EC Project Officer responsible and request clarifications and procedures to be followed.

Significant project changes and deviations from the work planned must be dealt with in writing. The participant involved or WP Leader proposing the change should forward a written communication to the PC

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explaining the reason behind the proposed changes and direct consequences in terms of budget, work programme, etc.

As a general rule, an amendment to the GA is necessary whenever the GA or its annexes shall be modified. In some cases, the GA gives the parties the possibility to carry out certain modifications without an amendment to the GA. Finally, there are cases where the need for an amendment must be assessed carefully.

If an amendment to the GA is necessary, the PC will request the amendment process to the Project Officer on behalf of the Consortium.

Small changes during the implementation of the activities and/or the plan defined in the DoA shall be understood as normal in a research project. However, these minor deviations shall be identified and explained in the description of the activities of the corresponding Periodic Report and corrective measures that were implemented (if any).

10.1.1 Changes which require an amendment

- Removal of one or more legal entities from the list due to their non-accession to the Grant Agreement
- Addition of one or more beneficiaries
- Change of PC
  - The PC remains in the consortium
  - The participation of the PC is terminated
- Partial transfer of rights and obligations
- Modification of project title and/or acronym
- Modification of duration and/or of start date
- Modification of RP
- Change of banking details
- Changes to European Commission's and PC's contact details
- Modification of Annex I (Description of the Action)
- Amendment requested for reinstatement of the work after suspension of the project
- Request from the PC for suspension
- Suspension by the EC
- Amendment reinstating the continuation of the Grant Agreement
  - Request from the PC for suspension
  - Suspension by the EC
  - Amendment reinstating the continuation of the Grant Agreement

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10.1.2 Changes which do not require an amendment

Changes which do not require an amendment but shall be duly notified to the EC via an information letter are the following:

- Change of name and legal details of a beneficiary
- Universal transfer of activity/or of rights and obligations
- Changes in accounting system of beneficiaries and mistakes in indirect costs calculation
- Procedure
- The specific case of change of authorised representative of beneficiary

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