

## **EIC PATHFINDER PORTFOLIO**

#### **ENGINEERED LIVING MATERIALS**

#### Strategic Plan

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# **EIC ENGINEERED LIVING MATERIALS (ELMS) INITIATIVE**

#### 1.1

# THE EIC ELMS CALL: GOALS AND CHALLENGES

The EIC identified the Engineered Living Materials as a priority area in March 2020. It was voted by far the most interesting possible EIC topics for the 2021 EIC Work Programme at the 2020 R&I Days. The HORIZON-EIC-2021-PATHFINDERCHALLENGES-01-05 Engineered Living Materials call was published in the EIC Work Programme 2021 with the accompanying ELMs Challenge Guide.

Engineered living materials (ELMs) are composed, either entirely or partly, of living cells. By being alive, ELMs represent a fundamental change in materials' production and performance, enabling new, better or similar functionalities, compared to traditional materials but with decreased costs and environmental impact. ELMs have the potential to transform virtually every modern endeavour from healthcare to infrastructures to transportation. At the time of the call and still now, the ELMs represent a truly new emerging field. An analysis performed in 2020 of publications in ELMs and EU funding showed Europe somewhat lagging behind. One of the goals of the call was to grab the opportunity to position strategically Europe in the ELMs field while still at its infancy and given its broad potential in many economic sectors by seeding a community of ELMs researchers and innovators through the ELMs portfolio activities.

While some proof of concept applications have been published<sup>123</sup> (probably the most advanced and high profile is the **living cement**), the field is far from having established platform technologies for the production of ELMs materials with precise, predictable and complex 3D architectures and functions across multiple scales that would enable moving from the lab to the market. Thus, the other goal of the call was to support the development of new capabilities in robust ELMs design principles and platform technologies to overcome the following challenges (for more information please access the **ELMs Challenge Guide**):

 control precisely cell morphogenesis, self-assembly and cellular-abiotic assembly of materials from micro to macro scale incl. the interplay between cellular and abiotic component;

Gilbert, C. and Ellis, T. (2019) Biological Engineering Living Materials: Growing Functional Materials with Genetically Programmable Properties ACS Synthetic biology 8: 1-15. DOI: 10.1021/acssynbio.8b00423

<sup>2</sup> Srubar III, Wil V. (2020) Engineered Living Materials: Taxonomy and Emerging Trends. Trends in Biotechnology, corrected proof. DOI: 10.1016/j.tibtech.2020.10.009

Nguyen et al. (2018) Engineered Living Materials: Prospects and Challenges for Using Biological Synthesis to Direct Assembly of Smart Materials. Advanced Materials 30 (19): e1704847. DOI: 10.1002/adma.201704847

- account and control for cell variability and external factors thus improving robustness, reproducibility, stability and performance of the materials;
- create materials with multi-cellular consortia across multiple scales with spatio-temporal controlled cell-cell communication leading to tuneable and autonomous patterning enabling different 3D architecture, material properties and functions within the same material;
- self-contain and control the lifespan of the genetically modified cells used in ELMs (e.g. for those applications that entail release in the environmental) to address concerns of safety and biocontainment;
- be able to adapt platform technologies for the reliable customisation of ELMs, i.e. for a wide variety of ELMs in terms of size, shape, cellular composition, properties and functions.

The call asked each applicant to propose two different ELMs not derivative of each other with application in two different sectors to encourage applicants to propose the development of technologies adaptable for multiple ELMs. It also asked to propose an integrative approach to assess the needs and implications for the technologies and its limits, including the safe and responsible development, societal (and consumers') acceptance, and ethical and regulatory requirements.

Extremely rare for funding calls, the ELMs call was mentioned and referenced in a technical review on ELMs taxonomy.

1.2

# THE CREATION OF THE EIC PATHFINDER ELMS PORTFOLIO

The proposals received were evaluated following the two stage evaluation described in the **EIC Work Programme 2021** and in the accompanying **ELMs Challenge Guide**. In the first stage, all applications were evaluated individually by external experts and scored against the evaluation criteria set out in the Work Program. All applications that pass the defined thresholds against the criteria were included in the second stage of the evaluation.

At the second evaluation step, the evaluation committee, chaired by the Programme Manager (PM), built a consistent Challenge portfolio, i.e. a set of actions supported by the EIC under Pathfinder. In order to do so, the evaluation committee allocated proposals into categories. These categories define the overall architecture of the targeted portfolio.

Before applying the categorization and the general considerations described here below each proposal had to satisfy the definition of ELMs, the specific conditions and specific expected outcomes described in the text call. For this specific Challenge, the evaluation committee considered the following categories:

- Hybrid Living Materials (HLMs)
- Biological ELMs

Within each of these ELMs categories, the evaluation committee will look for a diverse portfolio of platform technologies under closed-loop control with high accuracy in reproducing and predicting ELMs characteristics, and with claims based on specified metrics and on specific testbeds, using the following general considerations:

- **a.** proposals with some programmable cells; among these preference to proposals with multicellular ELMs if they are aligned with consideration a); in the event of comparison of proposals with unicellular ELMs diversification of the cellular components in the Portfolio (incl. accounting for the multicellular proposals) may be taken into account;
- b. diversity in the technological approaches proposed and generalizability of such technologies;
- **c.** diversity in material properties and functions.

Within the **HLMs category** in addition to the general considerations a)-c) mentioned above, the evaluation committee also **specifically considered** the diversity of the abiotic components.

Within the **biological ELMs category** in addition to the general considerations a)-c) mentioned above, the evaluation committee also used the following **specific considerations**:

- **a.** a balance or close to a balance shall be reached between proposals with mammalian cells and those without but only if it is aligned a);
- **b.** proposals with automatized and integrated platform technologies.

After evaluating the proposals within each category, the evaluation committee shall make a final selection of the proposals from both categories so that a **balance or close to a balance between proposals on biological ELMs and those on HLMs** was reached. The type of applications was not a portfolio consideration due to the intrinsic diversity present in each proposal as a consequence of the ELMs call's requirement of at least two ELMs with different applications (whereby "different applications" is meant applications in different sectors e.g. one in health and the other in environment). All the 7 ELMs projects funded started at the same time 01/11/2022 and they all are 5 years long except for Fungateria, which is 4.

PROJECT NUMBER	PROJECT ACRONYM	PROJECT TITLE	WEBSITE
101070953	BioRobotMiniHeart	Engineering a living human Mini-heart and a swimming Bio-robot	
101071145	Fungateria	Enlisting synthetic fungal-bacterial consortia to produce multi-cellular mycelium-based ELMs with computational capability	( <del>-</del> )
101071175	Furoid	Up-scaled continuous production of artificial hair, fur and wool follicles using FUROID and HAROID technology	

PROJECT NUMBER	PROJECT ACRONYM	PROJECT TITLE	WEBSITE
101070817	LoopOfFun	Closed-loop control of fungal materials	
101071159	NextSkins	Living Therapeutic and Regenerative Materials with Specialised Advanced Layers	
101070913	Prism-LT	PRInted Symbiotic Materials as a dynamic plat- form for Living Tissues production	
101071203	SUMO	Supervised morphogenesis in gastruloids	

Three new partners from Widening countries have joined the ELMs portfolio by successfully applying to the HORIZON-WIDERA-2022-ACCESS-07-01 (so called HopOn) to be added to the projects BioRobotMiniHeart, Fungateria and Prism- LT.

The Portfolio size might increase with the addition of relevant projects funded through future EIC Open calls. ELMs projects funded from the EIC Open calls will contribute to the Portfolio activities as described in the relevant EIC WP and their participation will be supported via the **EIC Booster grant**.

1.3

# PORTFOLIO ACTIVITIES' GUIDING PRINCIPLES

**Portfolio Activities** are a grant obligation. They are activities of a subgroup or the entire group of projects of the ELMs portfolio with the goal of:

- tackle common challenges in any of the target identified areas (see section 4);
- catalyze and leverage common opportunities in any of the target identified areas;
- amplify the impact of the portfolio and on the portfolio so that the impact of an activity is more than the sum of the activity done independently by each project.

Project Activities are activities carried out for specific and unique aspects of a given project.

1.4
ENABLING PORTFOLIO ACTIVITIES:
NDAS

**Facilitating exchange of information within the ELMs Portfolio**. Knowledge on the other ELMs projects is necessary to identify the common challenges, needs and opportunities. This is not possible without NDAs when the only public information on the projects is the abstract, title and the website. The need of NDAs was clearly voiced by projects of the ELMs in the initial interactions. All projects including the new HopOn partners have signed NDAs enabling the definition of the strategic plan described in section 2 and the implementation of the actions therein described for the lifetime of the ELMs portfolio.

**Facilitating exchange of information with "externals"**. The ELMs portfolio has also prepared an NDA template if activities organized with the participation of externals require sharing confidential information. The projects will assess whether there is a need of an NDA with these external parties and proceed accordingly.



# 2. ELMS STRATEGIC PLAN

#### 2.1

#### WHAT IS THE STRATEGIC PLAN?

The strategic plan is a dynamic document that defines the objectives (linked to needs, challenges or opportunities) of the portfolio, identifies the ELMs portfolio activities to reach those objectives and guides their smooth implementation by establishing a governance. It is also a grant requirement to be submitted in the form of a deliverable. The structure and content of the strategic plan is the product of a creative collaboration between the ELMs projects, the ELMs Project Officer (PO) and EIC PM. It is recommended that the strategic plan is re-evaluated for potential updates twice a year. Request for an update can come either from the PM, the PO or the steering committee of the ELMs portfolio (see governance).

#### MAIN COMPONENTS OF THE STRATEGIC PLAN



Objectives linked to unmet needs, challenges or opportunities in the target areas of the ELMs portfolio.



ELMs portfolio activities to reach the set objectives.



The governance to guide the smooth implementation of the portfolio activities.

#### THE MAKING OF THE STRATEGIC PLAN

The process to reach the current version of the strategic plan to be submitted as a deliverable for the first reporting period entailed:

- 1. Trilateral meetings between the Project Officer (PO), PM and each ELMs project for a technical introduction of the project, presentation on the concept of portfolio activities and collection of initial proposal of portfolio activities by the project (July-August 2022).
- 2. A "get to know" technical webinar in which each coordinator described his/her project (28 October 2022), while informative this webinar was limited in impact because the NDA were not yet in place.
- **3.** Brainstorming and drafting of the strategic plan by the ELMs coordinators (the steering committee -see governance) with inputs from the small working groups (WG) working in a given portfolio's area (see governance section). The Steering Committee has met with the PO (and at times the PM) on 18/11/2022, 06/12/2022, 12/12/2022 and 12/01/2023.
- **4.** Submission of the draft Strategic Plan by 05/02/2023, discussion with PM on 09/02/2023, revised version submitted on 20/02/2023 and discussion with PM on 21/02/2023.
- 5. Final submission of the Strategic Plan deliverable end of February 2023.
- **6.** Reassessment of the Strategic Plan at the ELMs SC meeting with the PO on 18/08/2023. It was concluded that no revision was needed at this point.

It is recommended that the strategic plan is re-evaluated for potential updates at twice a year. The next revision will occur tentatively February/March to incorporate any new opportunities or need of changes identified in the first Annual Meeting of the ELMs portfolio (see later Section 3). However, request for an update can come either from the EIC PM, the PO or the steering committee of the ELMs portfolio at any time (see governance).

#### 2.3

# ASSESSMENT OF THE PORTFOLIO ACTIVITIES

The participation of each project of the ELMs portfolio to the portfolio activities is a requirement of the grant agreement translated in the submission of relevant deliverables as well as reporting in the technical report. These materials are assessed during the regular review meeting organized by EISMEA with technical monitors and an Innovation Radar expert. The EIC PM may choose to attend this meeting as well. **The experts are asked uniquely to assess formally the contribution of the project to the portfolio activities**. To facilitate the experts' assessment, the reporting on the portfolio activities is structure as followed:

- **A.** Contribution from the WG this section reports all the progress in the given target area, it is written by the WG and it is identical for all ELMs projects. While not assessed formally, experts are instructed to provide their non-binding recommendations on the activities. All the recommendations from the experts from the review meetings of all the ELMs projects will be compiled, removed of identifiers, and shared with the ELMs SC to discuss possible changes in the Strategic Plan.
- **B.** Contribution from the project this section is written by the project and reports only the specific contribution of the project to some of the activities in the given target area (only participation to WG meeting is not considered a contribution). This is the section to be formally assessed by the experts and evaluated by EISMEA for the reporting and payment process.



Meetings of the ELMs Portfolio will be held annually. The first annual meeting will be in Brussels in hybrid mode on the 17th of January 2024 with participation in person from a minimum of three team leaders from each ELMs project (including the coordinator and back-up coordinator). Participation from students and post-docs is highly encouraged.

The final agenda has yet to be finalized but the meeting will include, in addition to the presentations from the 7 ELMs projects, a section showcasing ELMs relevant projects funded from past EIC Pathfinder Open calls (CyGenTiG 801041; Enlight 964497; and BioHhOST yet to start) and a section on Readiness for Investments with representatives from SynBioBeta and Potter Clarkson and eureKARE moderated by the CSO of Cellink, a partner of the ELMs portfolio.

Subsequent meetings will be organized at a geographical location closer to many partners. The next meeting is scheduled for October 2024. The ELMs Annual Meetings are grant requirements with an associated deliverable.

These meetings are also an opportunity to identify new specific collaborations between two or more projects leading to additional portfolio activities (e.g. session with SMEs and corporations, or with investors or regulators, etc.) or needs for a revision of the portfolio activities.

The PM or the PO can also propose sessions to be added to the annual meeting and invite key stakeholders.



Five main target areas are defined at portfolio level herein and in the Strategic Plan, Technology, Regulation, Exploitation, Environment & Sustainability and ELSA.

In addition, communication was identified as a cross-cutting area to amplify the impact of the activities in the targeted areas and reach out the public as well as outside stakeholders such as policy makers, investors, companies, etc.

Within each target area the strategic plan describes the objective(s), the activities that need to be carried out to meet the objective, the ELMs projects involved, an estimate of time for the implementation and any link of that activity to others in different targeted areas.

As described briefly in section 2.2 working groups assigned to each area contribute to the definition of the objectives and activities, and are responsible for their implementation.

For more details, see the governance section 5.

# 4.1 COMMUNICATION

The EIC ELMs Portfolio communication strategy aims at catalysing and leveraging common communication opportunities to outside stakeholders. To ensure a unified and compelling representation of EIC ELMs Portfolio. The Communication WG has prepared the ELMs Communication Guidelines (accessible in the Portfolio's Dissemination and Communication deliverable which is publicly available). The Portfolio Communication Strategy does not include activities, key-messages and audiences that are of exclusive interest to a project; however, it includes strategies to reach stakeholder that are of interest for a cluster of projects i.e., related to a specific application field.

#### 4.1.1

# PORTFOLIO COMMUNICATION (AND DISSEMINATION) MATERIALS

The Communication WG has already delivered the objectives related to communication materials to be used by the ELMs portfolio. These include the following.

#### 4.1.1.1 ELMS PORTFOLIO WEBSITE

The Portfolio web presence is ensured by including a dedicated webpage on the project website of each project part of the portfolio. In the upcoming years the content might be revised to include communication material and/or promote specific activities organized by the portfolio. The deliverable on website is publicly available.













# EIC Engineered Living Materials Portfolio

PRISM-LT is part of a portfolio of projects funded under the Engineered Living

<u>Materials Pathfinder Challenge</u> by the European Innovation Council and started on

November 2022.

With this Pathfinder ELMs Challenge, the EIC seeks to seize the opportunity to position strategically Europe at the forefront of the ELMs field. This Pathfinder

ELMs projects funded from the EIC Open calls actively contribute to the Portfolio activities with the aim to advance the scientific and technological development of ELMs and promote its dissemination across Europe, increase the visibility of the ELMs community internationally by sharing knowledge and building partnerships, engage with regulatory bodies to address ELMs portfolio needs, address ethical, legal and social aspects through early engagement with policymakers and the public, and to assess and address the need for standardization in the ELMs portfolio, identify barriers to the adoption and commercialization of ELMs and engage with stakeholders, guided by responsible research and innovation methods.

#### 4.1.1.2 ELMS COMMUNICATION GUIDELINES

One of the objectives of the Communication WG was to create a set of communication guidelines for the portfolio that could be used by all the partners when they talk about the portfolio within their dissemination and communication actions. The guidelines have been finalized and shared in the ELMs Teams GRP. The guidelines contain a list of Portfolio Target Audiences and Key Messages, including relevant audiences for clusters of projects. Furthermore, the document also contains a description of best practices related to EIC ELMs Portfolio Branding and the use of the content.

The Communication WG (see governance) has identified the main audiences to be targeted by the Portfolio communication identifying the main key-messages to be shared with each of them.

Consumers and citizens: this audience is engaged to build trust in ELMs, familiarize with key concepts and collect expectations associated with the technology. As some activity might require discussing ethical concerns, the activities will be supported by the ELSA Working Group. The main key message is to explain what Engineering Living Materials are, pointing out their peculiar features and highlighting the positive impact that they can have on several societal issues. The following definition can be used as guideline for the communication with citizens: "Engineered Living Materials (ELMs) is a rapidly evolving interdisciplinary field that combines principles from biology, materials science, and engineering to create living systems with novel functionalities. Unlike traditional materials, which are typically inert and non-living, ELM involves the design and manipulation of living organisms to produce materials with unique properties and capabilities. These materials can be grown via co-cultivation or bioprinted". The main key features to highlight during the communication are:

**Living Nature:** ELM involves the use of living organisms, such as bacteria, yeast, fungi, or even mammalian cells, as building blocks to create materials. These living components interact with their environment and respond to stimuli, making them suitable for case-specific solutions.

**Sustainability:** ELM holds significant promise in advancing sustainability efforts. Living materials can be designed to biodegrade, reducing environmental impact. Moreover, the processes involved in producing these materials often require less energy and resources compared to traditional manufacturing methods.

**Multifunctionality:** ELM allows for the integration of multiple functionalities into a single material. For instance, researchers can engineer building materials, while also providing structural support, can sense and respond to environmental changes.

**Versatility of Applications:** The portfolio projects comprise a large variety of real-world use cases that demonstrate the tangible advantages of ELM in diverse industries such as Biotech/Pharma, Environmental testing, Filtrations systems, Construction/ Architecture, Textile/Clothing, Food and Cosmetics.

Overall, ELMs offer sustainable solutions for several societal issues as demonstrated by the list of potential applications of ELMs and the related positive impact for society foreseen portfolio. The full list is available in the table below – it's advice to highlight as many applications as possible.

TARGET APPLICATION	POSITIVE IMPACT
Non-animal models for health applications e.g., drug development;	Reduce use of animal, increase accuracy of model in reproducing human physiology, speed up the drug development process, less failed iterations in the development-cycle
Smart tissues (hair, skin, bone, etc.) for therapeutic applications	Treatment of several conditions e.g., epidermal conditions;
Sensors and filters for toxicants in water or air e.g., wastewater analysis and purification, air filters	An eco-friendly alternative for purification, reducing reliance on chemicals and non-biodegradable sensor materials.
Building Materials to reduce air pollution e.g., building skins with carbon sequestration capabilities	Reducing use of resources (material and time) for the construction sector while contributing to CO2 reduction.
Sustainable Manufacturing via animal-free products (fur, wool, meat)	Offer sustainable alternatives to animal-derived row materials;
Smart and responsive products e.g., fun- gi-based furniture, self-repair clothing	Improve product functionality and durability

**Researchers in the field of ELMs:** the aim is to promote technology exchange on ELMs and to increase visibility of European ELM research. This audience is mainly reached by dissemination of project results or innovative methodology, highlighting the portfolio expertise and leadership in the field. As this audience is very technical, this activity is carried out mainly by the Technology WG.

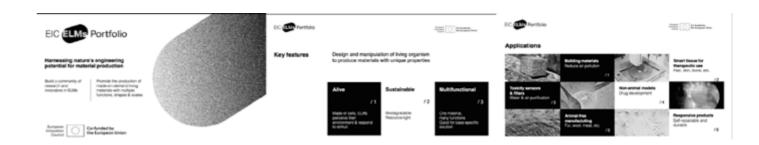
**Regulatory and standardization groups on ELMs and policy makers:** this activity is covered by Regulatory Working Group. Key messages and specific communication actions will be updated in future updates. Communication Channels and Activities are instead reported in Section 1.2.

**Specific stakeholders** can be engaged by clusters of projects that share applications in similar fields. In this case the objective is related to ensure technology uptake and transfer; collect feedback on applications and requirements; seek partners and join forces to tackle common struggles (e.g., regulatory pathway). The audiences identified so far are:

- 3Rs and Non-Animal Model Communities (BioRobotMiniHeart, SUMO, PRISM-LT, NextSkins, Furoid);
- Additive manufacturing and bioprinting companies (PRISM-LT, BioRobotMiniHearth);
- Plant-based consumers associations interested in alternatives to animal-based products (Furoid, PRISM-LT);
- Design practitioners interested in alternatives to fossil-based materials and new functionalities providing added design value (FUNGATERIA, LoopOfFun).

#### 4.1.1.3 ELMS MATERIAL FOR DISSEMINATION EVENTS

Each project partner actively participates in a variety of dissemination events, where they present their project through talks or posters. When relevant, partners are encouraged to include information regarding the EIC ELMs portfolio at the European level. In this regard, Communication WG has shared some slides that can be used by partners; other materials can be created to meet the needs of specific activities.



4.1.2

#### **OBJECTIVES OF THE ELMS PORTFOLIO IN COMMUNICATION**



#### OBJECTIVE 1: inform the general public at European and possibly world-wide scale on the ELMs.

- **ACTIVITY**: Propose ELMs as subject for a documentary film (see for example, The Creeping Garden https://www.imdb.com/title/tt3913550/) targeted to the general public.
- **IMPLEMENTATION**: i) networking among the film industry contacts to identify interested directors; ii) provide content for the fundraising campaign/grant applications, which will be led by directors; iii) portfolio partners offer themselves for interviews and filming at their premises.
- **NEED**: build trust in the technology, familiarize the audience with ELMs key concepts, showcasing the range of applications (health, consumer goods, environment, construction, food)
- **TIMING**: Starting at the end of 2023
- ALL ELMs or SUBSET: all ELM projects
- LINK TO/TO BE LEVERAGED BY: Synergies with all the other WGs

OBJECTIVE 2: increase awareness of the local general public (i.e. where or close to where members of the portfolio are located) on the ELMs and the ELMs portfolio.

- **ACTIVITY**: Participation to European Researchers' Nights or other outreach activities
- IMPLEMENTATION: i) get in touch with organizers of European Researchers' Nights in cities

reachable by portfolio partners; ii) develop communication material suitable for the general public about benefits of ELMs and their applications to multiple fields by proving real-world examples (existing and from portfolio's projects) iii) appoint local teams to attend the event(s) and represent the portfolio.

- **NEED**: foster public awareness about the collective efforts of European research projects in the field of ELMs, build trust in the technology, familiarize the audience with their benefits and applications.
- TIMING: Starting 2024 collect participation of each project to outreach activities
- ALL ELMs or SUBSET: all ELM projects
- LINK TO/TO BE LEVERAGED BY: Synergies with Technology and ELSA WGs

#### 4.1.3

# HELP FROM THE HORIZON RESULTS BOOSTER SERVICE FOR THE ELMS COMMUNICATION AND DISSEMINATION PLAN

The ELMs portfolio represented by project Prism-LT has successfully applied applied to the Horizon Results Booster Service 1 "Module B - Helping projects from the portfolio to design and execute a portfolio dissemination plan". The deliverables of this service include the development of communication material e.g. a short video describing the project results. This service is available only for projects who already have a dissemination plan and with certain commonalities that allow for joint dissemination, thus it perfectly applies to the EIC ELMs Portfolio. Work has started in Fall 2023 with an introductory meeting. As an outcome, it was decided that Horizon Results Booster will collect in the next months some material (via survey) and based on that they will produce **a short video that will help to reach out to a designed audience**.

# 4.2 TECHNOLOGY

The Technology WG pursues two goals:

- being at the forefront of technology within the portfolio
- and disseminating and sharing technology and research on ELMs with the broader scientific community.

Accordingly, the Technology WG will pursue portfolio-internal and portfolio-external activities that maximize the desired impact. The activities will be planned and executed as follows:

OBJECTIVE 1: To create a platform for the efficient exchange on technical challenges common to at least two consortia. ACTIVITY (completed): the WG has set up a TEAMS GRP with different channels for the "Technical Focus Groups":

- Filamentous fungal-based ELMs: Fungateria, LoopOfFun
- Mammalian ELMs: BioRobotMiniHeart, Furoid, SUMO
- **Yeast and bacteria co-culture**: NextSkins, PRISM-LM. Within the group, electronical means will be established for fast and low-entry level exchange such as chat channels (e.g., Slack) among the PhD/Postdocs and among the Pls of the participating consortia.
- NEED: Consortia working on similar organisms or field of application likely face similar technological challenges. Teaming up and exchanging the challenges and the solutions will provide mutual benefit for the consortia. CHALLENGE: To sufficiently understand the others need to address the technological challenges in a targeted and efficient manner. OPPORTUNITY: Implementing technical solutions in one's research that have not been on the original research agenda. Further, teams working on similar challenges can agree to methods/measurements they will do the same. Such 'standards' would increase interoperability between projects.
- TIMING: completed.
- **ALL ELMs or SUBSET**: It is suggested to form the Technical Focus Groups mentioned above. The Technical Focus Groups are open for participation of additional Participants.
- \*LINK TO/TO BE LEVERAGED BY: The activity will likely profit from the Technology Scouting Activity.

#### OBJECTIVE 2: To ensure to be up to date with the current global technological trends in the ELMs field.

■ **ACTIVITY**: Technology Scouting. This has been implemented by (i) Setting up in the channel "Technology Scouting" in the MS Teams GRP "Technical Focus Groups" a distribution list via which outstanding new ELM publications / patents will be shared among the portfolios. (ii) A joint access to a reference manager, where publications on ELMs can be uploaded, shared and searched for. This is optimally run by postdocs in the portfolio.

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- **NEED**: ELMs are a very rapidly developing area with novel findings and developments constantly being pursued. It is therefore crucial to maintain at the forefront of scientific literature and developments. CHALLENGE: To regularly search for and share new findings. OPPORTUNITY: To advance one's projects using the latest technological advance.
- **TIMING**: started and will run continuously.
- ALL ELMs or SUBSET: All consortia will participate with one email distribution list for sharing exciting new technologies and one responsible person per consortium curating the publication database.
- LINK TO/TO BE LEVERAGED BY: The Technical Focus Groups will likely profit from this activity.

## OBJECTIVE 3: To leverage the research of the portfolio and to increase Europe's competitive position in ELM by training PhD students and Postdocs in ELMs.

- **ACTIVITY**: Marie Curie PhD Programme on ELMs
- **NEED**: ELMs are a very rapidly developing area with strong activities in China and the U.S. In order not to miss this important field in Europe it is of highest priority to advance research in ELMs and to train scientists in this field. CHALLENGE: To compete with other scientific and technological fields for the competitive Marie Curie PhD Programme. OPPORTUNITY: To significantly increase the basis of experts in ELMs in Europe.
- **TIMING**: An application for the 2024 deadline is targeted.
- ALL ELMs or SUBSET: Optimally, all consortia will participate. However, also Marie Curie Applications from a targeted subset of consortia may be envisioned.
- LINK TO/TO BE LEVERAGED BY: A successful application will strongly synergize with the activities in multiple working groups.

# OBJECTIVE 4: Develop a state-of-the-art ELM research program to position the ELMs portfolio in the European synthetic biology map. ACTIVITY: Promoting ELM technology exchange by coorganizing / organizing a conference

- **NEED**: The global ELM community is growing with many ongoing technology developments. To promote advances, it is therefore critical to connect scientists and to share (unpublished) data as typically occurring at conferences. CHALLENGE: To attract the key global players to the event. OPPORTUNITY: To form new collaborations and get inspiration for own research.
- **TIMING**: Will depend on the schedule of other conference series on ELMs (The fourth international conference on ELMs is planned for early 2024 in Saarbrücken, Germany, but the date has not yet been decided and one of the organizer is a member of the ELMs portfolio). Likely 2024/2025 will be realistic.
- ALL ELMs or SUBSET: Optimally, all consortia will participate.
- LINK TO/TO BE LEVERAGED BY: Synergies with point 5, below on the special issue. A special issue with conference proceedings will increase visibility and impact of both activities.

## OBJECTIVE 5: Editing a special issue in a peer-reviewed journal focused on technologies developed within the ELMs portfolio.

- **ACTIVITY**: Selection of technologies under development to be included in the special issue of the scientific journal
- **NEED**: A special issue gives significantly higher visibility than papers distributed across multiple journals. CHALLENGE: To identify a high-profile journal offering a special issue. Avoiding journals with excessive publication fees. OPPORTUNITY: To promote visibility of ELM research among the scientific community and scientific editors.
- **TIMING**: Will depend on the availability of journals offering a special issue. Likely, late 2024/early 2025 will be realistic, when first results from the ELM consortia will be ready for publication.
- ALL ELMs or SUBSET: Optimally, all consortia will participate.
- LINK TO/TO BE LEVERAGED BY: Synergies with point 4, above on the conference. A special issue with conference proceedings will increase visibility and impact of both activities.

### OBJECTIVE 6: To promote ELMs among the next generation of scientists, especially high school students as well as students at B.Sc. / M.Sc. level.

- **ACTIVITY**: Fascinating the next generation of scientists for ELM research by event formats such as presentations, school experiments.
- **NEED**: With the strongly growing need for skilled workforce, it is a key priority to address potential co-workers early on and to fascinate them for the topic of ELMs.
- **CHALLENGE**: To gain sufficient attention among similar activities from other fields of research and technology.
- **OPPORTUNITY**: To early on establish links to individuals that may become later research group members in the participants' labs. To increase European ELM advances by fascinating and training next-generation scientists.
- **TIMING**: May start in 2024 given that some progress in the labs is needed to show fascinating demonstrators.
- PRIORITISATION: Will run in parallel to research progress.
- ALL ELMs or SUBSET: Optimally, all consortia will implement such events.
- LINK TO/TO BE LEVERAGED BY: Synergies with Communication WG.

# 4.3 REGULATORY

The seven projects in the ELMs have goals to collectively produce 15 "products" with use in different sectors. There are 6 products across 5 projects in the health sector, 4 products across 3 projects in the consumer goods sector, 3 products across 3 projects with environmental applications, 1 product in the construction sector and 1 in food. Given this diversity, in order to assess the need of portfolio regulatory activities the following projects' prerequisite is needed.

**Prerequisite by each ELM project (to be reported as project activity)**: identify regulatory legislation under which the two products are, the relevant regulatory bodies, preliminary regulatory requirements and challenges including initial unknown.

OUTPUT: report on regulatory framework of each ELMs projects to be included in the Technical Report for the first review meeting of each project and to be shared with the ELMs SC.

TIMING: October 2023

#### **REGULATORY PORTFOLIO OBJECTIVES**

These activities will require the participation of external experts, the WG will be in charge to identify those experts (ensure NDAs are in place if needed) and coordinate their participation always under the oversight of the ELMs Steering Committee. The ELMs portfolio is already in contact with EMA to raise the awareness of the Agency on ELMs with applications in Health (EMA has also flagged ELMs as an emerging health technological trend in its **2022 Horizon Scanning paper**¹) and to raise the awareness of the projects on the regulatory framework for health ELMs.

OBJECTIVE 1: Understand the regulatory framework of the ELMs in the portfolio incl. identification of common components and challenges.

- OPPORTUNITY: leverage the power of the ELMs portfolio to address regulatory challenges.
- **ACTIVITY A**: internal analysis at portfolio level of each regulatory reports from the individual ELMs project
  - **OBJECTIVE OF THIS ACTIVITY**: identify shared elements among the ELMs projects in the regulatory framework.
  - **TIMING**: May 2024
  - ALL ELMs or SUBSET: ALL ELMs
  - LINK TO/TO BE LEVERAGED BY: to be carried out with activity (1. B). The results of this activity will guide all the other activities in this WG, work will have to be done first individually by each project and then shared to the WG to identify common features.

- **ACTIVITY B**: engagement of regulatory experts (not of the regulatory bodies) in ad hoc organized meetings
  - **OBJECTIVE OF THIS ACTIVITY**: facilitate the identification of shared elements among the ELMs projects in the regulatory framework informed by experts' advice, if needed.
  - **TIMING**: May 2024
- ALL ELMs or SUBSET: ALL ELMs
- LINK TO/TO BE LEVERAGED BY: to be carried out with activity (1. A). The results of this activity will guide all the other activities in this WG, work will have to be done first individually by each project and then shared to the WG to identify common features.

The following objective and activities are highly dependent on the outcome of the activities of objective 1. If common regulatory elements (even for a or more subset(s) of projects) are identified, the following is proposed:

## OBJECTIVE 2: engage regulatory bodies to raise their awareness on ELMs products and start a dialogue on the regulatory framework of ELMs.

- **NEED**: ELMs are unique products; most regulated market had not seen anything like it. There is a need of early engagement with regulatory bodies to raise collectively their awareness and identify regulatory gaps/challenges.
- **ACTIVITY A**: ad hoc organized meetings and/or panel at ELMs Annual meeting with representatives from regulatory bodies to help in the identification of common challenges and advice on how to best engage regulatory bodies.
  - **TIMING**: from summer 2024 to end 2025 (contact with EMA has already been initiated)
- ALL ELMs or SUBSET: to be determined based on activity #1. Multiple subgroups of ELMs are likely.
- LINK TO/TO BE LEVERAGED BY: this activity depends on the results of objective #1. If indeed, the activity is carried out in full, the information will be useful to the Path to Market WG, to the Communication WG and it may for environmental application have link to the E&S WG. The results of these interactions will contribute to activity of objective #3.
- **ACTIVITY B**: joining forces with other ELMs stakeholders (e.g. other research groups or companies working on ELMs) when engaging with regulators in the activity 2. A above.
  - **OBJECTIVE OF THIS ACTIVITY**: to increase the impact of engaging the regulators for the ELMs. This is particularly relevant considering a fragmented framework.
  - **TIMING**: from summer 2024 to end 2025
  - ALL ELMs or SUBSET: to be determined based on activity #1. Multiple subgroups of ELMs are likely.
- LINK TO/TO BE LEVERAGED BY: this activity depends on the results of objective #1. If indeed, the activity is carried out in full, the information will be useful to the Path to Market

Herold, R. et al. Health horizons: Future trends and technologies from the European Medicines Agency's horizon scanning collaborations Sec Regulatory Science 9: 1064003. 10.3389/fmed.2022.1064003

WG, to the Communication WG and it may for environmental application have link to the E&S WG. The results of these interactions will contribute to the activity of objective #3.

## OBJECTIVE 3: strengthening the ELMs community in Europe by sharing valuable knowledge on the regulatory framework of ELMs in Europe

- **ACTIVITY**: white paper on lesson learnt on ELMs European regulation
- **OPPORTUNITY**: leverage the knowledge acquired by the ELMs portfolio to help the emerging European ELMs community navigating the European regulatory framework on ELMs.
- **TIMING**: 2026 to mid-2027
- ALL ELMs or SUBSET: to be determined, possibly all.
- LINK TO/TO BE LEVERAGED BY: this activity depends on the results of objective #1 and #2. If indeed, the activity is carried out in full it will require cooperation with WG Communication. The paper can be used for future activities such as engaging with policy makers and/or by recruiting other ELMs stakeholders to engage with regulators.

# 4.4 PATH TO MARKET

The seven projects in the ELMs have goals to produce 15 "products" with use in different sectors. There are 6 products across 5 projects in the health sector, 4 products across 3 projects in the consumer goods sector, 3 products across 3 projects with environmental applications, 1 product in the construction sector and 1 in food. During the drafting of this Strategic Plan (from December 2022 to January 2023), each project identified foreseeable hurdles in its path to market.

All consortia flagged "User acceptance" as a main hurdle on path to market. The majority of the consortia also flagged "costs of production", the "need for new business model" and "Regulation" as hurdles on bringing the ELM to market. On the first Path to Market WG meeting it was agreed that for the WG to tackle the "cost of production" and "User acceptance" we need to first understand what the product is and who would be the user and consequently start drafting/understanding a possible business model. This will be tackled in the following proposed activity. Since "Regulation" has its own Work Group, the Path-to-Market WG will not tackle this hurdle directly but instead will lease with the Regulation WG on a regular basis.

Defining the problem/solution for each ELMs product is key to assess if there is a business opportunity or not. This information is also essential to design portfolio activities to address common challenges/opportunities. Given the diversity of the ELMs projects, these activities are likely to be carried out by subsets of ELMs projects.

**Prerequisite by each ELM project (to be reported as project activity)**: With the help of the coordinator of this WG, each consortium will identify problems that each ELM technology could solve.

- **OUTPUT**: Definition of problem/solution for each envisioned ELM product and potential customer that could eventually buy such product
- TIMING: April 2023

#### PATH TO MARKET PORTFOLIO OBJECTIVES

OBJECTIVE 1: Understand the business opportunities of the ELMs in the portfolio incl. identification of common components and challenges.

- **OPPORTUNITY**: Leverage the power of the ELMs portfolio to address business development challenges.
- **ACTIVITY**: internal analysis of each problem/solution from the ELMs project to identify potential shared (or shared to a subset of products) elements among the ELMs projects in the business opportunities.
  - TIMING: June 2023 (completed and mentioned above))
- ALL ELMs or SUBSET: ALL ELMs
- LINK TO/TO BE LEVERAGED BY: to be carried out with activity (1. B). The results of this activity will guide all the other activities in this WG, work will have to be done first individually by each project and then shared to the WG to identify common features.
- **ACTIVITY**: engagement with specialized investors within EU network in ad hoc organized meetings: Validation of the Problem/solution business opportunities as investors are trained to evaluate market opportunities. Such discussion will bring more information to the table of the ELMs and elicit more questions that will help this WG to better formulate key hurdles that ELMs as a group will face on their path to market.
  - **TIMING**: February 2024
  - ALL ELMs or SUBSET: ALL ELMs
  - LINK TO/TO BE LEVERAGED BY: to be carried out with activity (1. A). The results of this activity will guide all the other activities in this WG, work will have to be done first individually by each project and then shared to the WG to identify common features.

The following objective and activities are highly dependent on the outcome of the activities of objective 1. If common business hurdles and opportunities elements (even for a or more subset(s) of projects) are identified, the following is proposed:

OBJECTIVE 2: Identify and engage the key stake holders that are responsible for the bottlenecks/hurdles identified in Objective 1:

■ NEED: ELMs are unique products. There is a need of identifying and early engage with

possible customers, suppliers and other key stake holders that are crucial for bringing ELMs products to market.

- **A. ACTIVITY**: Within the WG and with the possible help of external consultant we will identify key stake holders who are related with the business hurdle identified
  - **TIMING**: January 2025
  - ALL ELMs or SUBSET: to be determined based on activity #1. Multiple subgroups of ELMs are likely.
  - LINK TO/TO BE LEVERAGED BY: this activity depends on the results of objective #1. If indeed, the activity is carried out in full, the information will be useful to the Regulation WG, to the Communication WG.
- **B. ACTIVITY**: ad hoc organized meetings and/or panel at ELMs Annual meeting with representatives from the identified key stake holders
  - **TIMING**: from summer 2024 to end 2025
  - ALL ELMs or SUBSET: to be determined based on activity #1. Multiple subgroups of ELMs are likely.
  - LINK TO/TO BE LEVERAGED BY: this activity depends on the results of objective #1. If indeed, the activity is carried out in full, the information will be useful to the Regulation WG, to the Communication WG.

## OBJECTIVE 3: strengthening the ELMs community in Europe by sharing valuable knowledge on the business development of ELMs in Europe

- **ACTIVITY**: white paper on possible paths to market for ELM products and lesson learnt on ELMs European business hurdles
- **OPPORTUNITY**: Leverage the knowledge acquired by the ELMs portfolio to help the emerging European ELMs community by creating awareness of the possible path to market routes and possible solutions to common business hurdles.
- **TIMING**: 2026 to mid-2027
- ALL ELMs or SUBSET: to be determined, possibly all.
- LINK TO/TO BE LEVERAGED BY: this activity depends on the results of objective #1 and #2. If indeed, the activity is carried out in full it will require cooperation with WG Communication. The paper can be used for future activities such as engaging with policy makers and/or by recruiting other ELMs stakeholders to engage with regulators.

#### 4.5

#### **ENVIRONMENT & SUSTAINABILITY**

Six projects from the ELM Portfolio will take part in the Environment & Sustainability activities. These projects include at least one ELM with potential positive environmental impact (see table below). The environmental impact can be based on a material that "actively" cleans the environment (e.g. by removing toxins) or based on a more sustainable material fabrication/usage.

PROJECT	CONNECTION TO ENVIRONMENT/SUSTAINABILITY
BioRobot-MiniHeart	sensor for environmental toxin
Furoid	sustainable fur/hair production
Prism-LT	sustainable food production
Fungateria	bioremediation of contaminated sites, living building envelopes for carbon sequestration
NextSkins	sustainable production of tough garments (bike helmet, etc.), sustainable production of skin care / skin therapeutic material
LoopOfFun	sustainable production of furniture material, bioremediation/VOC removal

Prerequisite by each ELM project except SUMO (to be reported as project activity): Utility Mapping to Specific Environmental and Sustainability Issues being targeted (explicitly/implicitly) within each project domain.

- **OUTPUT**: Clear objectives and goals within the projects targeting specific environmental and sustainability challenges and opportunities.
- TIMING: Completed

OBJECTIVE 1: to assess the environmental impact and sustainability of ELMs and provide a fact-based argument for policy makers and investors of the positive contribution of ELMs.

- **NEED**: to establish shared methodology/criteria for environmental analysis of ELMs within the ELM portfolio
- **ACTIVITY A**: Brainstorming over environmental analysis strategy to identify from which type of analyses we would benefit, such as a quantitative Life-Cycle Analysis (LCA), to better describe

and optimize the environmental impact of ELMs. Identify the need for potential experts and, if needed, involve them for advice.

- TIMING: a first strategy for environmental analysis by March 2024
- ALL ELMs or SUBSET: all ELM projects except SUMO
- LINK TO/TO BE LEVERAGED BY: An online workshop on various environmental analysis approaches (including LCA) should be organized to provide the necessary knowledge to carry out this brainstorming session. This activity is crucial to decide if the LCA environmental impact analysis described below should be carried out.
- **ACTIVITY B**: Establish shared methodology/criteria for a quantitative environmental/LCA analysis of ELMs within the ELM portfolio. Dissemination to selected audiences.
  - **MEAN**: if it is decided to do an LCA, then it will be necessary to apply for Booster grant to finance this activity
  - **TIMING**: to be determined based on outcome of the internal analysis and selected environmental analysis strategy (very tentatively by December 2024 if we are not doing an LCA, December 2025 if LCA). Booster grant application to be done in mid-2024.
  - ALL ELMs or SUBSET: all ELM projects except SUMO
  - LINK TO/TO BE LEVERAGED BY: the two previous activities should determine if this activity should be carried out or not. Link to Communication and Path to Market.

Related to this objective, the ELMs WG with the PO has reached out to the **Horizon Standardization Booster** team of the **Danish Standard Institute** for three webinars. The first webinar was actually more linked to the Technology WG as it covered how standards can help in technology development. The second webinar was more linked to the Path to Market as it described how standards can help in CE marking. The third webinar is linked to how standards can help in LCA analysis and relevant to this WG.

- 19<sup>th</sup> of September 2023 (time 10:30-11:30) Workshop topic: Standards and how to influence standardization using ELMs relevant standards/committees as examples.
- 9<sup>th</sup> of October 2023 (time 14:00-15:00) Workshop topic: CE-marking products for the European market
- 30<sup>th</sup> of October 2023 (time 10:00-11:30) Workshop topic: Life Cycle Assessment Standards Note: for this workshop, Mirko Busto (LCA expert in the Prism-LT project) will give a 30 min introduction on LCA, followed by 1 h workshop on LCA standards by HS Booster.

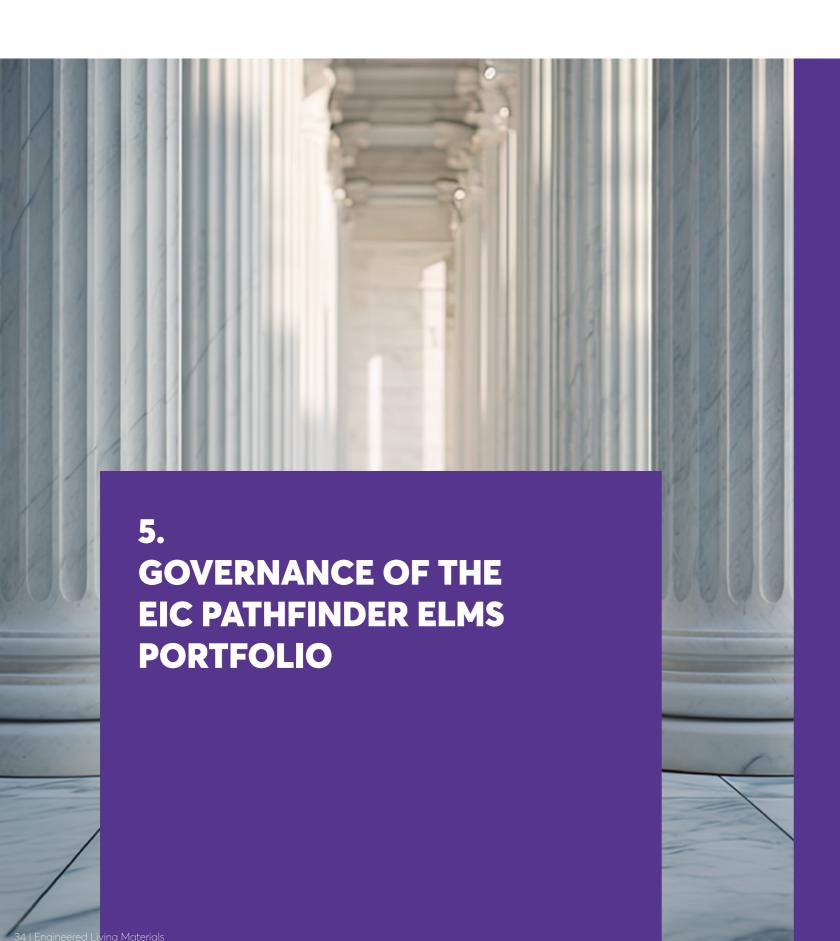


The overall goal of the activities within this ELM portfolio related to ELSA concerns reconnaissance for normative analysis of moral principles, societal values, and user experience aspects in the development of ELMs to ensure long-term applications and scaling-up possibilities. The main activity we propose combines sub-activities framing ELSA-related topics as cumulative rather than individual efforts. The combined approach to ethical and social aspects serves to assess and explore the basic technological vocabularies of the ELMs, in their impact for values and attitudes of all relevant stakeholders, including relevant public perceptions, and aid in steering the innovation. This will facilitate the adoption, application and embedding of the technologies under development.

As the work in the Regulation WG progresses, common legal issues might be identified. In that event, this WG will create a proposal to address these.

OBJECTIVE 1: to equip the next generation of ELM designers with a more in-depth knowledge, tools, and methods to familiarise with and implement social and ethical aspects of ELMs in the material development as an ex-ante design feature.

- **ACTIVITY**: Summer School on "Biodesign and Ethics for Society". We drafted a plan to organize a Summer School on "Biodesign and Ethics for Society". We propose to organize a 2-3 days (online) summer school for all PhD and Post Doc researchers of ELM projects including lectures, panel discussion, workshops, and brainstorming sessions, during which they can be immersed into the world of living materials- society- and ethics.
  - Topics to be covered in Ethical Aspects: Ethical analysis and integration of stakeholder values, perceptions and expectations, including impact for governance; to create a network for the ELM's societal embedding and impact; to develop and deploy an ethical approach to the ELM's,
  - **Topics to be covered in Social Aspects**: Understanding end user experience with living materials and integrate this understanding in the design of ELMs; to inspire new approaches to cocreation and inclusive material development.
- **NEED/CHALLENGE/OPPORTUNITY**: to establish shared understanding of what social and ethical aspects of ELMs entail and how we can align these qualities with social values, needs, preferences and desires.
- **TIMING**: We plan to organise the summer school during the 3rd year (in the summer)- since by that time, the projects already have some initial results. The location is Delft, Delft University of Technology; Industrial Design Engineering.
- ALL ELMs or SUBSET: all PhDs and Post Docs of ELM projects
- LINK TO/TO BE LEVERAGED BY: Communication WG, Path to Market WG.



Given the number of projects (7) and the numbers of research teams (37) in the ELMs Portfolio, a governance has been set in place for a smooth and efficient implementation of the strategic plan.

The ELMs portfolio is governed by the ELMs steering committee and by the PM (or the PO on his behalf). The ELMs steering committee (ELMs SC) is formed by the ELMs projects' coordinators and by their appointed back-ups. The PM (PO) can provide guidance and suggestions, and, in certain cases, he may be more involved in the implementation. The ELMs SC objectives are:

- Identify common needs, synergies and challenges (also with the inputs of the working groups).
- Ensure the implementation of the strategic plan by guiding and monitoring the portfolio activities in target areas (main responsibility)
- Monitor for needs of an update of the strategic plan and submit the revised version after the approval of the PM.

The steering committee regularly e-meets **at least once every two months at minimum** (this does not include the ELMs Annual Meeting). The PM and the PO shall be cc'd in the invitation. The PM and/or the PO may e-attend these meetings if their presence is asked by the coordinators or deemed necessary by the PM/PO. The ELMs SC is composed by the coordinator and by another team leader acting as a back-up coordinator for each project. composition is shown below. Each coordinator has identified a back-up to act on his/her behalf in the ELMs SC.

ELMS STEERING COMMITTEE		
PROJECT ACRO- NYM	COORDINATOR	Back-up Coordinator
BioRobot-MiniHeart	Jeroen LEIJTEN	Marcelo RIBEIRO
Fungateria	Phil AYRES	Eveline PEETERS
LoopOfFun	Wilfred WEBER	Kai SOHN
Furoid	Pedro COSTA	Matej BUZGO
NextSkins	Marie-Eve AUBIN-TAM	Tom ELLIS
PRISM-LT	Laura MARTINELLI	Massimo VASSALLI
SUMO	Stefan KRAUSS	Jesse VEENVLIET

The ELMs SC has two chairs rotating on annual basis and the appointment will be such that the role is equally distributed among all projects. The chairs of the following year should be identified 6 months before the start of the appointment. The chairs oversee the organization of the SC meetings, keeping the strategic plan updated, and coordinating the reporting of the small WG to the SC, and report to the PM/PO. However, the proper implementation of the portfolio activities and the revised strategic plan are a responsibility of the entire ELMs SC. The preparation of the portfolio activities deliverable is also a responsibility of the entire ELMs SC and the Working Groups under the coordination of the chairs.

ELMS STEERING COMMITTEE' CHAIRS			
YEAR	CHAIRS		
01/03/2023-29/02/2024	Phil AYRES (Fungateria); Laura MARTINELLI (Prism-LT)		
01/03/2024-28/02/2025	Jeroen LEIJTEN (BioRobotMiniHeart) Tom Ellis (NextSkins)		
01/03/2025-28/02/2026	Wilfried WEBER (LoopOfFun), tbd		
01/03/2026-28/02/2027	tbd		
01/03/2027-31/10/2027	tbd		

The implementation of portfolio activities in Communication and in the targeted area is carried out by working groups composed by at least one representative from each project unless the given activity is only for a subset of the ELMs portfolio. There are 6 WG in Communication, Regulation, Path to Market, Technology, Environment & Sustainability and ELSA. Thus, the groups' main responsibilities are:

- implement the portfolio activities under their given target area;
- coordinate with other working groups in joint portfolio activities;
- report to the steering committee and to the PO;
- keep regularly posted the PO (including cc'd in their meetings and communication).



# STRATEGIC PLAN FOR THE EIC PATHFINDER ENGINEERED LIVING MATERIALS PORTFOLIO

