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Proposal Reference OC-2025-1-29347

Title: **Optimizing mechanical testing of biological tissues and its use in computational models**

Acronym: **OPTICOM**

Summary

In silico medicine, which involves using computer models to develop medical treatments and devices, is a powerful tool for evaluating medical devices & therapies. However, for this approach to reach its full potential, there is a pressing need for reliable material property data, complete with uncertainty measures & biological variability. Currently, the lack of standardized methods for collecting, processing, and reporting the mechanical properties of biological tissues has led to inconsistent and highly variable data. Additionally, there are no suitable synthetic reference materials available to calibrate mechanical testing methods. This project aims to improve and standardize mechanical testing of biological tissues for use in computational modeling. Establishing broadly accepted testing standards would:

1) Facilitate comparison of results across different research groups,
2) Increase the longevity and applicability of experimental data, and
3) Enable quality assessment of material property data, which is essential for regulatory applications of computer models.

Our objective is to create a collaborative framework to support the development, validation, and dissemination of reliable, reproducible, and universally accepted testing standards for various biological tissues—from soft tissues like skin, tendons, and blood vessels to harder tissues such as bone and cartilage.

Key Expertise needed for evaluation

Medical engineering
Medical engineering and technology
Other engineering and technologies
Applied mathematics, statistics, non-computational modeling for other engineering and technology
Other engineering and technologies
Databases, data mining, data curation, computational modelling for other engineering and technologies

Keywords

biomechanical in vitro tissue testing

standardization

in silico medicine

constitutive modeling

TECHNICAL ANNEX

1. EXCELLENCE IN S&T AND NETWORKING

A. Main challenge

In silico medicine is a powerful tool for evaluating medical devices and treatments

Computational modelling has been effectively utilized for a number of years to address safety-critical challenges in the nuclear, automobile, and aerospace industries. The healthcare industry is also moving towards *in silico* medicine, i.e. the use of computer models that complement in vitro and in vivo (animal & clinical trials) studies. These computer models can be used in all phases of R&D, from product design, over development to the regulatory approval and post-market stage. Because of its reach and potential, the US' Food and Drug Administration (FDA) has identified enabling the regulatory use of computer models as a priority [1].

The credibility of a computer model depends on the accuracy of its input

To enable regulatory use, the credibility of a computer model needs to be guaranteed, for which standards and guidelines are being drafted by ASME (*VV40* [2]) and the FDA (*Assessing the Credibility of Computational Modeling and Simulation in Medical Device Simulations* [3]). Next to a clear definition of the context of use and a rigorous verification and validation process, also **the quality of the model input, including accurate material properties of the involved biological tissues, has a great influence on the model credibility**. However, ASME or FDA provide no guidelines on how to assess the quality of material properties. Ideally, a regulatory-grade material properties database of biological tissues would assure both modelers and regulating instances that the material properties used in a computer model are up to standards. Such a database is currently non-existent.

Widely accepted tissue testing protocols will prolong the lifetime of experimental results.

The scientific literature abounds with articles experimentally characterizing biological tissues. However, widely recognized testing standards for biological tissues are absent. This shortcoming leads to significant variability of test results [4], on top of the already high inherent variability exhibited by biological tissues. In addition, many publications do not provide the full details of their testing protocol. It is therefore currently impossible to compare test results between different research groups and the lifetime of experimental data is often limited to the study itself. **Establishing generally recognized tissue testing procedures or standards would make it possible to compare test results across various research teams, moreover, it would also prolong the validity of experimental findings and allow other groups to utilize them.**

An appropriate reference material will allow to quantify uncertainty & biological variability

One of the problems faced when trying to standardize test protocols and assess the quality of material properties, is the biological variability intrinsic to biological tissues. This complicates the assessment of variation among different research groups, but also affects repeatability and accordingly increases the number of samples per group when investigating different test conditions. Instead, **a synthetic material with very repeatable properties that are similar to those of biological tissues, is needed to optimize protocols and assess repeatability. Such materials will allow to differentiate between methodological uncertainties and biological variabilities.** Crossing the border between biomechanical experts & material scientists is necessary for the development of such a material. Note that synthetic bone material with representative mechanical properties is commercially available [5].

Optimizing test set-ups to maximize the data and minimize the uncertainty

Currently, biological tissue testing uses basic test set-ups such as uniaxial tensile testing, planar biaxial tensile testing and unconfined compression testing. The advantage of these test set-ups lies in the fact that 1) they are statically determinate (i.e. the stress can be assumed homogeneous and calculated analytically), 2) they could be standardized by using uniform boundary conditions and loading conditions, and 3) only basic instrumentation is necessary. However, this testing methodology is sensitive to the boundary conditions, to the geometry of the biological tissue sample, and the collected test data is poor such that for the characterization of a complex material intensive, testing is needed. The (non-biomedical) experimental mechanics community has very recently coined the term **'Material testing 2.0', which combines techniques such as a Digital Image Correlation (DIC), inverse Finite Element Modelling (FEM) and the Virtual Fields Method (VFM)** [6] **to optimize the design of test**

set-ups, with the aim to maximize the information collected from a single test and minimize uncertainties.

Therefore, the **central challenge** addressed by this COST Action is the **optimization and standardization of mechanical testing of biological tissues and its integration in computational models**. Despite the critical role that mechanical characterization plays in biomedical research, the field currently suffers from a lack of harmonized testing procedures. **The installment of widely accepted tissue testing standards, would 1) enable the comparison of test results between different research groups, 2) prolong and extend the use of experimental results, and 3) also enables the quality assessment of material properties data, required for (regulatory use of) computer models.** Our goal is to establish a collaborative framework that enables the development, validation, and dissemination of robust, reproducible, and widely accepted testing standards for biological tissues, spanning soft tissues such as skin, tendons, and blood vessels, as well as harder tissues like bone and cartilage.

These advancements are urgently needed for the biomechanical testing & modeling society

The urgency of this initiative is underscored by three converging factors. First, the demand for reliable biomechanical data is at an all-time high, driven by the rise of digital twins, personalized medicine, and AI-powered tools. Second, the technological landscape is rapidly evolving: advanced testing technology & data processing methods are widely available (e.g. full field measurements, virtual fields method, automated model discovery, …). Third, as long as international guidelines and standardized approaches are not installed, resources are spent ineffectively & reproducibility is hindered. Moreover, if the issue of quality assessment of material properties is not solved now, in silico medicine could make a false start, with performance below expectations, damaging the image of a truly promising advancement in medicine.

A community-wide approach to develop testing standards and enable the use of its results

Addressing this challenge requires a transdisciplinary and cross-sectoral network. The biomechanical community, comprising experimentalists and computational modelers, must join forces with experts in materials science, metrology, regulatory science, and industrial R&D. Collaboration between academia and industry is essential to ensure that protocols are not only scientifically rigorous but also scalable, cost-effective, and aligned with real-world applications. Engagement with standards organizations and regulatory agencies will also be critical to ensure uptake and impact.

A COST Action provides the ideal mechanism to tackle this challenge. Through collaborative working groups and regular networking activities, we will build consensus, share best practices, and develop guidelines & standardized protocols. The network will enable benchmarking across labs, foster interoperability of data and models, and promote the adoption of standards in both academic and industrial settings. By pushing the state of the art on multiple fronts—experimental design, computational modeling, regulatory alignment, and education—we will lay the foundation for a new era of reproducible, reliable, and impactful biomechanical research.

B. Objectives

Research Coordination objectives

The overall goal of this action is to optimize & standardize mechanical testing of biological tissues and its use in computational models. Through the combination of sharing know-how, infrastructure and skills, information will be gathered and analysed, in turn leading to new knowledge development. This overall goal is translated into the following 7 SMART objectives.

Objective 1: Coordinate the development of reference materials mimicking biological tissue behaviour
At least two reference materials will be developed that will be used throughout the Action. These materials mimic the mechanical behaviour of biological tissues, but show a more repeatable behaviour as the biological variability is replaced by the manufacturing one (more controlled).

Objective 2: Develop standardized testing protocols for simple test types
For minimum two relevant simple test types (e.g. uniaxial tension, unconfined compression, planar biaxial tension) consensus protocols will be developed and evaluated through round robin tests (aiming at minimum 20 participants/test type). The developed consensus protocols will serve as the basis to develop international testing standards.

Objective 3: Publish a good biomechanical testing practice
Regardless of the test type or tissue, many aspects of the experimental protocol are generic: from tissue harvesting, preservation and preparation, over the actual mechanical testing itself and the subsequent data analysis, to data reporting according to FAIR principles and quality assessment of testing data. This objective will bring all expertise in this respect together and assimilate it into a guideline document, analogous to 'Good Laboratory Practice' and 'Good Simulation Practice'.

Objective 4: Coordination of developments on Material Testing 2.0 & its data
The Material Testing 2.0 (MT2.0) paradigm uses heterogeneous mechanical experiments augmented with full-field measuring techniques (e.g., Digital Image Correlation) to extract significantly more information from single experiments compared to conventional homogeneous testing. This objective aims to bridge to the non-biological material testing experts and translate their innovative techniques to apply to biological tissues, including corresponding modelling approaches such as automated model discovery or stochastic material models.

Objective 5: Coordination of in silico uptake strategies
This objective aims to develop strategies to maximize the potential of the interaction between mechanical test data and computer modelling. On the one hand the mechanical test data can be used to calibrate, validate or verify the robustness of the computer model. On the other hand, the computer model can provide useful insights to improve the design and relevance of the mechanical test. A general overview and guidance document needs to be developed to support modelers and harmonize the strategies.

Objective 6: Coordinate publication and dissemination
Aim at minimum 5 journal papers and 10 conference abstracts per year by bringing together related results and creating synergies where possible. Advice on publication opportunities in peer-reviewed journals (e.g. through the creation of a special issue). Topics include quality assessment for different aspects of the complete mechanical testing workflow, MT2.0 for biological tissues, quantification of variability & uncertainty in testing, dealing effectively with variability & uncertainty in modeling. Next to publications, results will be disseminated by the development of guidelines, attendance to international conferences and by the organization of training schools, workshops and seminars to share the knowledge developed within the network.

Objective 7: Develop a roadmap
Development of a roadmap that describes the strategy to move forward after the Cost Action. This will include lessons learned, challenges to be tackled and novel opportunities, but also how the community developed within the network can continue to exist and develop.

Capacity building objectives

Objective 1: Building critical mass
International testing standards, guidelines and strategies are only relevant if enough critical mass has contributed to and is agreeing with these developments.

Objective 2: Bringing together experimentalist and modelers, and bridging material science & chemistry to biomechanics
Bringing these experts together will enable an acceleration in the developments and create synergies, especially for the development of the reference material and in the domain of MT2.0.

Objective 3: Develop strong links between all stakeholders
Increase the interaction between academy, industry & regulators through the organization of networking events and the attendance of trade shows. This ensures relevance and effectiveness of the developments within this Action.

Objective 4: Promote inclusiveness, young researchers & gender balance
The current network will identify and encourage female and/or junior counterparts and ITCs to join the network. At events organized by the Action, female, junior and/or ITC researchers or innovators will be given opportunities for key notes or similar sessions that provide visibility. Also within the management of the Action and the WGs, we will strive for balance in gender, seniority and ITC/non-ITCs. Where appropriate, we will foresee mentoring schemes.

Objective 5: Promote knowledge transfer & skill development
Support short-term scientific visits between partners for example to learn about computer modeling approaches or develop skills on mechanical testing. In addition, organization of seminars and workshops to transfer knowledge, create awareness and ensure adoption of developed guidelines & standards. These activities will support the development of a new generation of researchers, innovators and technicians skilled in standardized testing and modelling practices.

C. State-of-the-art

Development of biomaterials mimicking stress-strain curves of biological tissues

Traditionally, the mechanical requirements of biomaterials were focused on ensuring that materials would not fail when implanted, leading to materials with a high ultimate strength and high stiffness modulus. These material properties often strongly differ from the native tissues they are replacing and/or surrounding. Recent efforts are focusing on addressing this mechanical mismatch and developing biomaterials with mechanical properties that approximate the mechanical behavior of native tissues [7], [8]. Vatankhah-Varnosfaderani et al. on the other hand, focused on the development of elastomers that mimic stress-strain behavior but are not biocompatible [9]. We believe that both groups of materials might be appropriate as reference materials for biological tissues. The requirements for reference materials are 1) high repeatability, 2) similar mechanical properties as biological tissues, 3) scalable & cost-effective production process, and 4) acceptable shelf-life with no deterioration of mechanical properties.

The biomechanical testing community recently started a challenge for protocol harmonization

Next to the abundance of papers that appear every year with mechanical properties of specific tissues, there is also ongoing research focusing on the mechanical tissue testing methodology itself. Several studies try to quantify the variability present in tissue testing methodologies and/or to investigate the effect of certain methodological parameters on the outcome [10], [11], [12], [13], [14]. While some of these studies formulate guidelines, true protocol standardization in this domain was only recently initiated, through a community challenge C^{4}Bio. Within this initiative, a consensus protocol for a uniaxial tensile test on porcine aorta was developed, followed by a round robin tests to evaluate this consensus protocol. Their first finding illustrate the challenges in unifying testing methods across different research settings, underlining the necessity for further refinement of testing practices [15]. This Action will build further upon the findings of the C^{4}Bio initiative and methodological research.

Potential of Material testing 2.0 & data-driven modeling approaches

In parallel with the work on the mechanical characterization of biological tissues using simple test configurations (e.g. uniaxial tension, biaxial tension, unconfined compression), characterization methods using complex test configurations combined with full field measurements and identification methods (such as Inverse Finite Element Updating and Virtual Fields Method) have been developed [16] and applied to biological tissues [17]. In 2021, Pierron and Grédiac named this approach “Material Testing 2.0” [18]. Combined with AI tools, full field measurements have given rise to a method of mechanical characterization of materials independent of a behavior law, called data-driven identification [19], [20]. Associated to more complex loadings, this method has been applied to non-biological material [21]. More recently, among data-driven methods, the “model discovery” approach has been proposed and applied to arterial wall; it uses neural networks to automatically select and identify behavior models [22], [23]. Given the complexity of the mechanical behavior of biological tissues, complex test

configurations combined with data-driven identification methods offer a great potential for the personalized characterization and modelling of biological tissues.

Lack of measurement uncertainty data

Interestingly, Martonová et al. also investigated the robustness of a the model discovery method with constitutive neural networks when random noise of up to 7% was added to the data set [24]. However, this 7% is a rough estimate as actual quantitative data on measurement uncertainties in the biomechanical testing domain are, as far as we know, not available in literature. Indeed, quantifying measurement uncertainty, such as retest repeatability are not common practice, since the mechanical test is often destructive and no appropriate reference materials are available.

Accelerating the uptake of in silico medicine

Next to the development of advanced computational models, such as SimInSitu [29]) and Pelvitrack [31]), several European initiatives have recently been established to accelerate the uptake of digital twins in healthcare by developing standardized pipelines and unified frameworks to facilitate its use into clinical and regulatory applications (In Silico World [30], EDITH [27]). One central aspect is guaranteeing the reliability of these computer models, which is achieved via a combination of training courses and international guidelines such as the Good Simulation Practice, VV40 and Assessing the Credibility of Computational Modeling and Simulation in Medical Device Simulations. A gap in the current revisions of these documents, is the lack of guidelines on how to assess the quality of material properties.

D. Rationale for choosing networking to address the main challenge

The optimization and standardization of mechanical testing of biological tissues and its integration into computational models, is a challenge that is inherently multidisciplinary and requires a high level of expertise, that is fragmented per topic across institutions. A European network is not only appropriate but essential to address this challenge effectively.

Standardization is a community activity

The development of widely accepted consensus protocols and general guidelines on good biomechanical testing practices requires broad agreement across research groups, industry, and regulators. Networking facilitates structured dialogue through in-person discussions, but also short-term scientific missions, all beneficial to the development of these protocols & guidelines. Moreover, experience from experts in standard development for non-biological material testing will accelerate the process and increase the robustness of the method. Similarly, the development of the reference materials will benefit from knowledge brought by research centers on reference materials.

Combine fragmented expertise to bridge the gap

The central challenge requires experts in mechanical testing, material modeling and advanced computer modeling, but also in material science, chemistry and uncertainty quantification. These competences are distributed across institutions. Networking through a COST Action enables structural collaboration across these communities, fostering co-development to bridge the gap between the fields and creating synergies in the process.

Bridging sectors to accelerate innovation and ensure adoption

By bringing together academia & industry, research is aligned with real-world needs and research results are adopted faster. For example, by involving manufacturers of mechanical testing devices, the developed testing standard might be implemented in the testing software and required accessories might be offered as add-ons to the device. On the other hand, the required quality level of material properties will be indicated by regulators and industry, which academic researchers can use as a guideline in the standardization process of the mechanical testing.

Coordination of research will create synergies

The structured dialogue within the working groups will help to identify open problems, challenges & needs, common strategies, research results. This valuable information will be used to coordinate new

and ongoing research efforts to promote reproducibility & accelerate innovation. On the other hand, complementary data & results will be combined to create synergies.

E. Critical mass of the network

The proposed COST Action brings together a strategically composed network of researchers, institutions, and stakeholders with the critical mass and expertise required to address the central challenge of optimizing and standardizing mechanical testing of biological tissues and its integration into computational models.

The proposing network consists 49 participants from 26 institutions within 13 COST Countries and 1 international partner. The network spans from Western, Central, Eastern and Southern Europe. This geographical diversity is crucial to ensure a broad involvement in the development of testing standards which will facilitate adoption afterwards.

The proposing network has representatives from Medical engineering, Mechanical engineering, Biological sciences, Materials engineering, Civile engineering and Other domains. More specifically, the proposing network includes experts in:

- Biomechanical testing, essential for developing consensus protocols and executing round robin tests;
- Computational modelling and simulation in biomechanics, to ensure that experimental data are effectively used in computer models;
- Materials science, to i) support the development of a reference material, and ii) share knowledge on MT2.0.

While the core expertise is covered, we want to further expand our network especially with the following experts and sectors:

- Standardization organizations, enabling the development of internationally accepted testing protocols;
- Research centers on reference materials, to contribute to the development process of the reference material;
- Regulators, to provide feedback on the quality assessment of test data;
- Industry, increase the number of companies and domains.

The following actions will be taken to expand the network:

- Identification through existing network of proposing partners, followed by message via LinkedIn or regular e-mail with detailed information regarding the Action, its aim and benefits of participation;
- Organization of industry focussed activities, such as webinars, seminars and workshops;
- Attendance to international scientific conferences in other disciplines (e.g. BSSM for MT2.0), trade shows, with presentation of the Action where possible.
- Link through international associations that encompass certain disciplines or sectors (e.g. Avicenna Alliance for in silico medicine)

Specifically, we aim to grow the network by 50% in Year 1, 40% in Year 2, and 30% in Year 3. This proactive approach aims to address initial gaps in expertise and representation early on and effectively.

2. IMPACT

A. Impact related to objectives

This COST Action will have impact on science, industry and regulators, and society, and at different time scales.

Scientific impact

Standardization and reproducibility: the variation in mechanical testing protocols will be addressed by development of a reference material & consensus protocols. This in turn will significantly improve reproducibility and comparability of mechanical data of biological tissues, it will prolong the lifetime of

experimental data, and it will also allow to assess the quality of method & a generated dataset, crucial elements to assure the reliability of a computer model.

Knowledge generation and dissemination: the latest insights into variability, uncertainty, and modelling practices are captured and widely disseminated, accelerating scientific progress and reducing duplication of effort.

Impact for regulators and industry

The enabling of quality assessment of experimental data allows modelers and regulators to select and verify reliable input data for their computer model. As such, this Action also contributes to accelerate the uptake of in silico medicine for regulatory use.

Societal impact

Society will also benefit from this Action through improved medical device development. More specifically, being able to select reliable input data for computational models used in medical device design, therapy evaluation and personalized treatments, will contribute to improved outcomes, increased trust in the technology, reduced development time and improved patient safety.

Impact on research coordination and capacity building

The Action will provide a structural framework for networking & collaboration and will enable research coordination on a European level. We believe it will act as a catalyst for aligning fragmented research efforts across countries & disciplines. The main impacts on regarding research coordination are:

- Standardization of methodologies, data collection & sharing
- Foster synergies between different disciplines & sectors, accelerating innovation and enabling a more integrated approach to research challenges;
- Promote balance in gender, inclusiveness & seniority;
- Serve as a platform for developing joint research projects and funding proposals, and ensuring continuation of ongoing efforts, as the development of a future roadmap & strategy is one of the objectives.

The impact on capacity building should not be underestimated. First, combining research results will lead to the development of new knowledge and skills on standardized testing and modelling practices. Next, this knowledge and skill sets will be transferred through the organization of training schools, short-term scientific missions, seminars and workshops to researchers and technicians. Finally, in line with the COST Policy, underrepresented groups will be promoted to participate in the Action and invited to take up roles that give them visibility.

Timeline of impacts

This COST Action is designed strategically to deliver both immediate benefits and long-term transformation in the field of biomechanical testing and computer modelling:

- Short-term (Years 1-2): Network establishment & initial growth, research coordination and first results (a reference material, consensus protocol for 1 test type and a report on MT2.0 strategies applied to biological tissues).
- Medium-term (Years 3-4): Network consolidation and results of the WGs (consesnsus protocol for test type 2, publication of good biomechanical testing practice, insights to improve test design & or relevance).
- Long-term (beyond Year 4): Adoption of standards leading to improved quality & higher reproducibility, regulatory integration, sustained network collaboration, and strategic planning for future research directions.

B. Involvement of stakeholders

Stakeholder categories

For this COST Action, we have identified 6 stakeholders categories.

1. **Academic Research Groups**
    - *Role*: Core contributors to all of the WGs and tasks.
    - *Added value*: Provide relevant expertise and skills.
    - *Challenges*: Ensuring consistent engagement across diverse disciplines and geographic regions; managing variability in resources and expertise.
2. **Industry Partners** (e.g. manufacturers of test benches, reference materials, medical device manufacturers)
    - *Role*: Contribution to WG1 (reference materials), WG2 (adopting testing standards), and WG5 (developing computational models)
    - *Added value*: Provide insights into practical constraints and innovation needs, facilitate transfer and adoption of methods.
    - *Challenges*: Aligning academic timelines with industrial priorities, ensuring confidentiality and IP considerations are respected.
3. **Regulatory Bodies and Standards Organizations** (e.g. Notified Bodies in EU, Competent Authorities, ASME, FDA)
    - *Role*: Advisors in WG2 (testing standards development) and WG5 (using reliable data in computational modelling).
    - *Added value*: Ensure regulatory relevance and facilitate standard development process.
    - *Challenges*: Engaging early and maintaining interest despite long timelines for standard adoption.
4. **Policy Makers and Funding Agencies**
    - *Role*: Support dissemination and uptake of guidelines; inform future funding priorities based on strategic outcomes (Objective 7).
    - *Added Value*: Enable broader societal and policy impact; promote sustainability of the Action's outcomes.
    - *Challenges*: Translating technical outputs into policy-relevant language and frameworks.
5. **Early Career Researchers and Students**
    - *Role*: Participants in training schools, workshops, and dissemination activities.
    - *Added Value*: Build capacity and ensure long-term sustainability of expertise in the field.
    - *Challenges*: Ensuring equitable access and meaningful involvement across countries and institutions.

Engagement strategy

Stakeholders will be engaged through:

- Structured participation in test campaigns, workshops, and seminars;
- Advisory roles in working groups and standardization committees;
- Collaborative authorship of guidelines, publications, and strategy documents;
- Targeted dissemination through tailored communication channels (e.g. industry newsletters, regulatory briefings, scientific conferences of the target discipline).

The Action will actively monitor stakeholder engagement and adapt its strategy to ensure inclusivity, relevance, and impact across all categories, as stated in the section 2.C.

C. Communication, dissemination and valorisation

Communication strategy

The Action will maintain a strong and consistent communication presence, not only to all stakeholders involved but to the wider scientific community, COST members, and general public. These activities will raise awareness of the Action's goals and progress, foster community building, and encourage participation from new stakeholders. Specifically, the following communication activities will be carried out:

- A dedicated website and social media channels (e.g. LinkedIn, ResearchGate) to share updates, events, and results with a broad audience;
- Newsletters tailored to different stakeholder groups, including clinicians, industry partners, and regulatory bodies;
- Training schools, workshops, and webinars that highlight progress and provide open learning opportunities;
- Press releases and outreach materials targeting non-specialist audiences to enhance public understanding of in silico medicine and its societal benefits.

Dissemination of results

Dissemination is an important activity with the goal to inform & train researchers and innovators and ensure adoption of the developed testing standards, guidelines and strategies. Therefore, WG2-5 each have a task focused on dissemination of their developed results and it is also defined as one of the research coordination objectives. Specifically, we foresee the following activities:

- Publication of peer-reviewed journal articles and conference abstracts to target the academic and scientific community. We will consider issuing a special issues and organizing a thematic session at international conferences to highlight the Action's contributions.
- All developed documents and guidelines will be made publicly available to support adoption and implementation.
- Training schools and workshops to train the researchers and innovators on mechanical testing & computational modelling.
- Seminars and webinars to inform industry & regulators of developments & results (e.g. guidance documents) and promote their adoption.

In addition, targeted outreach will be done to:

- Regulatory bodies and standards organizations, to support the development of testing standards and reference materials and the development of the guidelines for industry & regulators on how to deal with different types of mechanical test data document.
- Policy makers, through the roadmap describing strategies to move forward after the Cost Action (Objective 7).

Valorization and exploitation

Valorisation will focus on translating the Action's results into tangible value for science, industry, and society. The strategy combines open dissemination of general outputs with targeted exploitation of innovations developed in collaboration with industry.

Key valorisation activities include:

- Co-development with industry partners to develop reference materials and standardized testing protocols, facilitating direct adoption by industry.
- Promoting the integration of developed knowledge, standards and guidelines into regulatory frameworks, enhancing the credibility of computational models in clinical and industrial settings.
- Enabling follow-up innovation by outlining next steps for continued collaboration (Objective 7), including joint research projects, new funding applications and potential spin-offs.

If relevant, intellectual property rights will be managed in accordance with COST policies and institutional guidelines. While most outputs will be open-access to maximize impact, specific innovations

(e.g. reference materials or software tools) may be subject to licensing or collaborative exploitation agreements, particularly where industry involvement is strong.

Together, these measures ensure that the Action's results are not only disseminated but also adopted, applied, and sustained beyond its duration and contributing directly to the credibility, reproducibility, and regulatory readiness of in silico medicine across Europe.

3. IMPLEMENTATION

A. Action Structure

To tackle the main challenge of optimizing and standardizing mechanical testing of biological tissues and ensuring its effective integration into computational models, we have defined 5 Working Groups (WGs) corresponding to the first 5 research coordination objectives. Each WG focuses on a key dimension of the problem, and together they provide a comprehensive and coordinated approach to the challenge. Each WG has its own objectives, yet their combined results will lead to synergies. Therefore, the interaction between the WGs is high and multidirectional (see Figure 1).

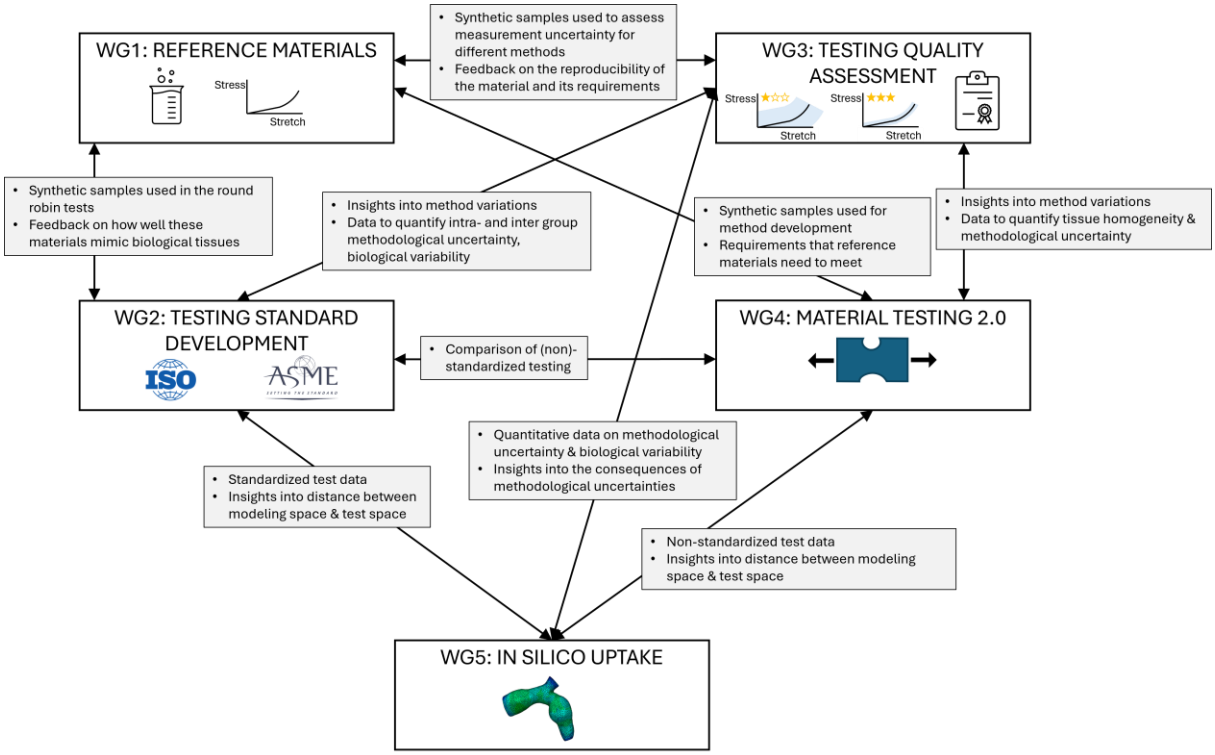

Figure 1: Overview of the WGs and their interactions.

We have intentionally avoided defining specific test types or tissue categories at this stage, as the aim is to develop a general, adaptable methodology that is independent of particular tissues or testing protocols. Where necessary, such specificities will be determined in consultation with stakeholders, such as industry partners, to ensure alignment with their priorities and practical needs.

WG1 Reference materials

WG1 focusses on the development of synthetic reference materials that replicate the mechanical behaviour of biological tissues. These reference materials have a high repeatability and are therefore more suitable as benchmarking tool than biological tissues which inherently suffer from biological variability and lower repeatability. These reference materials enable reproducibility across laboratories and facilitate inter-laboratory comparisons, two necessities for protocol standardization. The WG consists of experts in the field of material science, experts in biomechanical testing and in the development of reference materials.

WG2 Testing standard development

WG2 is dedicated to the development of testing standards for biological tissues testing. These testing standards will be developed in three phases: i) development of a consensus protocol, ii) evaluation of the consensus protocol through round robin tests (i.e. inter-laboratory comparisons), and iii) actual standard development. Extensive data analysis, collaborative workshops and short-term scientific missions, will contribute to the process. The round robin tests will use both synthetic reference materials & biological tissues to be able to quantify methodological uncertainty (intra- and inter-group) and biological variability. In this WG the focus lies on developing a repeatable method, rather than an optimized method (this is part of WG3). To ensure impact and effectiveness, this WG needs many experts in biomechanical testing, with a maximized geographical spread, and taking into account their available infrastructure. In addition, experts from standardization & regulatory organizations are part of this WG.

WG3 Testing quality assessment

WG3 focuses on the assessing the quality of specific (parts of the) testing workflow, by evaluating accuracy, robustness, sensitivity, repeatability and informativeness of existing and emerging techniques to identify sources of and quantify methodological uncertainty. Note that quality assessment in the field of biomechanical testing is currently almost non-existent, due to the lack of appropriate reference materials and the fact that most mechanical tests are destructive. With the developments & insights from the work in this WG, they will formulate best practices on biomechanical testing, put together advice on technique selection, and draft guidelines on assessing data quality helping experimentalists and modelers to select reliable data. The WG consists of biomechanical testing experts and works in high interaction with all other WGs.

WG4 Material testing 2.0

WG4 is dedicated to material testing 2.0 (i.e. complex test configurations that generate rich data sets). This approach aims to maximize informativeness and to minimize uncertainty, and is particularly useful when working with non-homogeneous and complex tissues. The aim of WG is to bridge to the non-biological material testing experts and translate their innovative techniques to apply to biological tissues. The WG consists of experts in imaging techniques & analyses, material science, biomechanical testing and modelling of tissues.

WG5 In silico uptake

WG5 focuses on providing guidance on how to use mechanical test data and uncertainty measurements in computer modelling, but also how computer modelling can provide useful insights for the experimentalists. These developments will lead to guidelines for industry & regulators. This WG consists of experts in modelling of tissues and computer simulations, complemented with regulating instances.

B. Work plan (tasks, activities and timeframe)

To achieve the main challenge and the specific objectives, each WG has a specific set of tasks, activities and milestones, which are described next.

WG1 Reference materials

T1.1 Define the requirements & list potential materials and production methods (Year 1)

Definition of all general and subtask-specific requirements for reference materials Examples are: repeatability, shelf life, stress-strain behaviour, failure properties, physical appearance. Next, list all potential materials, approaches and production methods.

T1.2 Production and evaluation of potential reference materials (Year 1-3)
Production of potential reference materials, building further on current efforts within the network. Synthetic reference samples will be evaluated in T2.2 (round robin), T3.1 (methodological uncertainty quantification) and T3.2 (method comparison); feedback & results will taken into account in the iterative development process. The selection of the tissue that will be replicated will be done in collaboration with T2.1.

T1.3 Formulate and initialize next steps for the development of reference materials (Year 4)
Possible next steps include upscaling & valorisation, for which dedicated funding might be applied for. In addition, a plan will be draft on which reference materials should still be developed & its priority.

Milestone 1: first reference material acceptable in terms of repeatability & representativeness (Year 1).

WG2 Standardized testing protocols

T2.1 Develop consensus protocol with open questions (Year 1-4)
A consensus protocol for a simple mechanical test will be drafted and updated based on the results of the round robin (T2.2) in an iterative process. Examples of tests that will be considered are: uniaxial compression of femur bone, unconfined compression of cartilage or hydrogels, planar biaxial tension of aorta, three point bending of tibia, … Note that some aspects of the workflow might be fixed (e.g. tissue preservation) and open questions, such as differences between a vertical & horizontal set-up, will be redirected to WG3, where these aspects will be investigated.

T2.2 Round robin testing & analysis (Year 1-4)
Biological samples and their synthetic reference material will be sent out to all round robin participants, who will test the samples using the consensus protocol (T2.1) and submit the results. All data will be analysed (including crossed post-processing) to evaluate the consensus protocol and identify aspects with high intergroup methodological uncertainty that still need improvement.

T2.3 Dissemination of the standardized testing protocol (Year 2-4)
Dissemination via two main activities: 1) organization of a training school on standardized testing, including both experiment & data processing and addressing all steps of the complete testing workflow, and 2) initialization of international standard formulation. Note that the network has ongoing collaborations with standardization organizations.

Milestone 2 & 3: Consensus protocol for two common test types (Year 2 & 4)

WG3 Testing quality assessment

T3.1 Quantification of methodological uncertainty & biological variability (Year 2-4)
Development of approaches for uncertainty quantification and its application to the data collected in T2.2 to quantify of methodological inter- and intra-group uncertainty and biological variability for specific test types.

T3.2 Method comparison (Year 1-4)
Development of an exhaustive list of all techniques and methods that need comparison, potential approaches (experimental study, numerical study, …) and a priority label (low, medium, high). Next, at least 5 high priority topics will be investigated. Options are: different clamping methodologies, use of markers vs DIC, 2D vs 3D DIC, tissue preservation methodologies, pre-stretching, …

T3.3 Dissemination (Year 3-4)
Dissemination will occur via 1) peer-reviewed publications on method comparison, 2) formulation of a Good Biomechanical Testing Practice (cfr. Good Simulation Practice or Good Laboratory Practice), covering all general aspects of the complete tissue testing workflow up and application of FAIR principles to biomechanical testing data, and 3) development of guidelines on quality assessment, both for experimentalist and modelers to optimize reuse of test data and assess its quality.

Milestone 4: Publication of Good Biomechanical Testing practice (Year 4)

WG4 Material testing 2.0

T4.1 Strategies to generate & dealing with rich data sets (Year 1-2)
In this task we will bridge with the strong society working on non-biological 'material testing 2.0'. While the non-biological material testing community deals with heterogeneity coming from the boundary conditions and/or the sample topology, a third source of heterogeneity is introduced in biological tissue testing: heterogeneity within the material (e.g. pathological tissues).
This requires novel methodologies tailored to these unique challenges. The task will: i) synthesize existing strategies for generating and analyzing rich datasets from complex test configurations, drawing on established approaches such as inverse finite element model updating, virtual fields methods, automated model discovery, and probabilistic modeling using Bayesian inference; and ii) identify specific challenges and coordinate the development of potential methodological solutions for handling heterogeneous biological tissues. The outcome will provide an overview for the biological tissue testing community to effectively leverage MT2.0 capabilities."

T4.2 Pre-standardization work (Year 2-3)
First approach to develop a consensus protocol to test a heterogeneous sample (for example a uniaxial tensile test on a sample with varying thickness), followed by a round robin test. The number of participants in this task, will be smaller than in T2.2, but similarly, both synthetic reference materials and biological tissues will be used. Results will provide insights into whether the standardization track should be pursued or focus should lie on user training & certification, combined with verification tests.

T4.3 Dissemination (Year 2-4)
Dissemination via peer-reviewed publications & organization of a training school on advanced testing approaches, covering both lectures and practical sessions (lab work & computer work).

Milestone 5: Comprehensive overview on MT2.0 strategies applied to biological tissues

WG 5 in silico uptake

T5.1 Guidance to deal with mechanical test data in computer modeling (Year 1-2)
Assessing the credibility of a computational model is achieved through the processes of verification, validation and uncertainty quantification (VVUQ). In this process, mechanical test data can be used for three distinct aspects: i) to calibrate the material model, ii) to validate the computer model, or iii) to perform uncertainty quantification in order to assess the sensitivity of the simulation outcome to variations in the numerical and physical parameters. The aim of this task is to develop a guidance document to support modelers in selecting appropriate modeling strategies based on the characteristics of the available experimental data. Factors such as the type of mechanical test, the nature of the data and its associated uncertainty & variability will influence the choice between deterministic and stochastic modeling approaches. To enhance transparency and consistency, this guidance will include a decision tree to assist users in navigating these choices systematically. Similar as in WG2, we will work with specific case studies such as for example mechanical testing and modelling of aortic tissue.

T5.2 Developing insights to improve test design and relevance (Year 3-4)
This task aims at using computer models to offer valuable feedback to experimentalists, helping to improve the design & relevance of the mechanical test through case studies. In a first case study, a sensitivity analysis will identify which physical parameters most significantly affect simulation outcomes. This enables experimentalists to prioritize reducing uncertainty in those key parameters, thereby efficiently & effectively improving the overall reliability of the data. The second case study, will focus on quantifying the gap between the modelling space (i.e. set of parameters, conditions & assumptions used in a computer model) and the testing space (i.e. all parameters and conditions that define the experiment). Ideally, you want both spaces to coincide (i.e. your experiment is a perfect replication of your simulation), but in practice, a virtual multidimensional distance between both spaces will exist, meaning that you're extrapolating your test data. The gap between the modelling space and the testing space will be quantified. Next, the gap will be narrowed through a collaborative approach of modelers and experimentalists to co-design a complex test configuration (WG4) that better replicates the simulation conditions, ultimately improving the alignment between physical experiments and computational models. In conjunction with WG3, this will also attempt to identify methods that minimize the uncertainty in the most relevant testing space.

T5.3 Guidelines for industry and regulators (Year 4)
This task will consolidate the findings from T5.1 and T5.2 into a set of practical guidelines tailored for industry and regulators. The guidelines will support informed decision-making when designing mechanical tests for modelling purposes, selecting appropriate modelling strategies based on available data, and minimizing the gap between testing and modelling spaces. They will include recommendations, decision trees, and example workflows to facilitate the integration of computational models into real-world applications. With ASME and FDA, we will explore options to include these guidelines as a part of a revision of the VV40 [2] and the Assessing the Credibility of Computational Modeling and Simulation in Medical Device Simulations [3].

Milestone 6: Insights developed to improve test design and/or relevance

Risk analysis and contingency plans

The following risks are identified, ordered from most to least severe, and with mitigation plan:

- The developed reference materials do not meet the requirements, for example in terms of replicating stress-strain behavior. The most important requirement is repeatable behavior. Depending on the exact issue, we will either use the developed materials, or use one that is already (commercially) available until the issue is solved.
- The intergroup variability remains high after the consensus protocol has been defined and it is unclear where the remaining variability might be coming from. In this case, a stepwise approach to reduce the complexity of the testing workflow should bring clarity, combined with short-term scientific missions to perform the tests together and identify any missing elements in the consensus protocol.
- Participants drop out of the round robin tests while the consensus protocol has not been finalized yet. This might lead to losing critical mass for standard development. To avoid drop out, we will lower the burden to participate as much as possible, and maximize the visibility of participants.
- It might not be straightforward to develop MT2.0 strategies to work with heterogenous materials. In this case, we will reduce the complexity until a working solution is found. Simultaneously, we will search and apply for dedicated research funds to tackle the problem.

C. Deliverables

This Action envisions the following deliverables, defined per WG:

WG1 Reference materials

- D1.1 Report with requirements for reference materials (Q2);
- D1.2 Reference material replicating the stress-strain behaviour of biological tissues (Q12);
- D1.3 Roadmap on the next steps for reference material development (Q16).

WG2 Testing standard development

- D2.1 Consensus protocols for two test types (Q11);
- D2.2 Report on round robin tests for each test type (Q13);
- D2.3 Training school on standardized tissue testing (Q15).

WG3 Testing quality assessment

- D3.1 Quantitative data on methodological uncertainty & biological variability (Q14);
- D3.2 Report with an exhaustive list on different techniques and methods in mechanical tissue testing and with the outcome of at least 5 studies comparing competing methods (Q16);
- D3.3 A Good Biomechanical Testing Practice document (Q14).

WG4 Material testing 2.0

- D4.1 Report providing an overview of MT2.0 strategies applied to biological tissues (Q6);
- D4.2 Report with findings of the round robin test (Q9);
- D4.3 Training school on MT2.0 (Q15).

WG5 In silico uptake

- D5.1 Guidance document on modeling strategies based on the characteristics of experimental data (Q8);
- D5.2 Report with findings on two case studies (Q13);
- D5.3 Guidelines for industry & regulators on how to deal with different types of mechanical test data (Q16).

D. Gantt chart

The Gantt chart of the Action is shown in Figure 2.

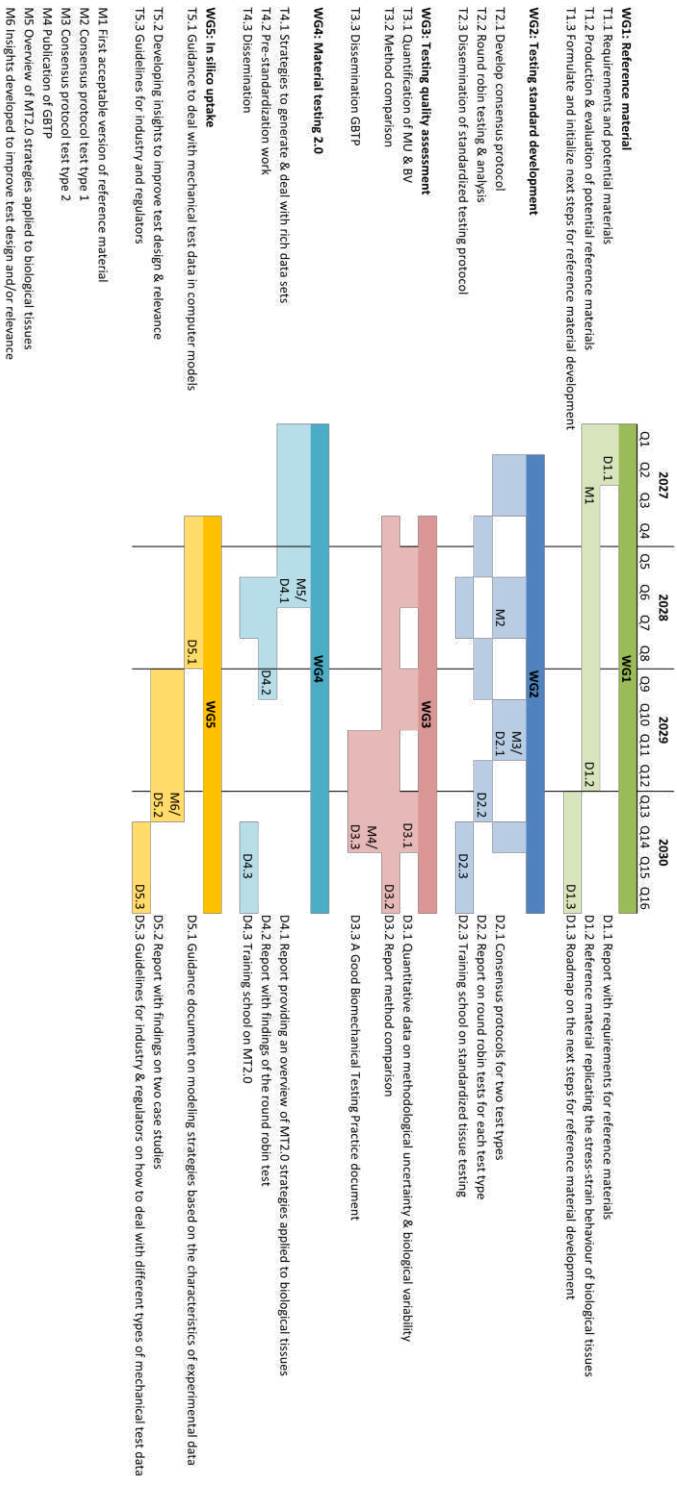

Figure 2: Gantt chart

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COST Mission and Policies

The OPTICOM proposal aims to create an interdisciplinary network of researchers and innovators to tackle the challenge of introducing standardization in the field of biomechanical testing of biological tissues and the use of its data in computer models, and therefore perfectly aligns with the COST mission.

OPTICOM is committed to achieving broad geographical representation across Europe, with a particular emphasis on involving researchers & innovators from Inclusiveness Target Countries (ITCs). Specifically, this Action will actively work to actively involve participants from ITCs and increase their visibility, by:

- Striving for at least 2 out of 5 WG leaders from ITCs

- Hosting at least 4 events (workshop, seminar, training school, ...) in ITCs.

- Ensuring balance in short-term scientific missions between ITC and non-ITC participants

- Giving ITCs researchers the opportunity to give a keynote lecture that provides visibility.

This broad geographical representation is also important to ensure a wide adoption of the developed standards, methods and workflows.

OPTICOM wants to involve young researchers and innovators to support & train the next generation of scientists. Young researchers and innovators will be empowered through:

- Assigning dedicated roles in Working Groups, including co-leadership opportunities and mentorship pairings with senior experts.

- Participation to training schools and workshops designed to build technical and transferable skills in mechanical testing and computational modelling.

- Short-Term Scientific Missions that allow young researchers and innovators to visit leading labs or gain hands-on experience in computational modelling.

This inclusive approach will accelerate career development, foster innovation, and ensure continuity in the field by cultivating a skilled and engaged new generation of biomechanical researchers.

Finally, OPTICOM will strive for gender balance and actively promote gender equality across all levels of participation and leadership. Specific measures include:

- Monitoring gender representation in Working Groups, leadership roles, and event participation, with corrective actions taken if imbalances arise.

- Ensuring gender-balanced panels and speaker lineups at workshops, conferences, and training schools.

By embedding gender balance into its governance and activities, the Action will contribute to a more equitable and inclusive research culture in line with COST’s values.

Network of Proposers - Features

COST Inclusiveness Target Countries
61.54 %

Number of Proposers
54

Country and Specific Organisation distribution of Proposers

Country/Specific Organisation	ITC/ non ITC/ other	Number of institutions	Number of researchers	Percentage of the proposing network
Belgium	non ITC	2	5	9.26 %
Canada	other	1	1	1.85 %
Croatia	ITC	1	2	3.7 %
Czech Republic	ITC	4	6	11.11 %
France	non ITC	10	12	22.22 %
Greece	ITC	2	3	5.56 %
Ireland	non ITC	2	5	9.26 %
Netherlands	non ITC	2	3	5.56 %
Poland	ITC	1	1	1.85 %
Portugal	ITC	2	5	9.26 %
Romania	ITC	2	2	3.7 %
Slovenia	ITC	1	1	1.85 %
Türkiye	ITC	3	3	5.56 %
United Kingdom	non ITC	4	5	9.26 %
Specific Organisation	other	0	0	0 %

Gender Distribution of Proposers
55.6% Males
44.4% Females

Number of Young Researchers and Innovators
25

Core Expertise of Proposers: Distribution by Sub-Field of Science
50.0% Mechanical engineering
33.3% Medical engineering
7.4% Materials engineering
3.7% Civil engineering
1.9% Biological sciences
3.8% Other

Institutional distribution of Network of Proposers

96.3% Higher education, research-performing & associated organisations
3.7% Business enterprise (small- or medium sized; SME)

Higher education, research-performing & associated organisations:52
Business enterprise (small- or medium sized; SME):2

COST Full Member (13) : Belgium, Croatia, Czech Republic, France, Greece, Ireland, Netherlands, Poland, Portugal, Romania, Slovenia, Türkiye, United Kingdom
International Partner (1) : Canada
European RTD Organisation (0)
EU Institutions, Bodies, Offices and Agencies (EC/EU) (0)
International Organisation (0)

Network of Proposers - Details

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Slovenia

Prof Gregor Harih (University of Maribor, Faculty of Mechanical Engineering)
Participating as Secondary Proposer
Core Expertise: Mechanical engineering: Product design, ergonomics, mechanical engineering aspects of man-machine interfaces
Gender: M
Is Young Researcher and Innovator: Yes

Türkiye

Prof KEREM PEKKAN (Koç University [School of Engineering])
Participating as Secondary Proposer
Core Expertise: Medical engineering: Databases, data mining, data curation, computational modelling
Gender: M
Is Young Researcher and Innovator: No

Dr Kevser Banu Kose (Istanbul Medipol University [Biomedical Engineering])
Participating as Secondary Proposer
Core Expertise: Medical engineering: Medical engineering and technology
Gender: F
Is Young Researcher and Innovator: No

Prof Can Yucesoy (Bogazici University [Institute of Biomedical Engineering])
Participating as Secondary Proposer
Core Expertise: Mechanical engineering: Biomechanics
Gender: M
Is Young Researcher and Innovator: No

United Kingdom

Prof Sam Evans (Cardiff University [School of Engineering])
Participating as Secondary Proposer
Core Expertise: Medical engineering: Medical engineering and technology
Gender: M
Is Young Researcher and Innovator: No

Prof Louise Jennings (University of Leeds)
Participating as Secondary Proposer
Core Expertise: Medical engineering: Medical engineering and technology
Gender: F
Is Young Researcher and Innovator: No

Dr Hayley Wyatt (Cardiff University [Engineering])
Participating as Secondary Proposer
Core Expertise: Medical engineering: Medical engineering and technology
Gender: F
Is Young Researcher and Innovator: Yes

Prof Hazel Screen (Queen Mary University Of London [School of Engineering & Materials

Science])

Participating as Secondary Proposer
Core Expertise: Medical engineering: mechanobiology
Gender: F
Is Young Researcher and Innovator: No

Dr Ankush Aggarwal (University of Glasgow)

Participating as Secondary Proposer
Core Expertise: Medical engineering: Databases, data mining, data curation, computational modelling
Gender: M
Is Young Researcher and Innovator: Yes