pan-European Management of Biological toxin incidents through standaRdisAtion initiatives for Crisis response Enhancement

D1.1
EMBRACE Project Guide

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Revision history

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0.1	21/10/2024	TEL	Table of Contents
1.0	29/11/2024	TEL	Complete draft
1.3	16/12/2024	TEL	Final
2.0	27/01/2025	TEL	New template, additional SAB member

Abbreviations

BTF	Biotoxin Task Force
BKN	Biotoxin Knowledge Network
DoA	Description of Action
EAB	Ethics Advisory Board
EC	European Commission
FTX	Field Trial
GA	Grant Agreement
GDPR	General Data Protection Regulation
KPIs	Key Performance Indicators
PM	Project Manager
PO	EMBRACE Project Officer appointed by the EC
SAB	Security Advisory Board
WP	Work Package

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1 INTRODUCTION

1.1 Background

The EMBRACE project was awarded in response to the call: HORIZON-CL3-2023-DRS-01-03: Operability and standardisation in response to biological toxin incidents (Annex A).

1.2 Purpose and Scope

The *EMBRACE Project Guide* (D1.1, M3) defines the joint responsibilities of project partners that pertain until the complete discharge of all obligations under the EC Grant Agreement, 101168322. Our goal is to secure commitment from all partners to facilitate the successful delivery of project results and to maximise the lasting impact of EMBRACE. This document has been constructed as a practical source of reference for consortium members and is intended to provide useful links to information that might be needed.

The project plan details project policies and procedures, work breakdown and overall management approach as well as guidelines for required actions. The plan is implemented within the collaboration platform, Teamwork, to provide a transparent, integrated project workspace and a continuous record of progress and project health.

1.3 Document Structure

This document is structured as follows: Section 2 describes the project management structural organisation and breakdown of responsibilities; Section 3 addresses issues of collaboration and communication between consortium members; Section 4 details the schedule of planned meetings and events throughout the project duration; Section 5 defines the quality management plan, designed to ensure that deliverables are of good quality and delivered on time; Section 6 describes the approach to live risk monitoring and mitigation; Section 7 addresses security concerns, and procedures to ensure that any sensitive material is identified and protected; Section 8 details measures and procedures to ensure that ethical and legal aspects of the project are properly addressed; and finally, Section 9 presents guidelines for enhancing the visibility and maximising the impact of EMBRACE. Annex A contains the original call to remind us of the vision of the funding programme, and Annex B is a short introduction to the implementation of the project in Teamwork with tips on its usage.

1.4 Partners

The consortium consists of 18 partners from 14 countries, a core group which EMBRACE aims to build upon to create a thriving biotoxin expert community.

Partner	Partner	Acronym	Country
1	TELESTO TECHNOLOGIES PLIROFORIKIS KAI EPIKOINONION EPE	TEL	Greece
2	DCNA DISASTER COMPETENCE NETWORK AUSTRIA	DCNA	Austria
3	OSTERREICHISCHES ROTES KREUZ	ARC	Austria

4	POMPIERS DE L'URGENCE INTERNATIONALE	PUI	France
5	MEDIZINISCHE UNIVERSITAT GRAZ	MUG	Austria
6	HELSINGIN YLIOPISTO	VER	Finland
7	SAITAMA MEDICAL UNIVERSITY EDUCATIONAL CORPORATION	SMU	Japan
8	BIOTALENTUM TUDASFEJLESZTO KFT	BIOT	Hungary
9	AIRSENSE ANALYTICS GMBH	AIRS	Germany
10	MOBILITY ION TECHNOLOGIES SL	MION	Spain
11	PROMETECH BV	PRO	Netherlands
12	IANUS TECHNOLOGIES LTD	IANUS	Cyprus
13	THE LISBON COUNCIL FOR ECONOMIC COMPETITIVENESS ASBL	LC	Belgium
14	TECHNOLOGICKA PLATFORMA ENERGETICKABEZPECNOST CR	TPEB CR	Czech Republic
15	CESKA AGENTURA PRO STANDARDIZACI	CAS	Czech Republic
16	URAD PRE NORMALIZACIU, METROLOGIU A SKUSOBNICTVO SLOVENSKEJ REPUBLIKY	UNMS	Slovakia
17	RESILIENCE ADVISORS LTD	RAN	United Kingdom
18	BIOXHALE LTD	BIOX	United Kingdom

Table 1. The EMBRACE Consortium

2 PROJECT ORGANIZATION

2.1 Project Management Structure

EMBRACE will adopt an agile approach to project management, in which solutions are developed iteratively/incrementally towards completion of the project, thereby enabling solutions to be evaluated and their further development to be informed by these evaluations. At its heart agility depends on trust, flexibility, and collaboration to attain success, and to benefit from new opportunities as they arise. The organisational structure of the consortium is therefore open, transparent, and egalitarian.

The **Project Coordinator (TEL)** is responsible for overall management, communication, and coordination of the project and will chair the two main project bodies, the Project Coordination Team and the Plenary Board.

The **Project Coordination Team** acts as a central coordinating hub, responsible for the planning, execution and management of the project, and communications with the EC. Team members include:

- A **Project Manager (PM)**, appointed by the coordinator, to monitor compliance with the Grant and Consortium Agreements, maintain communications (internal, and with the EC), plan and organise EMBRACE procedures and meetings, monitor progress, and oversee reporting processes. The PM will establish procedures for ensuring deliverable quality and conformity, including sign-off procedures, reporting requirements, and report templates.
- **Scientific and Technical Leads** will advise on scientific and technical issues, and propose solutions, modifications, and reallocation of resources, as required for achieving objectives. They will act to facilitate collaboration on tasks and ensure the scientific and technical and quality of deliverables.
- The **Ethics Lead** will advise on social, legal, and ethical issues (including gender-related issues) arising from EMBRACE activities.
- **WP Leaders** (see table 6) will oversee work in each work package, coordinate work package teams, and update the consortium on progress and any deviations from the grant agreement, should they arise.

Role	Member	Partner	Country
Project Manager	Susan Denham	TEL	Greece
Scientific Lead	Hanna Hakulinen	VER	Finland
Technical Lead	Sebastian Simonsen	PRO	Netherlands
Ethics Lead	Kurt Zatloukal	MUG	Austria

Table 2. EMBRACE Coordination Team

2.1 Project Bodies and Key Roles

2.1.1 Project Advisory Board

The **Biotoxin Task Force (BTF)**, once established (M12), will act as an external advisory group to guide the strategic directions of the project. During the initial stage of EMBRACE, partners, led by Jonathan

Hall (RAN), will reach out to the community to identify the most active and well-informed people with expertise required for the BTF. Selected people, who together can provide comprehensive coverage of the expertise and experience needed to deal with biotoxin incidents, will be invited to join the BTF. A constitution will be drawn up for the BTF to enable it to become a self-refreshing, sustainable body, that will provide a readily available resource for expert Biotoxin advice to agencies of the European Union, as agreed with the Commission.

2.2 Plenary Board

The Plenary Board is the ultimate decision-making body of the Consortium. The Plenary Board is composed of one representative from each Partner, each having one vote. It is chaired by the coordinator, who has the deciding vote in case of equal votes. The Board will meet at least twice per year to review and plan project work. Any partner may raise issues to be addressed in the plenary discussions. Partners may nominate substitutes from their organisation in the event they cannot take part in a Plenary meeting. Membership of the Plenary Board is as shown in the table below.

Partner	Member
TEL (coordinator)	Dimitrios Drakoulis
DCNA	Christian Resch
ARC	Danka Foitik Schmidt
PUI	Philippe Besson
MUG	Kurt Zatloukal
VER	Hanna Hakulinen
SMU	Makoto Sawano
BIOT	András Dinnyés
AIRS	Bert Ungethüm
MION	Mario Amo
PRO	Gert Wijnalda
IANUS	Andria Hadjithekli
LC	Francesco Mureddu
TPEB CR	Vit Střítecký
CAS	Miroslav Čermák
UNMS	Jana Mikušová
RAN	Jonathan Hall
BIOX	Paul Thomas

Table 3. Plenary Board members

2.1 Security Advisory Board

A Security Advisory Board (SAB), coordinated by Hanna Hakulinen (VER), has been established. The role of the SAB is to review project outputs to assess whether they include any security sensitive information and to introduce timely measures for preventing the dissemination of sensitive information.

Member	Partner	Professional role	Areas of competence	Country
Hanna Hakulinen	VER	VERIFIN Director	Chemistry	Finland
Vít Střítecký	TPEB CR	Associate Professor in International Security	Security	Czech Republic
Daoíz Zamora	MION	Industrial & control engineer	R&D, engineering	Spain
David Crouch	RAN	University professor, Company director	Counter-CBRN, standardisation	United Kingdom

Table 4. The Security Advisory Board

The SAB will convene twice a year (in the spring and fall). It will produce an annual report on security-related actions taken within EMBRACE. A summary of these reports will be included in the periodic reports for communication with the EC.

2.1 Ethics Advisory Board

Ethical and legal issues related to the work performed within EMBRACE refer to the use of human biological samples and associated medical data, as well as the participation of people in the performance of experimental studies, field trials and evaluations.

The **Ethics Advisory Board (EAB)**, coordinated by MUG, will be responsible for overseeing ethical and legal matters in EMBRACE, including reviewing ethical application documents to ensure implementation of proper ethical procedures, and monitoring work to address emerging ethical compliance issues. The board consists of an internal group, represented by partner institutions, complemented by invited external experts.

Member	Partner	Professional role	Areas of competence	Country
Kurt Zatloukal	MUG	Secretarial assistance to the EAB	Former member of the Ethics Board of the Federal Chancellery of Austria	Austria
Hannes Kern	DCNA	Scientific coordinator	CBRN, Industrial hazards, first responders	Austria
Danka Foitik Schmidt	ARC	Manager, Psychotherapist	Disaster management, First & Second responder	Austria
Iliana Korma	PUI	EU Project Coordinator	Research and development	France

András Dinnyés	BIOT	General Director	Ethics of human stem cells, samples, 3Rs, EU ethics reviewer	Hungary
Josef Haas	External 1	University professor	Former chair of the Ethics commission at the Medical University of Graz	Austria
Emmanuelle Rial-Sebbag	External 2	Research Director, Lawyer	Leading European ethicist	France

Table 5. The Ethics Advisory Board

The internal EAB will convene twice a year to oversee ethical compliance of project activities and to advise on any ethical issues arising, the expanded EAB with external members will meet once a year. Ethical and Legal guidelines for the project are detailed in Section 8.

2.1 Further Project Roles

2.1.1 Work package and Task Leaders

Work Package Leaders are responsible for managing their WPs as self-contained entities in cooperation with their task leaders and work teams. Their responsibilities include coordinating, monitoring, and assessing progress of their WP to ensure that the WP and Task objectives are met in compliance with specified costs and timelines. WP leaders, and Task leaders are identified in Tables 6 and 7.

WP	Title	Lead Partner	Person
1	Project management, quality assurance, ethical and legal issues	TEL	Susan Denham
2	Crisis management of biotoxin incidents	DCNA	Laura Essl
3	Detection, sampling, and identification of biotoxins	VER	Hanna Hakulinen
4	Solutions to reduce risk and harm	MUG	Julia Rieger
5	Biotoxin escalation pathway and first responder wellbeing	PRO	Sebastian Simonsen
6	Validation trials and intersectoral inter-operability	ARC	Danka Foitik Schmidt
7	Design and implementation of the Biotoxin Reference and Stakeholder Hub	IANUS	Andria Hadjithekli
8	Valorisation, Sustainability and Foresight	RAN	Jonathan Hall

Table 6. Work Package Leaders

Task	Title	Lead Partner	Person
T1.1	Project management	TEL	Susan Denham
T1.2	Scientific and Technical management	VER, PRO	Hanna Hakulinen, Sebastian Simonsen
T1.3	Quality and Risk management	TEL	Susan Denham
T1.4	Social, Legal, and Ethical management	MUG	Julia Rieger
T2.1	Establish a Biotoxin Task Force	RAN	Jonathan Hall
T2.2	Identify gaps and needs in current civil protection mechanisms for dealing with biotoxin incidents	DCNA	Laura Essl
T2.3	Requirements and CONOPs for an effective biotoxin response capacity	DCNA	Laura Essl
T2.4	Development of new training material required for dealing with biotoxin incidents	VER	Matti Kuula
T3.1	Sampling and forensic chain of custody [PRO	PRO	Sebastian Simonsen
T3.2	Procedures and guidelines for forensic analysis of biotoxin	VER	Matti Kjellberg
T3.3	Validation of portable devices for biotoxin identification	MION	Beatriz Ramis
T4.1	Methods for biothreat risk assessment of biotoxin exposure in the hot zone	IANUS	Eirini Barri, Andria Hadjithekli
T4.2	Evaluation of personal protective equipment (PPE) for first responders	MUG	Eva Reininghaus, Kurt Zatloukal
T4.3	Legally compliant sampling procedures for forensic investigations of biotoxin incidents	MUG	Sarah Heinze
T4.4	Breath and urine sampling for rapid mass screening of people potentially affected by biotoxin incidents	BIOX	Paul Thomas
T4.5	Evaluation of surface decontaminants and decontamination procedures	VER	Matti Kuula
T4.6	Biomarkers and diagnostic devices for biotoxin exposure	MUG	Kurt Zatloukal
T5.1	Intoxicated persons' care chain tracking from first symptoms to eventual outcome	PRO	Florian Käding
T5.2	Automated biotoxin alerting and multi modal source estimation	PRO	Florian Käding
T5.3	Enhancing first responder wellbeing through integrated stress monitoring and thermal prediction	MUG	Eva Reininghaus, Kurt Zatloukal

T6.1	Trial Coordination	ARC	Danka Foitik Schmidt
T6.2	Table-top based Trial	ARC	Danka Foitik Schmidt
T6.3	Field based Trials, FTX1, FTX2	PUI, MUG	Iliana Korma, Julia Rieger
T6.4	Evaluations	DCNA	Laura Essl
T6.5	Design and develop a reproducible biotoxin TX Toolbox	IANUS	Eirini Barri, Andria Hadjithekli
T7.1	Requirements and architecture	IANUS	Eirini Barri, Andria Hadjithekli
T7.2	Data curation, security, and access gateways	TEL	Chrisostomos Symvoulidis
T7.3	Module development and customisation	TEL	Chrisostomos Symvoulidis
T7.4	System integration	IANUS	Eirini Barri, Andria Hadjithekli
T8.1	Stakeholder Community Building and Sustainability	RAN	Jonathan Hall
T8.2	Visibility (Communication, Dissemination)	LC	Aikaterini Beli
T8.3	Standardisation Road Map; gaps and needs for biotoxin incidents	TPEB CR	Eliška Špeldová
T8.4	Valorisation of EMBRACE outcomes	TEL	Susan Denham, Dimitrios Drakoulis

Table 7.Task Leaders

2.1.1 Risk Management Team

Risk management in EMBRACE is overseen by the **Scientific and Technical Leads**, and the **WP leaders**, who are collectively responsible for identifying and monitoring risks (including conflicts, should they arise), and ensuring appropriate mitigation actions are taken on a timely basis.

2.1.2 Valorisation Teams

Each result identified in the Grant Agreement will be assigned a valorisation team, to include: the result owner(s), a member with expertise in standardisation, the technical/scientific lead, and the valorisation lead. Each valorisation team will be responsible for identifying and taking actions necessary for unlocking the full potential of a specific project result. If during the project, further results are identified, then they too will be assigned valorisation teams.

2.1.3 Visibility Team

Partners LC and RAN will together oversee the visibility of EMBRACE, ensuring that it is becomes widely known and an important presence in the Disaster Resilience community. In addition to overseeing the creation of a clear visual identity the team will provide guidance to consortium members on visibility issues, especially on the use of social media.

3 COLLABORATION AMONG PARTNERS

3.1 Decision Making and Conflict Resolution

During the project, decisions will normally be taken by the people responsible for the work to be performed, according to the description of work in the Grant Agreement, the Consortium Agreement, or subsequent plans approved by the consortium. In addition, the consortium may make higher level decisions based on new technical or scientific developments, emerging commercial ideas or community building opportunities, for example.

In the case of a dispute between two or more team members or partners, the escalation procedure described below will be followed:

a) Lodge the dispute**.** This form will ask you to describe the nature of the dispute, the parties involved, and the positions they take. Once you submit it, a conflict resolution task will be launched in Teamwork, where the measures taken to resolve the dispute will be recorded.
b) Attempt to resolve the disagreement through discussion at the point at which the conflict emerged.
c) Document the outcome of these discussions in the task comments. For important/complex issues, the discussions and agreement may take the form of a short report that should be approved by all those involved in the decision-making process.
d) If no agreement can be reached at that level, then the following escalation path must be followed, until the point that agreement can be reached: Task → WP → Project Coordination Team → Plenary Board.
e) At each level of escalation, the outcome of the discussions at that level should be recorded.
f) The Plenary Board will be the final arbiter in all project conflicts, and will reach consensus through voting, one vote per partner. All partners will be bound by this decision.
g) Once the conflict has been resolved, the PM will enter a summary of the dispute and resolution in the Conflict Resolution notebook in Teamwork.

3.2 Communication among Partners

3.2.1 Information Flow

Information flow within the Project depends on:

- Exchange of emails and technical and business documents.
- Monthly progress, WP, and consortium meetings.
- The exchange and sharing of comments and documents within the Teamwork collaboration environment. The following Teams have been created within Teamwork to facilitate communications. New teams can be created as needed, upon request.
    - EMBRACE - all members of the consortium working on the project
    - Security Advisory Board
    - Plenary Board
    - WP Leaders
    - W1, W2, W3, W4, W5, W6, W7, W8
- Notifications of new events and publications through membership of the CMINE community and its various special interest groups, or through the EMBRACE website and social media channels

- Sharing of information gained through participation in external meetings and events.

All documentation generated by the Project will be exchangeable in electronic format, according to the set of guidelines agreed and documented in the Data Management Plan, Deliverable D1.2.

3.2.1 Project mailing lists

The domain name EmbraceBiotoxHub.eu has been purchased, and the set of mailing lists shown in the table below have been created. The lists are maintained by the project coordinator.

Mailing List	Description
All@EmbraceBiotoxHub.eu	For subjects concerning entire consortium: admin, financial, legal, announcements, plenary meetings etc.
sab@EmbraceBiotoxHub.eu	For subjects concerning the Security Advisory Board
eab@EmbraceBiotoxHub.eu	For subjects concerning the Ethics Advisory Board
btf@EmbraceBiotoxHub.eu	For subjects concerning the Biotoxin Task Force
WPLeaders@EmbraceBiotoxHub.eu	For subjects concerning WP Leaders
WP1@EmbraceBiotoxHub.eu	For subjects concerning WP1
WP2@EmbraceBiotoxHub.eu	For subjects concerning WP2
WP3@EmbraceBiotoxHub.eu	For subjects concerning WP3
WP4@EmbraceBiotoxHub.eu	For subjects concerning WP4
WP5@EmbraceBiotoxHub.eu	For subjects concerning WP5
WP6@EmbraceBiotoxHub.eu	For subjects concerning WP6
WP7@EmbraceBiotoxHub.eu	For subjects concerning WP7
WP8@EmbraceBiotoxHub.eu	For subjects concerning WP8
info@EmbraceBiotoxHub.eu	For information requests or people wanting to get in contact with EMBRACE

Table 8. EMBRACE Mailing lists

The following internal email guidelines should be respected by consortium members:

- All internal email subject headings must start with the text “EMBRACE”. Additional header information can be added to specify relevant work packages, tasks, deliverables, and topics, as needed.
- Messages should be kept as concise as possible.
- When multiple issues are covered, they should be clearly distinguished, numbered and organised in sections.
- Keep the recipient email list as short as you can. Please avoid broadcasting to the entire consortium unless strictly necessary.
- When forwarding or re-posting communications of another party, the original content should be preserved verbatim, the source acknowledged, and their permission obtained in advance.

3.3 Teamwork

Teamwork is an all-in-one project management tool that has the functionality needed to support the efficient delivery of EMBRACE. It will act as a central source of trusted information, that provides tools for collaboration, work planning and task allocation, document sharing, data gathering, procedure automation, communication channels, and much more. All members of the consortium working on EMBRACE have been invited to join the Teamwork environment. An overview of the structure and functionality of Teamwork as set up for the EMBRACE Project is presented in Annex B. Useful links into Teamwork are included throughout this document.

4 MEETING SCHEDULE

The plan for meetings, agreed following discussions at the kick off meeting, is as follows. In person **Consortium (Plenary) meetings** will be held roughly every 6 months, with dates chosen to coincide with significant project events, thereby making project travel more cost effective. **Monthly progress meetings** will be held online, using a generic agenda that will be tailored to meet the project's needs each month. These meetings will be held at the same time on the first Tuesday of each month to create a regular EMBRACE slot in member's diaries. In addition, online meetings of the **SAB**, **EAB** and **BTF**, and **WP** and **valorisation team meetings**, are expected to occur on a regular basis.

4.1 Consortium meetings

Consortium (Plenary) meetings are planned to coincide with project milestones, and/or significant events as follows:

Meeting Month	Milestone. Deliverables	Event / Activity	Lead/Host Partner	Location	Date
M6	1: D1.1, D1.2, D8.1	User Requirements Workshop – engagement with stakeholders	IANUS	IANUS, Cyprus	11-13 March 2025
M13	2. D2.1, D2.2, D4.1, D7.1, D8.3, D8.5	Biotoxin Task Force launch; Biotoxin Knowledge Network initiated, biothreat risk assessment tool, CONOPs gaps and needs identified, BRSH requirements, initial standardisation and valorisation actions.	VER	OPCW ChemTech Centre, The Hague, Netherlands	14-15 October 2025
M18	3. D2.3, D2.5, D3.1, D3.3, D4.5, D7.2	TTX, Table-top Trial, evaluations of initial concepts and prototypes.	DCNA / ARC	Vienna, Austria	Feb / March 2026
M26	4. D2.7, D3.4, D3.6, D4.2, D4.3, D5.1, D5.2, D5.4, D6.1, D8.6	Field Trial, FTX1.	ARC / PUI	La Souterraine Training Centre, Limoges FR	November 2026
M32	5. D4.7, D6.2, D6.4, D8.2	Field Trial, FTX2.	ARC / MUG	Sim Campus, Styria, AT	May 2027
M36	6. D1.3, D2.4, D2.6, D2.8, D3.2,	Final project event Details to be confirmed.	TEL	<to be decided>	September 2027

	D3.5, D3.7, D4.4, D5.3, D5.5, D6.3, D7.3, D8.4, D8.7	Wrap up & forward plans			

Table 9. Consortium meeting schedule

At least one month before each meeting a consortium meeting agenda will be shared with the consortium, and members invited to add agenda items as needed.

4.2 Monthly progress meetings

Monthly progress meetings will be held on the first Tuesday of each month throughout the project. All those with key roles in the consortium, and at least 1 representative from each partner are expected to attend these meetings. Attendance will be recorded. The meetings will use a standard agenda that covers project progress as follows:

- **WP Leaders** (and task leader where appropriate) present an overview of progress in their WP, and raise issues for discussion, as needed. For consistency, WP Leaders should use the WP Flash Report template.
- **Project manager** reports on general management, administrative, financial, and reporting issues, communications with the project officer, and overall progress against project milestones
- The **Scientific, Technical and Ethics Leads** present an overview of scientific, technical and ethics developments and any issues that require corrective actions or strategic decisions
- Reports from the representatives of the SAB, EAB and BTF will also be included when available
- Notices of upcoming events or news items
- Topics requiring consortium wide consideration

At least one week before each meeting a meeting agenda will be shared with the consortium, and members invited to add agenda items as needed.

The Monthly Progress Meetings notebook in Teamwork, will be used to record the agenda, meetings minutes, attendance, outcomes and actions for each meeting.

4.3 WP Team meetings

WP team meetings will be held at the discretion of the WP Leader. These are expected to occur at least once per month while the WP is active. Due to their diversity, some WPs may choose to have monthly task meetings instead.

4.4 Meetings of other project bodies

The **SAB**, **EAB** and **BTF** will all hold regular meetings. The schedule of meetings and meeting minutes will be shared with the consortium.

5 QUALITY MANAGEMENT PLAN

5.1 Overview

The purpose of this plan is to ensure that EMBRACE completes its tasks on time and on budget, work is carried out to a high standard, deliverables and other outputs are of high quality, and that the project achieves its objectives and target outcomes. The plan, which falls into two parts, continuous monitoring, and quality control of deliverables, describes the set of quality management procedures to be followed by the consortium. Adherence to these procedures is the joint responsibility of all project partners.

5.2 Continuous monitoring of project progress

5.2.1 Approach

Continuous monitoring of project activities includes maintaining a record of the work performed, meetings and events attended/organised, and publications and other outputs produced. This information will be gathered from the Monthly Progress Meeting presentations, records of activity and progress in Teamwork tasks, and live records of outputs, supplemented by a set of Key Performance Indicators (KPIs), which will be monitored and updated as needed throughout the project.

5.2.2 Recording project activity

Each WP Leader is responsible for presenting an up-to-date report on activity, progress, and issues arising within their WP at the Monthly Progress Meetings. Only those WPs and tasks active at the time of the meeting should be included. The WP Flash Reports should be emailed to the PM **before the meeting** for inclusion in the meeting presentation pack (which will be uploaded to the corresponding meeting file repository).

Each task leader is responsible for maintaining a record of task progress, and work carried out for the duration of the task. A combination of task comments, work documents, and Teamwork Task notebooks may be used.

All consortium members are responsible for registering their publications (subject to security procedures), and information on meetings they have organised or attended in the course of their work on EMBRACE. To record this information, please use the following links:

- Publications – apply for security clearance
    - Once security cleared the publication information will be saved in the Publications notebook
- Meetings/workshops/conferences organised or attended, including presentations and invited talks

5.2.3 Key Performance Indicators

A live table of KPIs is available in Teamwork. Each KPI will be monitored and updated as relevant data is acquired. The table can also be seen as a guide to the questions which should be asked of the

community during the trials. Sources of KPI data, the project aspect for which it provides evidence, responsibility for monitoring, and whether the KPI has been achieved, are all included in this table.

All KPIs are currently red – not achieved. The table can be updated by entering the data counts/measures as appropriate. Change the colour of the row to Green to indicate that a KPI has been achieved.

EMBRACE Objectives, Outcomes and Impacts all depend on project outputs and KPIs, as defined in the GA. Tasks associated with each have been created. These tasks will be closed once all indicators documented in the task description have been satisfied.

5.2.4 Data gathering and project monitoring

Where possible, Teamwork forms (questionnaires) will be created to gather the data required to support the internal project monitoring processes. In addition, live records of task progress, and shared documents, e.g., Teamwork notebooks, provide further information for project monitoring.

Beyond this, an Interim Work Report and Interim Financial Report (see Annex C for more details) will be required **from each partner at the end of each 6-month period**. In these reports, partners should describe their project activities, including their actions for each WP, publications or dissemination actions taken, and their person-hours effort per WP to provide a justification of costs for the 6-month period.

WP Leaders should use the information from partners to produce an Interim WP Report covering the objectives of their WP for the interim reporting period, and for each active task are required to document achievements, problems encountered, risks and mitigation actions, deviations from planned work, completed deliverables, other outputs, and plans for the next period (templates, populated with partner information to be provided – see Annex C for more details).

Based on these reports and the continuous reporting information, the PM will produce an integrated 6 monthly **Project Health report**. This report will consist of two parts:

a) The **working progress report** will integrate the WP reports with reports from the advisory boards.
b) The **financial report** will include information on person-months per WP per partner for the 6-month period, an estimation of over/under spending, and justification for any deviation between the two.

5.3 Quality control procedures for deliverables

5.3.1 Approach

Procedures for ensuring the quality of project deliverables, and their timely delivery include the creation of early of internal deadlines, and a schedule of agreed reviewing responsibilities.

5.3.2 Policy on deadlines

EMBRACE will strictly adhere to the deliverable schedule documented in the GA. Quality control procedures are scheduled with respect to these constraints.

5.3.3 Quality procedures

Each project deliverable is assigned to a leading responsible partner. This partner takes responsibility for ensuring that the deliverable is of high quality and delivered in good time. Checking that the scientific and technical aspects of the deliverable are sound and, where appropriate, advance the current state-of-the-art in research/TRL is the responsibility of the corresponding WP Leader. Any issues related to a deliverable that might endanger the success of the corresponding WP, or the project, must be reported by the WP leader immediately, and if necessary, escalated for discussion by the Coordination team.

Deliverable documents, once submitted, will be reviewed against the following criteria:

- Content is consistent with the GA and previous relevant documentation (e.g., technical specifications, requirements definitions, etc).
- Format is consistent with the deliverable document template
- The language is idiomatic and grammatical.
- Typographical errors are absent.

The schedule for deliverable quality control is as follows (where SD is the Submission Deadline specified in the GA):

- Table of contents is submitted for approval by the named reviewers, SD – 90 days
- Internal submission of complete draft document for review, SD - 28 days
- Internal review comments communicated to responsible partner, SD - 21 days
- Response to the review and revised deliverable returned to review team, SD – 14 days
- Conformance check and approval by the reviewer, SD – 7 days
- Final quality and security checks, SD – 3 days
- Submission – PM to upload the document in the EC portal, SD – 1 day

Deliverable prototypes and demonstrators: will follow similar review procedures, as follows:

- Functional specification of the demonstrator is submitted for approval by the named reviewers, SD – 90 days
- Internal submission of demonstrator documentation, SD - 28 days
- Internal review comments communicated to responsible partner, SD - 21 days
- Response to the review and revised deliverable returned to review team, SD – 14 days
- Conformance check and approval by the reviewer, SD – 7 days
- Final quality and security checks, SD – 3 days
- Submission – PM to upload the document in the EC portal, SD – 1 day

These procedures have been built into the Teamwork Framework. Instructions for triggering a review of the Table of Contents and Deliverable document, are contained in the corresponding tasks for each deliverable (see Annex B). In these tasks, documents and comments can be exchanged and recorded. The reviewed and internally approved deliverable documents will be held within the Teamwork file repository. The project website will include notifications of deliverables submitted and offer deliverable download options for the wider community.

SEN deliverables: are those deliverables which were identified in the Description of Action (DoA) as potentially containing sensitive information. They will follow the same reviewing procedures as other deliverables but will then be considered by the SAB before submission. See section 7 for more details.

5.3.4 Deliverable Schedule with Nominated Reviewers

The deliverable schedule in date order, together with responsible partner, and nominated reviewers are contained in Table 10, below (red dividers indicate milestone points; pale gold indicates SEN deliverables).

Deliverable	Title	Level	Responsible Partner	Due Date	Reviewer 1
D1.1	Embrace Project Guide	PU	TEL	31/12/2024 M3	PRO
D1.2	Data management plan – 1st Iteration	PU	TEL	31/03/2025 M6	MUG
D8.1	Visibility Strategy & Plan – 1st Iteration	PU	RAN	31/03/2025 M6	ARC
D2.1	Biotoxin Task Force	PU	RAN	30/09/2025 M12	TEL
D2.2	Crisis management of biotoxin incidents	SEN	DCNA	30/09/2025 M12	VER
D4.1	Biothreat risk assessment framework - 1st Iteration	SEN	IANUS	30/09/2025 M12	MION
D7.1	BRSH Requirements and Architectural Framework	PU	IANUS	30/09/2025 M12	PUI
D8.3	Standardization roadmap - 1st Iteration	PU	TPEB CR	30/09/2025 M12	MUG
D8.5	Exploitation and impact evaluation – 1st Iteration	PU	TEL	30/09/2025 M12	AIRS
D2.3	A UCPM biotoxin response capacity -1st Iteration	PU	DCNA	31/03/2026 M18	UNMS
D2.5	CONOPs for biotoxin incidents – 1st Iteration	PU	DCNA	31/03/2026 M18	PUI
D3.1	Sampling devices and sample tracking - 1st Iteration	PU	PRO	31/03/2026 M18	BIOT
D3.3	Analysis of target biotoxins and analysis ROPs - 1st Iteration	SEN	VER	31/03/2026 M18	MUG
D4.5	Grab and Go integrated multiphase sampler - 1st Iteration	PU	BIOX	31/03/2026 M18	TEL
D7.2	BRSH implementation - 1st Iteration	SEN	IANUS	31/03/2026 M18	TEL

D5.1	Intoxicated person registration & tracking system	PU	PRO	29/05/2026 M20	AIRS
D6.1	TTX evaluation report	PU	DCNA, ARC	29/05/2026 M20	PUI
D2.7	Biotoxin training materials - 1st Iteration	PU	VER	30/09/2026 M24	PRO
D3.4	Analysis of target biotoxins and analysis ROPs - 2nd Iteration	SEN	VER	30/09/2026 M24	MUG
D3.6	Portable biosensing devices and validation - 1st Iteration	SEN	MION	30/09/2026 M24	TEL
D4.2	Biothreat risk assessment framework - Final Iteration	SEN	IANUS	30/09/2026 M24	DCNA
D4.3	PPE efficacy and usability	PU	MUG	30/09/2026 M24	DCNA
D5.2	Biotoxin incident escalation tool - 1st Iteration	PU	PRO	30/09/2026 M24	TEL
D5.4	First responder stress and thermal prediction system - 1st Iteration	PU	MUG	30/09/2026 M24	PUI
D8.6	Exploitation and impact evaluation - 2nd Iteration	PU	TEL	30/09/2026 M24	LC
D6.4	TX toolbox	PU	IANUS	30/11/2026 M26	ARC
D6.2	FTX - France, Austria - 1st Iteration	PU	DCNA, PUI	29/01/2027 M28	VER
D4.7	Biomarkers of early biotoxin exposure and prototype field diagnostics devices	PU	MUG	31/03/2027 M30	VER
D8.2	Visibility Strategy & Plan - Final Iteration	PU	RAN	31/03/2027 M30	ARC
D4.4	Evaluation of decontaminants	PU	MUG	31/05/2027 M32	VER
D8.4	Standardization roadmap - Final Iteration	PU	TPEB CR	31/05/2027 M32	UNMS
D2.4	A UCPM biotoxin response capacity - Final iteration	PU	DCNA	30/06/2027 M33	LC
D2.6	CONOPs for biotoxin incidents - Final Iteration	PU	DCNA	30/06/2027 M33	ARC

D2.8	Biotoxin training materials - Final Iteration	PU	VER	30/06/2027 M33	AIRS
D1.3	Data management plan - Final iteration	PU	TEL	30/07/2027 M34	ARC
D3.2	Sampling devices and sample tracking - Final Iteration	PU	PRO	30/07/2027 M34	BIOT
D3.5	Analysis of target biotoxins and analysis ROPs - Final Iteration	SEN	VER	30/07/2027 M34	MUG
D3.7	Portable biosensing devices and validation - Final Iteration	SEN	MION	30/07/2027 M34	TEL
D5.3	Biotoxin incident escalation tool - Final Iteration	PU	PRO	30/07/2027 M34	TEL
D5.5	First responder stress and thermal prediction system - Final Iteration	PU	MUG	30/07/2027 M34	PUI
D6.3	FTX - France, Austria - Final Iteration	PU	DCNA, MUG	30/07/2027 M34	SMU
D7.3	BRSH implementation - Final Iteration	SEN	IANUS	30/07/2027 M34	BIOT
D8.7	Exploitation and impact evaluation - Final Iteration	PU	TEL	30/07/2027 M34	TPEB CR
D4.6	Grab and Go integrated multiphase sampler - Final Iteration	PU	BIOX	30/09/2027 M36	DCNA
D4.8	In vitro risk analyses of biotoxin exposure	SEN	BIOT	30/09/2027 M36	MUG
D4.9	Standardised sampling procedures	PU	MUG	30/09/2027 M36	VER

Table 10. Deliverable schedule with assigned reviewers

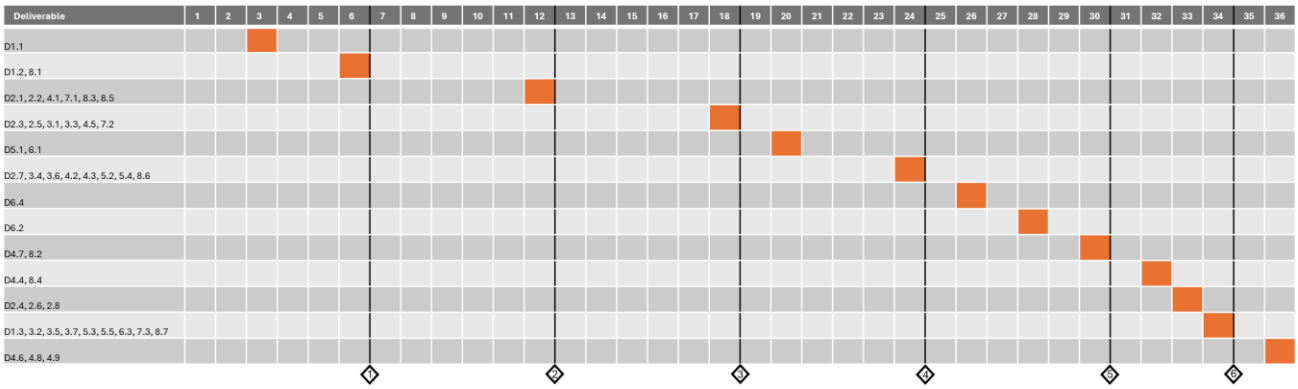


Figure 1. Deliverable Gannt chart with milestones

6 RISK MANAGEMENT PROCEDURES

Risk Management Plan

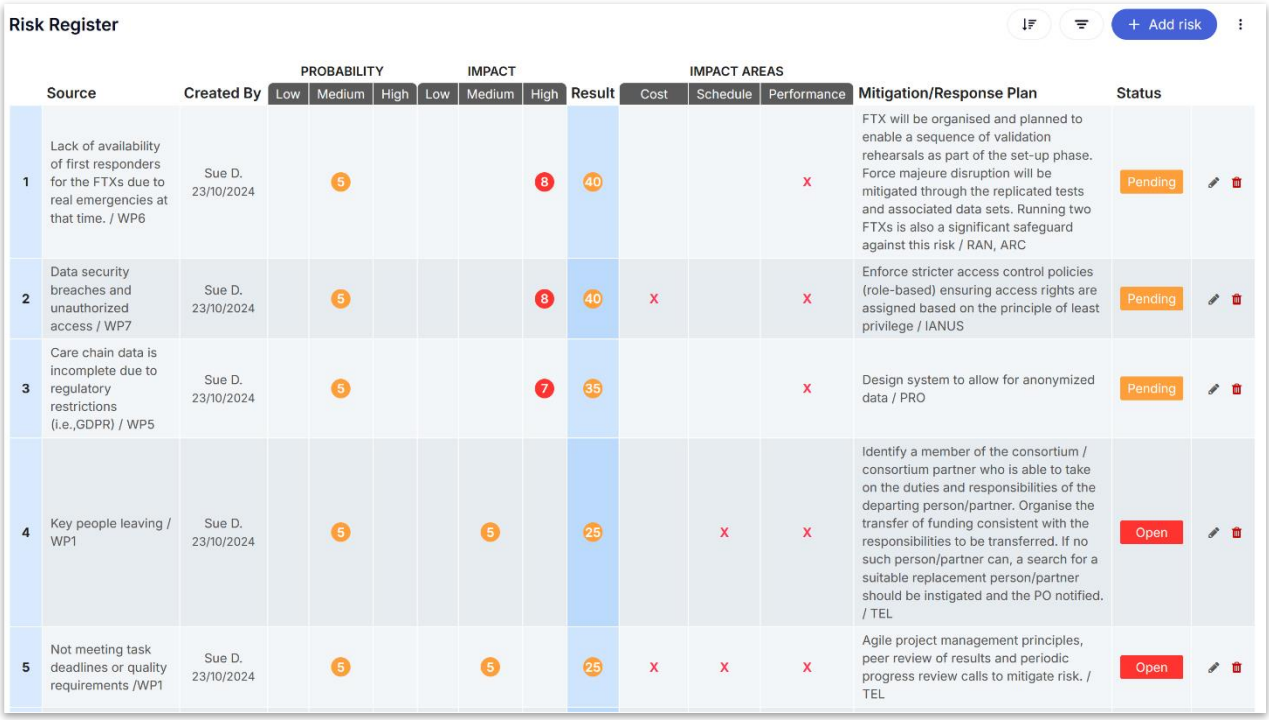
The risk management methodology adopted by EMBRACE follows the following 4 steps:

1. identification
2. quantification
3. mitigation / control
4. reporting.

Risk Register: Steps 1-3 are embodied in a live Risk Register within the Teamwork project management environment. The Risk Register in Teamwork was created from the Risk Table in the Grant Agreement, and further risks, identified during preparations for the kick-off meeting.

The Risk Register holds the following information:

- **Risk Source**: A description of the identified risk and the WP which it affects
- **Created By**: name of the person creating the risk entry. Any person in the team can do so (though currently, the creator is the person who built the table, SD).
- **Probability:** an estimate of the likelihood of the risk occurring on a scale of 1-9; Low (1-3), Medium (4-6), High (7-9).
- **Impact:** the effect on the project if the risk does occur on a scale of 1-9; Low (1-3), Medium (4-6), High (7-9).
- **Result:** Probability*Impact (calculated by Teamwork) is used to rank risk severity.
- **Impact Area:** an indication of what aspect(s) of the project will be impacted if the risk occurs - Cost, Schedule and/or Performance
- **Mitigation/Response Plans:** what to do if the risk occurs, and the partners responsible.
- **Status:** current status of the risk – Open/Pending/Closed.



Risk Register

+ Add risk

	Source	Created By	PROBABILITY			IMPACT			Result	IMPACT AREAS			Mitigation/Response Plan	Status
			Low	Medium	High	Low	Medium	High		Cost	Schedule	Performance		
1	Lack of availability of first responders for the FTXs due to real emergencies at that time. / WP6	Sue D. 23/10/2024		5				8	40			x	FTX will be organised and planned to enable a sequence of validation rehearsals as part of the set-up phase. Force majeure disruption will be mitigated through the replicated tests and associated data sets. Running two FTXs is also a significant safeguard against this risk / RAN, ARC	Pending
2	Data security breaches and unauthorized access / WP7	Sue D. 23/10/2024		5				8	40	x		x	Enforce stricter access control policies (role-based) ensuring access rights are assigned based on the principle of least privilege / IANUS	Pending
3	Care chain data is incomplete due to regulatory restrictions (i.e.,GDPR) / WP5	Sue D. 23/10/2024		5				7	35			x	Design system to allow for anonymized data / PRO	Pending
4	Key people leaving / WP1	Sue D. 23/10/2024		5			5		25		x	x	Identify a member of the consortium / consortium partner who is able to take on the duties and responsibilities of the departing person/partner. Organise the transfer of funding consistent with the responsibilities to be transferred. If no such person/partner can, a search for a suitable replacement person/partner should be instigated and the PO notified. / TEL	Open
5	Not meeting task deadlines or quality requirements /WP1	Sue D. 23/10/2024		5			5		25	x	x	x	Agile project management principles, peer review of results and periodic progress review calls to mitigate risk. / TEL	Open

Figure 2. Project Risk Register – top 5 entries, ranked on severity.

Work package leaders have permission in Teamwork to update, create and delete risks, as deemed appropriate, and may do so on an ongoing basis. This register is intended to be a live record of risks as they emerge and/or pass throughout the duration of the project, and the potential issues recorded here should be regularly monitored by the corresponding WP Leaders and partners.

Note: as the Risk Register is rather large, the use of filters to focus on your area of interest is advised. E.g., partner acronyms or work package identifiers (WP1, WP2, .., WP8) are most useful.

Risk Reporting: the final step in the risk management methodology. In the event that a risk is triggered, then the situation, and the mitigation actions taken should be recorded in the Risk Management Actions notebook.

7 SECURITY

7.1 Summary of security issues in EMBRACE

EMBRACE deals with biological toxin incidents and crisis response enhancement, thereby raising security concerns.

Sensitive information with security recommendations:

Section 5.1 of the DoA, Part B lists the deliverables with limited dissemination (SEN) requirements. They are not labelled as classified but cannot be disseminated to third parties not listed in the section without prior authorization from the granting authority. However, these "sensitive" deliverables may have a public deliverable document with sensitive annexes, allowing the public part to be publicly disseminated.

Beneficiaries may disclose sensitive information to their personnel or other participants involved in the action only if they (cf. Art 13.1 of GA):

(a) need to know it in order to implement the Agreement and

(b) are bound by an obligation of confidentiality

The parties must keep confidential any data, documents or other material (in any form) that is identified as sensitive in writing ('sensitive information') — during the implementation of the action and for at least 5 years after final payment.

During the negotiations, the following deliverables were considered as potentially containing sensitive information and their dissemination level was marked as 'SEN', with the stipulation that: **Only the EC and consortium members are authorised for access to these documents, except for public parts of the documents.**

Deliverable	Lead Partner	Month due
D2.2: Crisis management of biotoxin incidents	DCNA	M12
D3.3: Analysis of target biotoxins and analysis ROPs – 1st iteration	VER	M18
D3.4: Analysis of target biotoxins and analysis ROPs – 2nd iteration	VER	M24
D3.5: Analysis of target biotoxins and analysis ROPs – final iteration	VER	M34
D3.6: Portable biosensing devices and validation – 1st iteration	MION	M24
D3.7: Portable biosensing devices and validation – final iteration	MION	M34
D4.1: Biothreat risk assessment framework-1st Iteration	IANUS	M12
D4.2: Biothreat risk assessment framework Final Iteration	IANUS	M24
D4.8: In vitro risk analyses of biotoxin exposure	BIOX	M36
D7.2: BRSH implementation - 1st Iteration	IANUS	M18

D7.3: BRSH implementation – Final Iteration	IANUS	M34

Table 11. Deliverables listed in the DoA which are considered to contain sensitive information

7.2 Security policy

The principal aim of the Security Advisory Board (SAB) is to identify sensitive information produced by work in EMBRACE, to ensure protection of sensitive information. The main method of protection is to restrict the sharing of sensitive information; the basic level of protection being a restriction to sharing sensitive information only with the consortium and the EC. To this end, EMBRACE will establish and operate a shared private data space to which only consortium members have access. Furthermore, the selection of reviewers for SEN deliverables is restricted to a small set of partners (**VER, MION, TPEB, DCNA, MUG, BIOT, IANUS, TEL**) thereby avoiding unnecessary sharing of potentially sensitive information.

The SAB will adopt a proactive approach to protecting sensitive information, focussed on with three main areas of operation, deliverables, dissemination, and communications, under the understanding that the nature of the audience is an important factor in deciding whether certain information is suitable for inclusion or not.

Deliverables: Before M6, the SAB will consider all EMBRACE deliverables to decide whether the list of SEN deliverables should be extended. The complete list of SEN deliverables, following the SAB review, will be made available within Teamwork, and all SEN deliverables will clearly be marked as such.

Dissemination: Dissemination in this context means publishing or presenting scientific or technological discoveries and developments in papers or conferences aimed at specialist audiences. All EMBRACE outputs falling within this category will require security clearance from the SAB. To obtain clearance, authors are advised to avoid including sensitive material, and to bring any potentially sensitive information to the attention of the SAB. Dissemination can only take place with the approval of the SAB.

Communications. Communication activities are aimed at a wider more general audience. The SAB will work closely with the Visibility Team to define a set of guidelines for ensuring that sensitive material is not communicated inadvertently. The Visibility Team will be responsible for overseeing compliance with these guidelines.

Consortium members are advised that if they are ever in doubt about the sensitivity of the material they are about to share outside of the consortium, then they should consult the SAB.

General security awareness: Following the advice of Horizon Europe Programme Security Instructions (PSI) – Ares (2022)211078 - 12/01/2022, the Visibility Team and consortium members are encouraged to:

- Monitor social media interest in EMBRACE
- Notify the SAB in case of contacts from journalists that show a strong interest in the project e.g. asking for access to non-public deliverables, or if they notice any abnormal activities around EMBRACE

In any of these occur, the EMBRACE PO will immediately be notified by the PM.

Dual-use items

Activities in EMBRACE project should always consider, when necessary, Regulation (EU) 2021/821 of the European Parliament and of the Council of 20 May 2021 setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items, source.

7.3 Procedures for protecting sensitive information

Deliverables: Before submission SEN deliverables must be submitted to the SAB for security checks. (All deliverables currently labelled as SEN will be reviewed by at least one member of the SAB. Therefore, their review automatically includes an assessment of security by the SAB).

To enable public dissemination of non-sensitive information the following procedures will be followed:

a) The SAB will identify sensitive information within the deliverable.
b) **For documents**: If sensitive information is found, then the authors will be required to extract such information and store it within a SEN-designated Annex, leaving the main document suitable for public dissemination.
c) **For demonstrators**: the information made available by, or contained within, the demonstrator will be similarly considered and sensitive information removed from publicly accessible areas.
d) Only the material judged to be non-sensitive will be permitted to be disseminated outside of the consortium and EC.
e) All sensitive information must remain confidential to the consortium and the EC.
f) In the event that sensitive information is identified, access to this information will be restricted, protected by end-to-end encryption, and carefully controlled using specific permissions. Secure storage of the sensitive information will be the responsibility of the lead partner responsible for the generation of the information. Details of the procedures for protecting sensitive information, approved by the SAB, will be communicated with the responsible partners.

If during the review process, reviewers of other deliverables have concerns about the sensitivity of the material in the deliverable, then they should consult the SAB.

Dissemination: Before publication the responsible partner is required to submit a Security Clearance Request form. Submission of this form automatically triggers a task for the SAB to review the request. The submitter of the form will be notified of the decision of the SAB within 7 days. Publication is only permitted once the approval of the SAB has been received.

Guidelines for avoiding communication of sensitive information have been drawn up in collaboration between the SAB and the Visibility Team. Consortium members are responsible for ensuring that their communications comply with these guidelines. If in doubt they should consult the Visibility Team, who can escalate the decision to the SAB if needed. Communications are only permitted if they adhere to the guidelines.

8 ETHICAL AND LEGAL ISSUES

8.1 Principles and Guidelines

Compliance with international and European legislation

EMBRACE partners will respect all relevant International Conventions and codes of conduct and conform to EU and national legislation and follow relevant standards of Good Scientific Practice, Clinical and Epidemiological Practices at International and European levels.

EMBRACE will be conducted in strict accordance with the Convention for the Protection of Human Rights and Fundamental Freedoms and EU regulations on ethical issues including General Data Protection Regulation (GDPR) Regulation (EU) 2016/679 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, as well as Directive 2005/28/EC relating to the implementation of good clinical practice in the conduct of clinical trials, and Regulation (EU) 2017/746 on in vitro diagnostic medical devices. The project will also take into account opinions of the European Group on Ethics in Science and New Technologies (EGE), as required by Art.6(1§) of the Seventh Framework Programme (Decision No. 1982/2006/EC).

Concerning work with biotoxins, the WHO Laboratory Biosafety Manual, the Laboratory Biosafety and Biosecurity Risk Assessment Technical Guidance Document, and the CEN Workshop Agreement on Laboratory Bio risk Management CWA 15793:2011, will be followed.

All studies will be conducted in EU/Affiliated Member States, which since 2004 have adopted a harmonised regulatory system to protect the safety, rights and dignity of clinical trial subjects, while safeguarding the integrity of trial outcomes.

All beneficiaries involved in any activities involving human subjects have a long track record and experience in human (clinical) studies and evidence of strict compliance with European and International regulations in such studies.

Compliance with national regulations:

EMBRACE will be conducted in strict compliance with national ethical and regulatory requirements and will work closely with national and local regulatory authorities.

8.2 Ethical and privacy principles

Work in EMBRACE will respect the following principles:

- respect for human dignity and the principles of non-exploitation, non-discrimination and non-instrumentalization;
- individual autonomy, entailing the giving of free and informed consent, and respect for the privacy and confidentiality of personal data;
- just and equitable distribution of the burdens and benefits of research;
- beneficence and non-maleficence, with regard to the improvement and protection of health;
- proportionality, including use of research methods that are necessary to the aims pursued and for which no alternative more acceptable methods are available.

EMBRACE does not carry out research activities:

- aimed at human cloning for reproductive purposes;
- intended to modify the genetic heritage of human beings, which could make such changes heritable;
- intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

Under GDPR rules, personal data will be processed in accordance with principles and conditions that aim to limit the negative impact on the persons concerned and ensure fairness, transparency and accountability of data processing, data quality, data minimisation, and confidentiality.

8.3 Ethical procedures for voluntary participation in EMBRACE activities

EMBRACE will carry out a number of studies and trials involving human participants, including:

- field and tabletop trials for evaluating new technologies, training materials, and crisis management procedures;
- studies (trials) for evaluating the use of personal protective equipment (PPE) and the well-being of first responders.

For each study involving human participants, ethical application will be made to the Ethics Board of the host institution of the leading partner for the study.

For help in preparing the study the following information is available:

- General guidance on ethical approval and data management procedures
- Templates for informed consent forms and information sheets

For each study involving human participants a Study Approval Record containing the following documents and information should be uploaded in one package prior to enrolment of the first study subject:

- Final version of study design as submitted to regulators/ethics committee(s)
- Ethics applications form, informed consent forms, and information sheets
- Registration number of the study, if relevant
- Approvals (ethics committees and national competent authority, if applicable) required for invitation/enrolment of first subject at least in one clinical centre

Requirements for compliance with GDPR:

- Beneficiaries processing identifiable information and responsible for a study (/trial/workshop) must confirm that they have appointed a Data Protection Officer (DPO) and that the contact details of the DPO are made available to all subjects involved in the activity.
- An explanation of how all data that is intended to be processed is relevant and limited to the purpose of the project (in accordance with the “data minimization” principle) should be provided to the Ethics Board for review.
- A description of security measures that will be implemented to prevent unauthorized access to personal data or equipment used for processing the data should be provided to the Ethics Board

A report on each study and field trial will be submitted as a deliverable, according to the deliverable schedule, see Table 10.

8.4 Ethical procedures for EMBRACE activities involving clinical samples

EMBRACE will carry out studies involving human clinical samples, aimed at the detection of human biomarkers for biotoxin intoxication. Ethical applications will be made to the Ethics Board of the host institution of the leading partner in each study.

Since the assays and training material will be defined and developed in the first year of the project, trial protocols will be written and submitted for approval once the information necessary for each study design is available.

For each study involving clinical samples a Study Approval Record containing the following documents and information should be uploaded in one package prior to enrolment of the first study subject:

- Final version of study protocol as submitted to regulators/ethics committee(s)
- Registration number of the clinical study in a WHO- or ICMJE- approval registry (with the possibility to post results)
- Approvals (ethics committees and national competent authority, if applicable) required for invitation/enrolment of first subject at least in one clinical centre

8.5 Non-EU countries

The EMBRACE consortium includes partners from UK and Japan. However, the work program does not foresee exchange of human samples, tissues or personal (identifiable) data with these partners.

9 MAXIMISING IMPACT

The success of EMBRACE depends in part on ensuring that its results and outcomes scale beyond its immediate scope, and have an impact on policies, markets, and scientific and civil resilience communities beyond the immediate consortium and beyond the conclusion of the Grant arrangement. To this end, EMBRACE's Visibility and Sustainability strategy defines a set of actions and procedures to proactively promote the project and its results and build a thriving community of biotoxin-related experts thereby ensuring a lasting legacy. While these activities are led by RAN and LC, all partners are named in the DoA / work plan and resourced as contributors so are encouraged to engage in promoting EMBRACE and in adhering to the project's dissemination and communication guidelines.

9.1 Visibility

9.1.1 Project visual Identity

Measures taken to create a striking visual identity for EMBRACE include a new logo and project branding design. These form the basis for the creation of a project flyer, banners, and project templates. All material is available for download in Teamwork:

- Logos
- Other promotional materials
- Report and presentation templates
- Guidelines for the use of social media and external communication

Partners should use these materials in their own dissemination and communication activities.

9.1.2 Acknowledging EU funding

Obligations for recipients of EU funding programmes 2021-2027

"Since 2021, all recipients of EU funds have the legal obligation to acknowledge that their action has received EU funding. This requirement applies to all programmes, including Horizon Europe [..]. All beneficiaries, managing authorities and implementing partners have to display prominently the EU emblem and funding statement on all the communication materials, dissemination activities and any equipment, infrastructure, vehicle, supply or result financed by the grant."

Figure 3. Required use of the EU symbol for acknowledging EU funding.

In addition, a generic statement acknowledging funding should be included in publications and presentations:

"EMBRACE is funded by the European Union's Horizon Europe Research and Innovation funding programme, Grant Agreement N° 101168322."

Non-EU partners, should append acknowledgement of their funders to this statement, as required.

9.1.3 Communication channels

Communications with the public and wider biotoxin community will use the following channels:

- **Website**: A combined portal for access to the latest news and results, event invitations incorporating aspects of the EMBRACE knowledge sharing hub.
- **Social media**: Sharing updates and engage stakeholders in the conversation.
- **Newsletters**: Downloadable flyers with key announcements about results, invitations to participate in project activities/events, and special features on biotoxin-related topics.
- **Multimedia videos/podcasts**: Interviews with experts/participants, and project promotional material.
- CORDIS Wire and CMINE can also be used to advertise significant project events and results.

Partners can participate in these activities by providing news items about project results and activities for further coverage by the Visibility team.

9.1.4 Workshops, Conferences, and other external events

Participation

All consortium members who attend external events should take care to use the recommended EMBRACE poster/presentation template, ensure that they have the permission of the SAB, and that their communications are of high quality and factually correct.

Organisation

Any consortium members organising Conferences, Workshops or similar events should notify the Visibility team of the event and provide sufficient details for event advertisement using the EMBRACE communications channels.

The source of funding should be acknowledged in all promotional material using the EU emblem (see section 9.1.2) and the statement:

"This workshop (/conference/..) was funded by the European Union's Horizon Europe Research and Innovation funding programme, Grant Agreement N° 101168322."

9.1.5 Publications

All consortium members who have a paper or article accepted for publication should ensure that they security clearance for publication from the Security Advisory Board, and that the source of funding is clearly acknowledged:

"This study was funded by the European Union's Horizon Europe Research and Innovation funding programme, Grant Agreement N° 101168322."

9.2 Sustainability

From the point of view of the EC*: "A Horizon Europe project can be considered as successful when its impact can be measured by the sustainable value of the project results".*

EMBRACE has a multi-pronged approach to sustainability, including creating a group of specialist advisors (the BTF), community building (the BKN and BRSH), engaging with other initiatives, and creating an active valorisation programme for all project results. Sustainability actions require the contributions of all partners.

9.2.1 Creating a Biotoxin Specialist Presence within the wider CBRN community

From the outset EMBRACE is engaging with the wider CBRN crisis management community through its relationship with CMINE. Consortium members should apply to join CMINE in their individual capacity. There they can join any special interest groups that they think relevant, especially the EMBRACE biotoxin special interest group, which will be launched shortly.

CMINE provides a great source of information about a wide range of CBRN related events and can also be used to advertise EMBRACE events and activities.

The PEERS project offers links to the EU CBRN-E standards community and provides another gateway for EMBRACE to engage with other initiatives in highly relevant fields.

9.2.2 Standardisation and Valorisation Procedures

Following EC Recommendation (EU) 2023/498 and the development of valorisation codes of practice, an EMBRACE result-focused standardisation gap analysis will be undertaken, and a detailed valorisation strategy for each project result identified in the GA will be developed, and continually updated. In addition, all partners should bring to the attention of the Project Coordination Team any unexpected results emerging from work on EMBRACE which they consider valuable and worth supporting in this way.

10 REFERENCES

N/A

ANNEXES

Annex A. HORIZON-CL3-2023-DRS-01-03 call

Operability and standardisation in response to biological toxin incidents

Research and Innovation Action.

Indicative budget €6 million.

Expected Outcomes:

- Improved European crisis management in case of an incident with biological toxins through the development of a pan-European task force of security practitioners, taking into consideration existing intersectoral actions on bioterrorism;
- New and existing portable devices, technologies and methods for responders to perform on-site detection of biological toxins are brought to the market;
- Recommendations for effective decontamination measures for personnel, equipment and facilities exposed to biological toxins are provided based on solid experimental testing;
- Development of an operational European response network of specialised and forensic laboratories, taking into account existing initiatives such as e.g. the HERA Laboratory Network and harmonised procedures/guidelines for forensic analysis of biological toxins applicable to a range of relevant technologies and toxins;
- The risks for responders from exposure to biological toxins in the hot-zone are assessed and recommendations of protective equipment for working with biological toxins in the hot-zone are developed;
- Building on existing initiatives and networks, a consolidated platform is established providing support for standardisation efforts in the analysis of biological toxins.

Scope:

Recent incidents in Europe and worldwide have highlighted the current threat posed by several biological toxins falling under the Chemical and Biological Weapons Convention. The incidents demonstrated the urgency for countries individually and collectively to improve crisis management capabilities, to advance standardisation efforts and to interconnect security practitioners such as first responders (including health emergency services), law enforcement agencies, specialists from public health (e.g. epidemiologists, environmental health experts), as well as specialised and forensic laboratories across Europe. In order to ensure cross border interoperability, existing and new national procedures need to be developed and implemented in an operational and coherent European crisis response network capable of addressing the threats posed by biological toxins.

To properly manage and minimise the effects of an attack with biological toxins, fast and reliable detection and identification of the used agent is critical. Portable devices, technologies and methods for responders to perform on-site detection of a panel of biological toxins remain to be developed. There is a need for evaluation, training and advancement of on-site detection methods for responders, as well as the integration of emerging detection technologies into marketable solutions.

The safety of responders relies on correct risk assessment and the use of appropriate protective equipment. The risks from exposure to biological toxins in the hot zone are largely unknown. In order to recommend appropriate protective equipment for first responders and to guide the use of effective

decontamination measures, the risks from exposure need to be assessed, taking into account sex susceptibility to toxins exposure. The Commission stockpiles personal protective equipment, and links should be sought with this joint DG ECHO-HERA action to make proposals as useful as possible.

Following an attack, exposed personnel, equipment and facilities needs to be decontaminated and declared safe as quickly as possible, in order limit the effects on society. Most decontamination procedures are developed for chemical or biological (i.e. organisms and viruses) agents, but based on their characteristics, biological toxins are at the interface of classical biological and chemical agents. Therefore, the efficiency of existing decontamination procedures should be evaluated for the decontamination of biological toxins.

Previous initiatives have initiated standardisation efforts for lab-based detection and identification of biological toxins. Analytical tools and reference materials are available and comprehensive training and proficiency-testing programs were organised, however, the need for further technical and operational improvement was demonstrated. Building on existing initiatives and networks, a consolidated platform should be established providing analytical tools (including Certified Reference Materials), training and intercomparisons among laboratories. Following the initial detection of the used biological toxin, a more detailed analysis is needed in order to link the agent to confiscated materials. In support of criminal investigations, new procedures and guidelines for comprehensive forensic analysis of biological toxins are needed. The developed methods and procedures should be shared among specialised and forensic laboratories. This action is also expected to engage with the European Health Emergency Preparedness and Response Authority (HERA).

In this context it is important to remind that standardisation should support operations and policymaking to supplement it but should by no means substitute it. While standardisation of technology may be more straightforward, the right balance does especially have to be sought for processes. The action should ensure close synergies with standardisation activities on European (e.g. CEN/TC 391) and international level (e.g. ISO/TC 292).

Annex B. Teamwork: Structure, useful features and tips

Work plan

The work package structure, task breakdown, task assignment, and timeline are all taken from the grant agreement. Work package leaders can elaborate on this starting point and create and modify tasks and subtasks, assign people to work on the task, and set task parameters as needed. In the screenshot(s) below, you can see the list of Work packages. Clicking on one, e.g. WP2, will open the task list, showing assignees, dates, and so on.

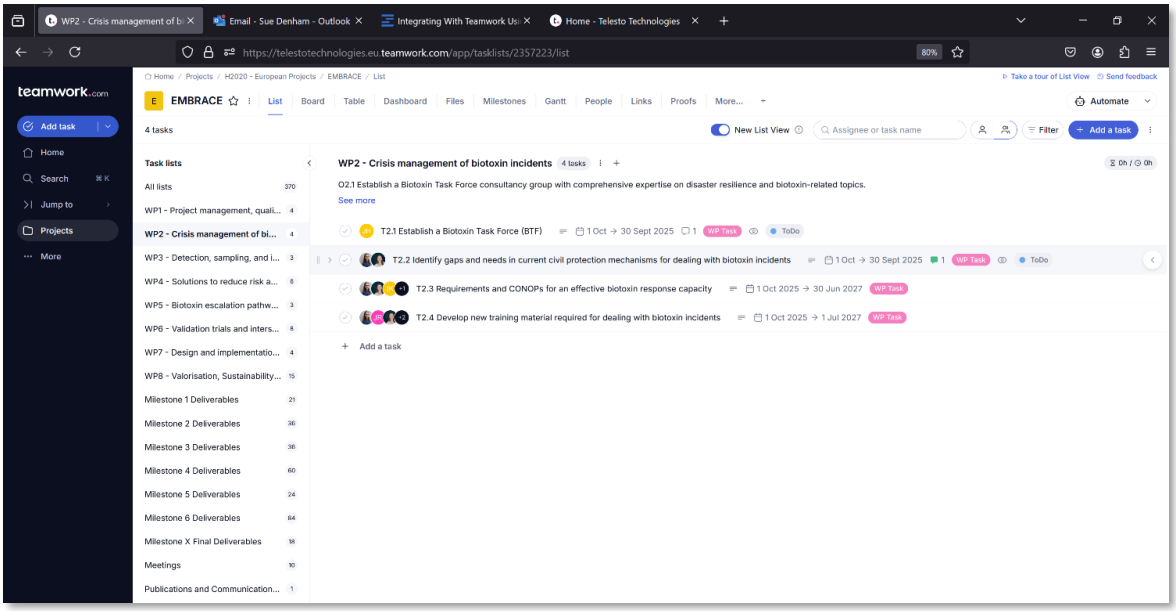
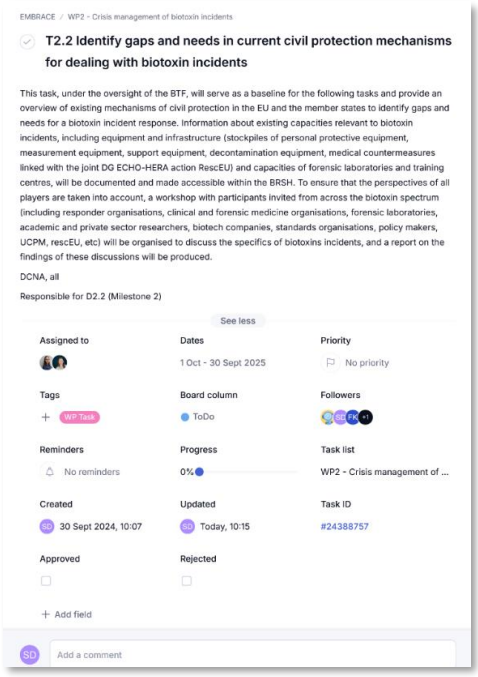


Figure 4. A Work package task list

Tip: to open a task list click on the > symbol - DO NOT click on the ✓ - this indicates that the task is complete, and it disappears from view!



Tip: To help with navigation it is useful to see the task lists at the left side – to activate turn "NewListsView" on (top of the screen, as shown).

To view (or edit) details of a task, click on its name. this opens a window with full description and details of any deliverables for which it is responsible. Here, importantly you can see the deliverables for which the task is responsible and which Milestone they fall under. Files can be uploaded, and comments exchanged all within the task.

It is important to maintain a record of work on EMBRACE either through the task comments, or other documentation which can be uploaded for sharing with the task team.

Tip. Move the Progress Bar to indicate your estimate of progress on the task.

Figure 5. An individual task definition.

Board usage

Tasks may also be viewed and moved on a Kanban board to show task status, if preferred. Moving your tasks on the board is an easy way to show what state your task is in.

Document Repository

Documents of any type can be uploaded and stored in the Teamwork document repository. A set of folders (termed categories in Teamwork) has been defined, as shown below. New categories and subcategories can be added as needed to structure the file store.

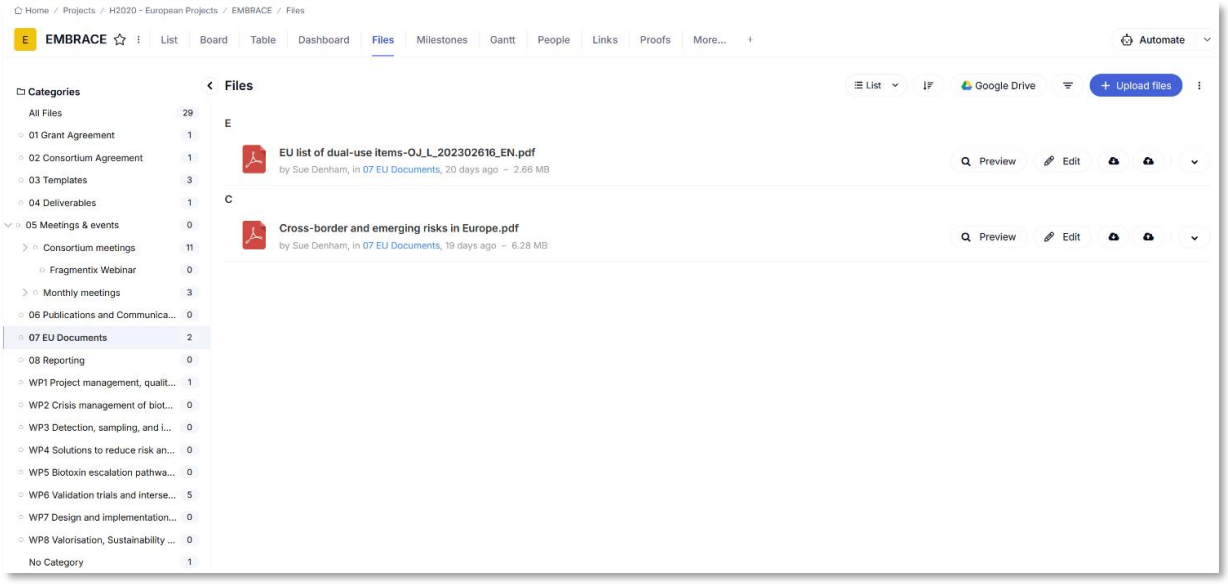
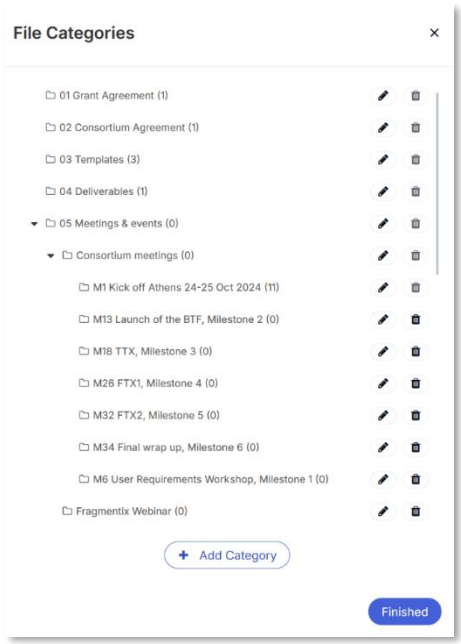


Figure 6. Document repository structure



To upload a document, go to the category where you want it to be stored, then upload by drag and drop.

To add a category, click on the symbol next to category in in Figure 6 to bring up the window in Figure 7.

A new category may be placed at the top level or nested under an existing category to create a hierarchy, as needed.

Figure 7. Creating new file category

Security clearance

The security clearance procedures for documents and other communications agreed by the SAB are embedded in the processes of the **Publications and Communications - Security Clearance** task list. Instructions for security clearance are contained in the task list description which can be viewed by clicking on it. This links directly to a form which allows the document owner to provide all necessary information to the SAB. A security clearance task and notification to the SAB is automatically generated. The SAB can check the task and set the "Approve" or "Reject" field to indicate their decision and explain their reasoning in the task comments.

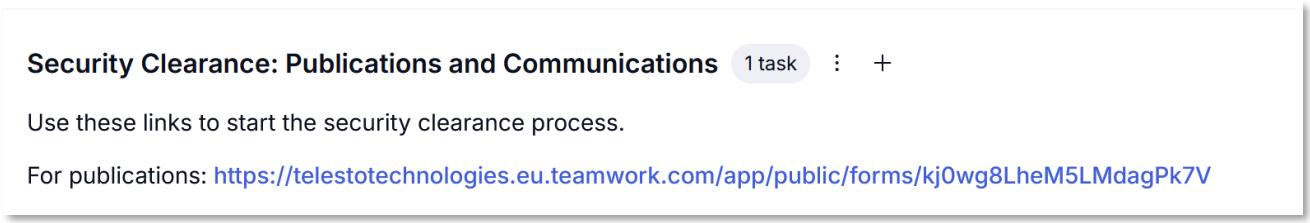


Figure 8. Security clearance task header

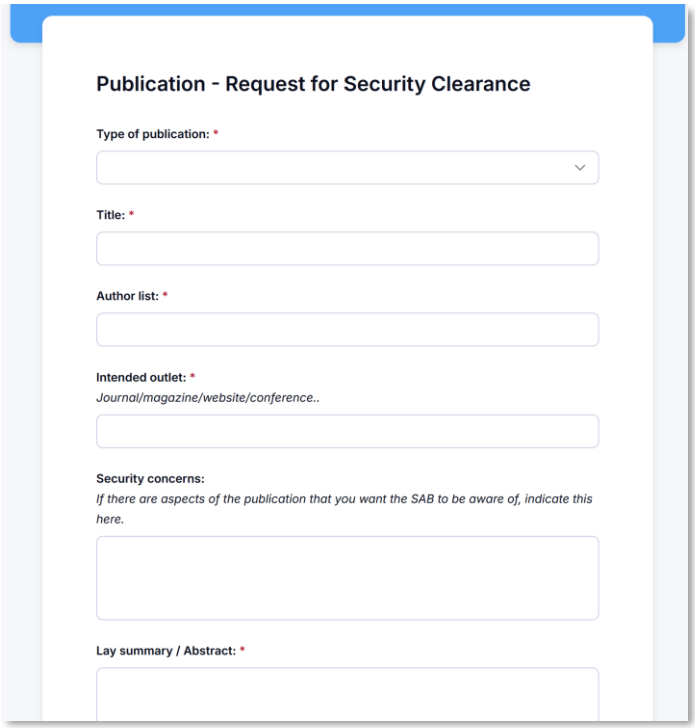


Figure 9. Security clearance form – Submit to obtain security clearance from the SAB

Quick feedback on work – Proofs

A useful way for consortium members to get quick feedback, or approval on their work is by using the Proofs tab within a task (near the bottom) or the tab at the top of the screen. Clicking "+ Add Proof" pops up the following window, which once completed automatically generates a proofing task for the reviewers specified.

Tip: when adding people start typing their name and it will pop up. If you only want feedback not approval (a stricter requirement), use the option "can Review" in the lower right corner.

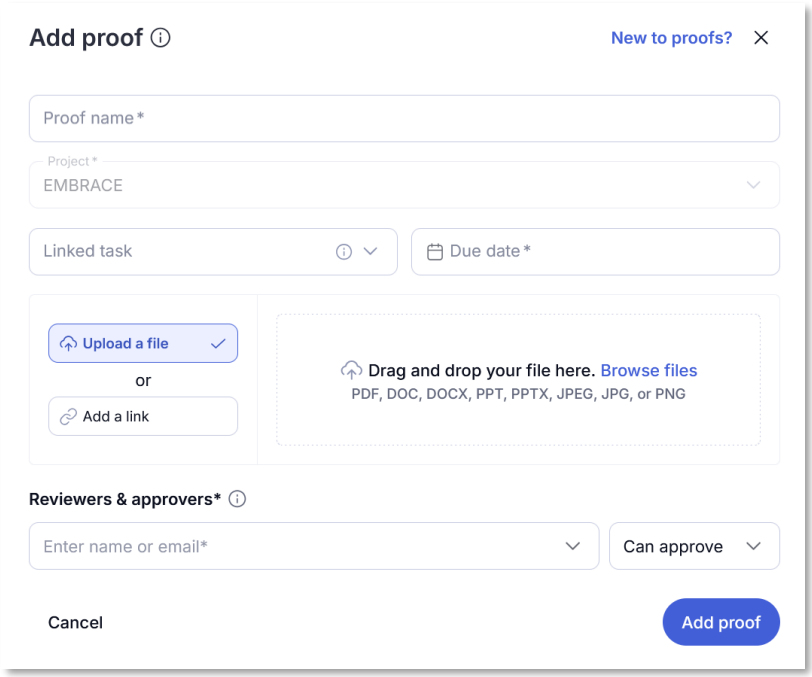
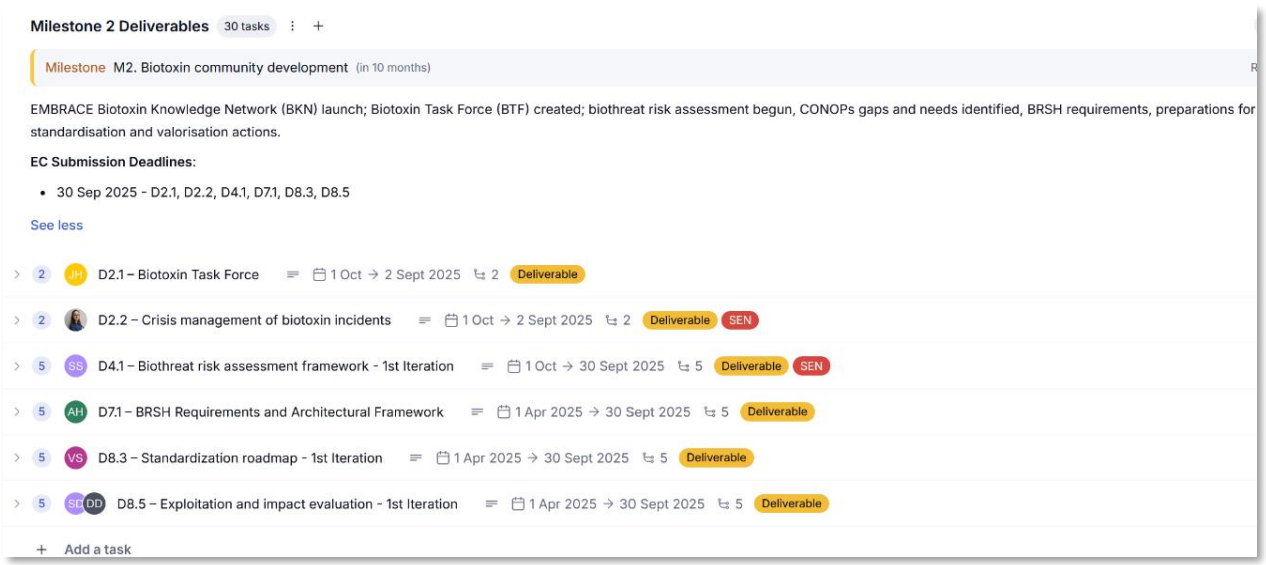


Figure 10. Defining a new Proof request

Quality control of deliverables

The quality control procedures for deliverables, described in Section 5.3 are implemented in Teamwork as tasks and automations to facilitate smooth operation.

Deliverables all fall into specific Milestones, which are implemented as a set of Task Lists, "Milestone N Deliverables", which can be accessed from the list on the left-hand side of the screen in the List view. Clicking on a Task List, e.g. "Milestone <N> Deliverables", exposes the list of Deliverables which



fall under that Milestone – see Milestone 2 Deliverables below, for example.

Figure 11. Milestone 2 (M12) deliverables

Each deliverable has a main task and 3 subtasks, with assignees and due dates clearly shown.

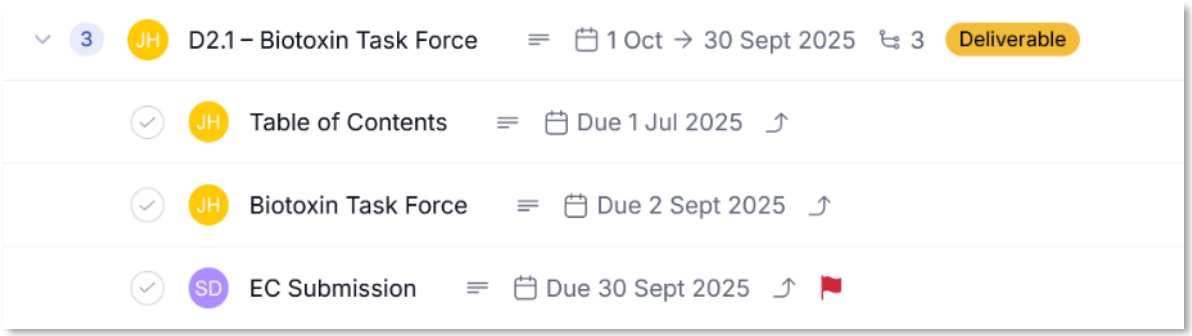
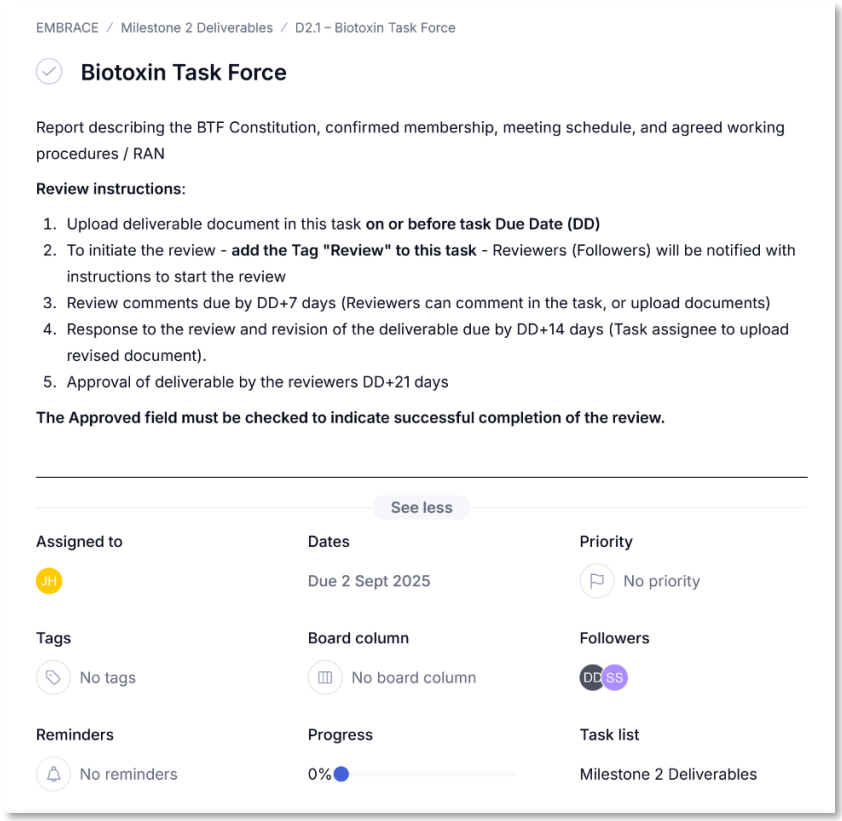


Figure 12. Quality control tasks for deliverables

The first subtask (table of contents for the deliverable document) and the second subtask (the main deliverable document) both involve an approval process which is detailed in the respective task headers. The third subtask includes final quality and security checks and upload of the completed deliverable to the EC portal. Once the 3 subtasks are completed, the deliverable is complete.



Followers on these tasks are the Reviewers who have been assigned to the deliverable, and they will be notified of the review when the Tag addition is made by the Assignee (see step 2 in figure 13).

The instructions are there for reference, but the process is largely automated. When "Approved" is checked by the Reviewers, then the task is moved to Done and closed, and the Submission Task is initiated.

Figure 13. Task instructions for initiating the deliverable review process

Meetings and events

Tasks involving preparations for each of the consortium meetings and related events have been created and can be consulted for information. All documents related to the event are stored in the corresponding Document Repository.

Internal Communications

Teamwork generates notifications that appear near your profile icon, bottom left. These notifications inform you of changes in tasks to which you are assigned or follow. There is also a chat channel which you can use to message colleagues directly.

Tip: a link to most pages and objects in Teamwork can be generated using a right button click – you can insert these links in your messages or emails to direct people straight to the place you want them to go.

Tip: If you want to communicate with specific people in your task comments, type @ and a list of consortium members names will pop up – simply select the one you want.

Gathering Data – Forms

Forms can be easily generated to gather data from groups of people. You can send your forms internally and externally, using a link generated as described above. Data received when a form is submitted can be viewed directly or inserted into a spreadsheet using the following steps:

1. Hover over a form and click the "..." icon that appears.
2. Within the menu click "View Submissions" to launch the submission screen.
3. At the top of the table showing all your form responses locate and click the "Export to CSV" option. This will allow you to download a .csv file containing the responses.

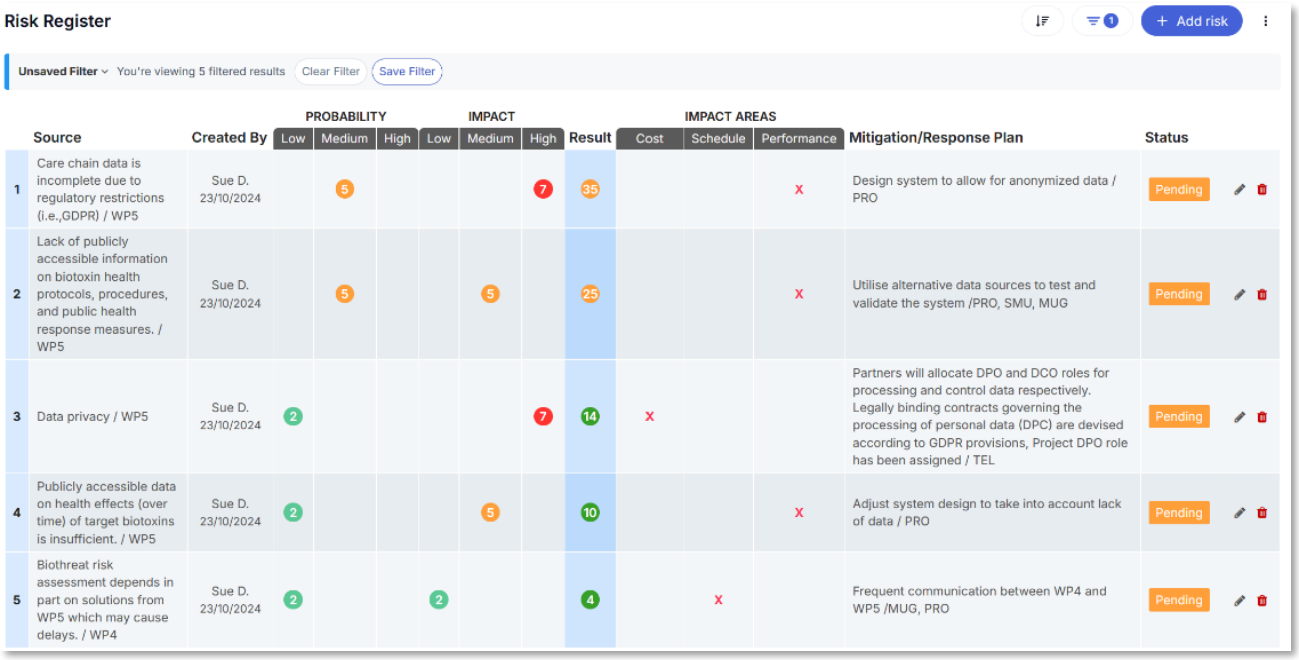
Risk Table

A live risk table which currently holds the risk information from the Grant Agreement is accessible by clicking on Risks along the top option line (you may have to go to More to see it). See section 6 for a screenshot of the risk table. Anyone can add risks, modify them, and delete them. However, there are a lot of risks in this table so you may want to filter them.

Personalisation – Filters, Profile (notifications)

A useful feature of Teamwork is the ability to filter information. You can filter tasks to only show the ones you are assigned for example, and you can filter the risk table to show the risks for a particular WP, e.g. WP5 –Note the filter symbol upper right in Figure 14.

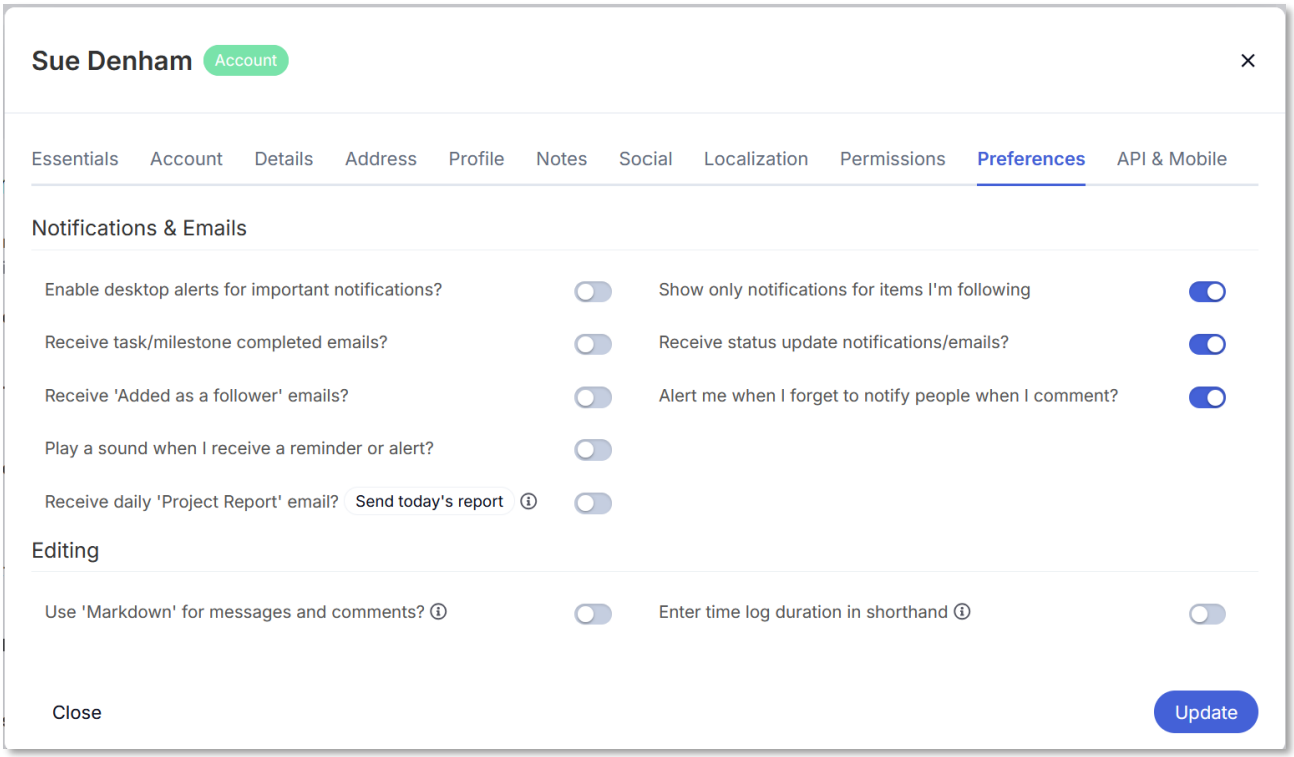
Tip. If you use filters – don't forget to clear them!



	Source	Created By	PROBABILITY			IMPACT			Result	IMPACT AREAS			Mitigation/Response Plan	Status
			Low	Medium	High	Low	Medium	High		Cost	Schedule	Performance		
1	Care chain data is incomplete due to regulatory restrictions (i.e.,GDPR) / WP5	Sue D. 23/10/2024		5				7	35			x	Design system to allow for anonymized data / PRO	Pending
2	Lack of publicly accessible information on biotoxin health protocols, procedures, and public health response measures. / WP5	Sue D. 23/10/2024		5			5		25			x	Utilise alternative data sources to test and validate the system /PRO, SMU, MUG	Pending
3	Data privacy / WP5	Sue D. 23/10/2024	2					7	14	x			Partners will allocate DPO and DCO roles for processing and control data respectively. Legally binding contracts governing the processing of personal data (DPC) are devised according to GDPR provisions, Project DPO role has been assigned / TEL	Pending
4	Publicly accessible data on health effects (over time) of target biotoxins is insufficient. / WP5	Sue D. 23/10/2024	2				5		10			x	Adjust system design to take into account lack of data / PRO	Pending
5	Biothreat risk assessment depends in part on solutions from WP5 which may cause delays. / WP4	Sue D. 23/10/2024	2			2			4		x		Frequent communication between WP4 and WP5 /MUG, PRO	Pending

Figure 14. The Risk table, filtered for WP5

To modify your personal profile, set preferences, and so on, click on your symbol in the lower left side of Teamwork. Click Edit profile to modify many different settings, including your notification



preferences!

Figure 15. Customisations and personal settings

Annex C. Interim Reporting Information

Partner Interim Work Reports. The report form, accessible via the link, is to be completed and submitted by each partner. Information required includes work carried out per WP/Task, Deviations, and Dissemination and Communication activities.

Partner Interim Financial Reports. A template spreadsheet, accessible via the link, should be completed and uploaded to the reporting period subcategory, e.g., M01-06. The spreadsheet requires the following information for each 6-month reporting period:

a) Total person-hours per WP
b) Total eligible Personnel Costs excluding overheads per WP
c) Travel and Subsistence Costs, with details of Event (Title, Location, Date, and Participants) for each claim
d) Other Direct costs, with description of costs

Interim WP Reports. A template populated with information from the Teamwork system, and the Partner reports for the 6-month period will be provided to each WP Leader. The WP reports will contain the following key points:

- A summary overview of work and progress, and partners involved
- Detailed progress report, organised by task giving details of:
    - objectives for the period, and to what extent they were achieved
    - deliverables, milestones, and KPIs for the period
    - the work carried out by each partner involved
    - dissemination and communication activities
- Deviations, if applicable, with explanations justifying differences between expected (from the DoA) and actual work carried out.
- Risk monitoring, and mitigation actions taken, if any
- Summary of plans for the next period

All reports should be uploaded to the corresponding reporting period subcategory, e.g., M01-06.