Call for Tenders

TD1

DYNAMO project has received funding from the European Union's Horizon Europe Research and Innovation Programme under the Grant Agreement No. 101095516. The sole responsibility for the publication lies with the editor and does not necessarily reflect the opinion of the European Commission or Agency. The European Commission is not responsible for any use that may be made of the information contained herein.

Revision History

The revision history is be kept as one changelog for all documents contained as a separate file in the archive of documents.

Preface

This Request for Tenders should be read in conjunction with other documents related to this Pre-Commercial-Procurement (PCP), listed hereunder:

Phase	Description	Documents
Tender	Central documents on conditions, content, and challenge	**TD1 Call for Tenders (current document)** TD2 Challenge Brief (includes Annex A-D)
Proposal to be submitted	Administrative Forms to be filled by tenderers	TD3a Declaration of Honour - Exclusion Criteria TD3b Declaration of Honour – On/off Award Criteria TD4 Power of Attorney
	Application Templates to be filled by tenderers	TD5 Tender Application Template – Administrative TD6 Tender Application Template – Technical TD7 Tender Application Template – Financial
Project	Contract Templates to be signed by successful contractors	TD8 PCP Framework Agreement TD9 PCP Specific contract for Phase I-II-III

The files are ordered chronologically regarding when documents will typically be handled and / or assessed.

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List of abbreviations

CET	Central European Time
EU	European Union
GDPR	General Data Protection Regulation
GPA	Government Procurement Agreement
ICT	Information and communication technology
IPR	Intellectual Property Rights
OMC	Open Market Consultation
PCP	Pre-Commercial Procurement
PIN	Prior Information Notice
PPI	Public procurement of innovative solutions
Q&A	Questions and answers
R&D	Research and Development
TDx	Tender Document x
WTO	World Trade Organisation

Foreword

Acceptance of all the information stated in this document is a prerequisite for placing a tender to this call. All tenderers that bid for the tender are deemed to have accepted the rules stated in this document and the provisions of the Italian law.

1 General context and background

This innovation procurement follows a pre-commercial procurement (PCP) model. In PCP, public procurers engage market innovators through an open, transparent, and competitive process to devise new solutions. These solutions address complex, longer-term challenges of public interest, necessitating novel Research and Development (R&D) services. The distinctive features of PCP include:

- Phased competitive development to discern the most cost-effective solutions.
- Public Procurement specifically of R&D services.
- An open, transparent, and non-discriminatory process, excluding large-scale deployments.
- Equitable distribution of IPR-related risks and benefits under market conditions.
- Exemptions from EU public procurement directives, the WTO Government Procurement Agreement (GPA), and EU state aid rules.
- An Open Market Consultation (OMC).
- Availability of EU funding.

1.1 Competitive development in phases to discern the most cost-effective solutions

PCP addresses scenarios demanding transformative R&D, where no near-market solutions exist. Given that R&D has not occurred yet, there is no evidence pinpointing the most effective solution. With various providers possibly envisioning diverse solutions, PCP awards R&D contracts to multiple competitors simultaneously. This approach allows different solution strategies to be juxtaposed, giving innovators a platform to benchmark their solutions. Additionally, it facilitates obtaining an initial customer reference from the testing nations of the procurers.

The R&D process is divided into three stages:

- Phase I: Solution design
- Phase II: Prototype development
- Phase III: Original development and testing of a limited series of products or services.

After each stage, evaluations refine the selection, focusing on solutions aligning with customer needs and value. This iterative model lets contractors refine subsequent phase proposals based on prior feedback. The incrementally enlarging contract scope across phases facilitates small and medium-sized enterprises (SMEs) participation, enabling gradual business expansion.

A preparatory Phase 0 has been already carried out, encompassing preliminary market research and several Open Market Consultation (OMC) events. Relevant findings from OMC, which shaped the tendering process, can be found annexed to the Challenge Brief (TD2).

Procurers may or may not decide to follow-up the PCP with a public procurement to deploy the innovative solutions at large scale (PPI).

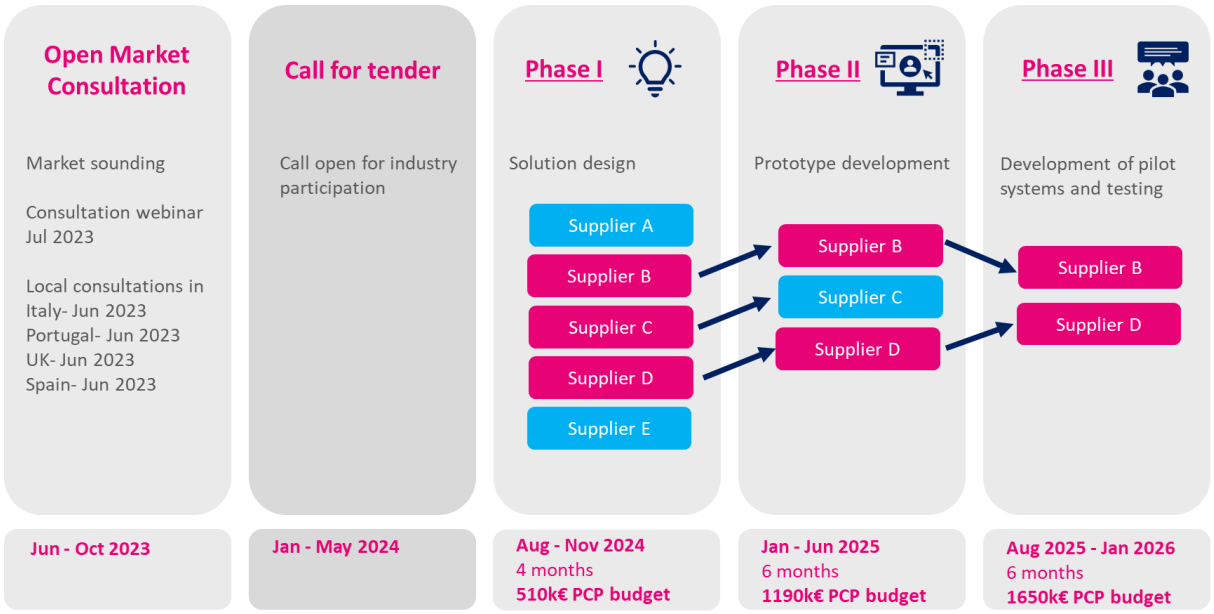

Figure 1. DYNAMO PCP Phases

1.1.1 Joined procurement by public organisations represented by a Lead Procurer

The PCP process is a joined procurement involving multiple public organisations. These organisations collectively form the *Buyers Group*, which is managed by a designated *Lead Procurer*. The Lead Procurer is responsible for initiating the procurement process and signing contracts on behalf of all member organisations in the Buyers Group.

In case of the Dynamo PCP, the Lead Procurer also handles invoicing and payments, thereby reducing the administrative burden for contractors. The parties involved in this procurement are listed in Section 2.3.

1.2 Public procurement of R&D services

PCP targets public procurement needs in the medium to long term where either no market-ready solutions exist, or current offerings have inherent limitations necessitating further R&D. It acts as a catalyst for the market to develop remedies for these challenges. By zeroing in on specific needs and incorporating customer feedback from early R&D phases, PCP amplifies the potential for successful commercialization of new solutions.

For a deeper understanding, refer to the PCP communication COM/2007/799 and its related staff working document SEC/2007/1668. The R&D services cover research and development activities ranging from solution exploration and design, to prototyping, right through to the original development of a limited set of 'first' products or services in the form of a test series. Original development of a 'first' product or service may include limited production or supply in order to incorporate the results of field-testing and demonstrate that the product or service is suitable for production or supply in quantity to acceptable quality standards. R&D does not include quantity production or supply to establish the commercial viability or to recover R&D costs.[1] It also excludes commercial development activities such as incremental adaptations

[1] See also Article XV(1)(e) WTO GPA 1994 and the Article XIII(1)(f) of the revised WTO GPA 2014.

or routine or periodic changes to existing products, services, production lines, processes or other operations in progress, even if such changes may constitute improvements.

1.3 Open, transparent, non-discriminatory process – No large-scale deployments

PCP is open to all operators on equal terms, regardless of size, geographical location or governance structure. There is, however, a place-of-performance requirement that they must perform a predefined minimum percentage of the contracted R&D services in EU Member States or Horizon Europe associated countries.

At least 50% of the contracted R&D services are required to be performed in EU Member States or Horizon Europe associated countries.

At least 50% of the contracted R&D services are required to be staff related cost.

Any subsequent public procurement of innovative solutions (PPI), for the supply of commercial volumes of the solutions, will be carried out under a separate procurement procedure past this project. Providers that did not take part in this PCP (or were not chosen to go through as far as the last phase) will thus still be able to compete on an equal basis in any subsequent procurement looking for contractors to provide a solution on a commercial scale.

1.4 Equitable distribution of IPR-related risks and benefits under market conditions

PCP procures R&D services at market price, thus providing contractors with a transparent, competitive, and reliable source of financing for the early stages of their research and development.

In giving each contractor the ownership of the IPRs attached to the results it generates during the PCP, it means that they can widely exploit the newly developed solutions commercially. In return, the tendered price must contain a **financial compensation** for keeping the IPR ownership compared to the case where the IPRs would be transferred to the procurers (the tendered price should reflect a 'non-exclusive development price'; see section 2.7). Moreover, the procurers must receive rights to use the R&D results for internal use and licensing rights subject to certain conditions.

- *Contractors must provide financial compensation for keeping IPR ownership.*
- *Contractors must grant rights to procurers for internal use of results.*

1.5 Exemptions from EU public procurement directives, the WTO Government Procurement Agreement (GPA), and EU state aid rules

PCP procurements are exempted from the **EU public procurement directives** because the procurers do not retain all the benefits of the R&D (the IPR ownership stays with the contractors).[2]

They are also exempted from the **WTO Government Procurement Agreement (GPA)** because this Agreement does not cover R&D services[3] (the PCP being limited to such services — and any subsequent PPI procurements relating to commercial-scale supply of such solutions not being part of the PCP procurement).

PCP procurements do not constitute state aid under the **EU state aid rules**[4] if they are implemented as defined in the PCP communication[5], namely by following an open, transparent, competitive procedure with risk- and benefit-sharing at market price. (The division of all rights and obligations *(including IPRs)* and the selection and award criteria for all phases must be published at the outset; the PCP must be limited to R&D services and clearly separated from any potential follow-up PPI procurements; PCP contractors may not be given any preferential treatment in a subsequent procurement for provision of the final products or services on a commercial scale.)

1.6 Open Market Consultation

The Open Market Consultation (OMC) comprises a series of events designed to:

- Inform potential suppliers about DYNAMO's pre-commercial procurement opportunities.
- Clarify the pre-commercial procurement process.
- Gather feedback regarding the requirements, challenges, and the procurement's scope.
- Facilitate collaborations among potential suppliers, ensuring they can comprehensively address the procurers' needs.

Before initiating the PCP, an OMC Consultation was announced online via a Prior Information Notice (PIN document number 2023/S 066-198224). Most of Dynamo's OMCs were conducted as online webinars. However, the Italian OMC on 22nd June 2023 was a hybrid event, blending both in-person and online modes.

The objectives of these OMCs were to:

- Disseminate information about Dynamo's opportunities to potential suppliers.
- Elaborate on the procurement process.
- Collect feedback about the requirements and common challenges.
- Promote potential collaborations among potential suppliers.
- Evaluate current technologies and pertinent R&D&I projects in the domain.

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2 See Article 16(f) of Directive 2004/18/EC (Article 14 of Directive 2014/24/EU), Article 24(e) of Directive 2004/17/EC (Article 32 of Directive 2014/25/EU) and Article 13(f)(j) of Directive 2009/81/EC.

3 See the EU's Annex IV of Appendix I to the WTO GPA.

4 See Point 33 of the Commission Communication on a framework for state aid for research and development and innovation (C(2014) 3282).

5 Commission Communication: Pre-Commercial Procurement: driving innovation to ensure sustainable, high quality public services (COM(2007) 799) and PCP staff working document (SEC(2007)1668).

An accompanying online survey (OMC questionnaire) was launched to gain deeper insights into existing technologies. Additionally, a matchmaking service was presented by the project to aid potential bidders in identifying collaboration opportunities.

Over 200 industry professionals and stakeholders took part in the OMC sessions. Through the OMC questionnaire, participants contributed valuable insights about their cutting-edge technologies, including identifying gaps, trends, and potential implications. Their feedback also informed the Dynamo Challenge Brief. It's worth noting that attending the OMC sessions is not mandatory for tender submission.

All details from the OMC events, including Q&As, are accessible on the project's website for both participants and other interested parties https://dynamo-pcp.eu/omc/.

1.7 EU funding

This PCP is part of a project that is funded by the European Union's Horizon Europe Research and Innovation Programme, under grant agreement No 101095516– Dynamo *(see https://dynamo-pcp.eu/)*.

The procurement must therefore comply with the rules imposed by the EU Horizon Europe grant agreement.

ⓘ For more information, *see 'innovation procurement' and 'links to regional policy' in the Funding & Tenders Portal Online Manual*.

Note: The EU is not participating as a contracting authority in this procurement.

2 Tender profile

2.1 Description of services to be procured

This procurement is for R&D services to develop original and innovative solutions to tackle the following challenge shared by the Buyers Group: Health and care systems worldwide face challenges from disruptive threats such as pandemics, natural disasters and economic crises, among other short-term crises. Resilience of health and care systems characterised by their ability to adapt and maintain services is crucial for coping with these threats. Delivering high-quality health and care is inherently complex, requiring multi-disciplinary collaboration and coordination. The Covid-19 pandemic exposed weaknesses in existing health and care infrastructures emphasising the need for an adaptable and flexible solution for care pathway planning during crises. The Buyers Group seeks an innovative solution aimed at enabling the use of data from various organisational IT systems and other databases or records, to promote evidence-supported care pathway planning adaptable to disruptive care situations.

The PCP includes the purchase of a limited set of prototypes and first test products and services resulting from the R&D. The cost of prototypes must be lower than the cost of R&D services.

2.1.1 PCP challenge

A dedicated document (TD2 – DYNAMO Challenge Brief) provides a detailed description of the expected scope and functionality of the DYNAMO solutions and is complemented with the description of (site-specific) requirements. The Challenge Brief is the guiding document for all technical proposals and R&D.

Background, current situation, expected demand

Disruptive threats to health systems such as pandemics, natural disasters or economic crises, as well as short-term crises such as heatwaves or prolonged cold weather, have profound impact upon and implications for population health, economic progress, and social cohesion. These unexpected, systemic shocks challenge the absorptive capacity of a health and care system to maintain the same level (quantity, quality, and equity) of service provision and protection of the population despite adverse impacts on available resources. Health system resilience – the ability to adjust to both expected and unexpected conditions while maintaining services, their functionality, and their performance– is key to coping with such threats. Trends like ageing populations and the increase of chronic diseases evoke further challenges to the transformative capacity and capability of the health and care system to adjust to these shocks.

Providing high- quality healthcare tends to be a complex process which is difficult to manage even under normal conditions. The delivery of efficient and effective healthcare services involves health and care staff from different professions, institutions and sectors needing to work together in a flexible and coordinated way. Multi-disciplinary care pathways are seen as one instrument to develop and communicate collaborative health and care service delivery processes. They describe the operational process of interdependent events, tasks and activities in the sense of a "patient journey" through the health and care system, either for individuals or for patient groups.

A pressing need exists for a streamlined, versatile solution capable of managing, connecting, and analysing data from diverse organisational IT systems, including external databases and even paper records when required, coupled with information relating to existing care pathways for specific population groups. Based on all the data and information entered, the solution needs to generate re-designed care pathways, especially for those with complex requirements, that should address the procurers' challenging crisis scenarios. The recent Covid-19 pandemic

highlighted the shortcomings of current health and care IT infrastructures, which fall short in effectively automating the design and deployment of these response strategies for various crisis situations.

The common challenge

The DYNAMO solution will foster the response capacities and capabilities of existing health and care ecosystems when a systemic crisis occurs. As mentioned earlier, multi-disciplinary care pathways are one instrument to enable care continuity and facilitate communication to ensure coordinated response processes as they are able to bundle interdependent tasks and activities organising care and support on the individual and population (group) level. Existing care pathways tend to be static and unable to be adapted to fit a dynamic environment and patient and system outcomes are then suboptimal. During the Covid-19 pandemic, we have also learned that such pathways need to be aligned to structural conditions prevailing, such as staffing resource availability nationally, regionally, and even locally to be practically implementable. This makes it difficult to transfer existing health and care pathways from one implementation context to another without adapting and tailoring them to a different environment and constraints accordingly, whether during an exceptional health system crisis or in normal times.

As a result, adapting existing health and care delivery processes to short-term shocks and long-term structural developments has remained a challenge to established health and care ecosystems. This is not so much due to lacking methodologies and approaches for care pathway design in general, but due to the lack of supportive tools enabling a diverse range of stakeholders to flexibly collaborate in pathways design across established organisational boundaries and service domains. There is also a lack of tools enabling evidence-supported pathway design and their associated workflows and care planning at the individual and population levels at the service planning stage which allows for a swift assessment of desired and undesired impacts of alternative pathway options already during the design phase.

The DYNAMO procurers therefore seek a digital solution that enables evidence-supported planning and modelling of sharable multi-disciplinary, non-proprietary care pathways. Such a pathway planning tool is required to support flexible adaptation to changing conditions during crises. In this sense, the solution is expected to effectively support a dynamic adaptation of routine care pathways across hitherto disconnected service silos, with a view to significantly accelerating the response time for re-planning of health and care delivery processes and improve the quality of the resulting response when a systemic crisis occurs. It should also support the design of, and resources required for new service pathways which can be temporarily provided while a system crisis occurs and closed again once the crisis ends.

The envisioned crisis care pathway tool shall consist of three primary functional components:

1) Dynamic pathway modelling
2) Task planning and skills matching
3) Impact assessment re alternative pathways

The primary users of the DYNAMO solution will be senior representatives from health and care delivery organisations, alongside other stakeholders specific to each crisis scenario (emergency services, local authorities, and others). Together, these senior representatives will form the ‘crisis response planning group’ (Local Modelling Group) using DYNAMO for strategic planning and overseeing the implementation of re-designed care pathways during a crisis and thus aiding health and care systems in becoming more resilient and responsive.

As the DYNAMO solution is intended to be a socio-technical system, interlinking human action with computational algorithms its processes will service three purposes:

1) Assist the regions represented in the Buyers Group of the to focus and fact check their initial ideas and, via co-design with regional stakeholders, tailor them to regional requirements.
2) To inform and guide the pre-commercial procurement (PCP) through all its three phases, providing a realistic reference for suppliers in terms of functional requirements and overall system design.
3) After being tested and evaluated during the PCP phases, become the usual mode of operation for the DYNAMO solution in real-life implementations.

In general terms, the DYNAMO solution will be used by the members of the procurer site LMGs (the "social half" of the socio-technical DYNAMO process) to plan the adaptation of existing health and care service delivery processes to structural health and care threats. To this end, they will collaborate in the DYNAMO operations rooms. All members of the operations room will have role-based access to those parts of the DYNAMO solution that they require for their task.

At each procurer site, the LMG will apply the DYNAMO solution according to a generic process model. This model was developed in co-operation with all members of the Buyers Group and represents a common view of DYNAMO that was abstracted from the specific requirements of a number of high-pressure scenarios proposed for simulation purposes throughout the different PCP phases. The generic process model consists of five sequential steps taking each Local Modelling Group (LMG) through setting up, planning, modelling, testing and operations and finally scenario sharing.

Alongside this model, sits the functional architecture of the DYNAMO solution (the "technical half" of the socio-technical DYNAMO process) which is envisaged to include a business intelligence (BI), a workflow engine and a comms engine. As part of the DYNAMO core system, these components are envisaged to be functionally separate but integrated on the data level, allowing BI-results to be computed as part of workflow engine, the workflow engine to tailor and send communications via the comms engine and received communications to flow back into the workflow engine. All end-user-facing components shall have suitable user interfaces. A fourth key component is a data interface that on the one hand connects DYNAMO to existing data (IT) systems in each organisational setting but also allows for easy entry of data that is not available in semantic form (e.g., passed on verbally from somebody, taken from a paper report, and the like). The connection to existing data systems is envisaged as a way to securely transfer data files extracted from other systems in combination with a tool allowing for the pseudonymisation of identifiers (names, insurance numbers etc.) in a way that still allows for individual level linkage of different datasets where required. Pseudonymisation is envisaged as a distributed process, with identifiers being pseudonymised or even anonymised in their respective source systems using predefined algorithms and security keys. Depending on the scenario, a trust centre might be implemented between the DYNAMO operations rooms and the different data owners. Above all, this component will follow GDPR, and other relevant information governance guidance and procedures in the procurer sites.

A future requirement will be to have a deeper interface with existing data systems for the automatic extraction of real-time data. The requirements elicitation among the Buyers Group however showed that this is currently not necessary to deliver the planned high-pressure scenarios. As a planning and management tool, DYNAMO will not be a direct part of (emergency) operations of affected organisations (such as healthcare providers). This eliminates the need to directly link into the working processes of these organisations to, for example, guide service provision for individual patients. Rather, DYNAMO supports provider organisations and others by planning, resource management and triaging on a group level. For the same reason there is also no immediate need to work with real-time data, as asynchronous dataflows that are e.g., updated every night are sufficient for the intended purposes. This also means that working with pseudonymised, anonymised or even aggregated data could be

sufficient for a given task. Doing so in turn reduces the data privacy footprint of the DYANMO solution, making operations easier.

2.1.2 Expected outcomes per phase

This procurement is organised in stages in accordance with the PCP instrument, as laid out in the previous chapter.

Summary

The proposal sets the foundation for the R&D endeavours, setting the stage for the subsequent competitive phases.

Tenderers are asked to provide a comprehensive description of their strategy for modelling and dynamic assessment of crisis care pathways addressing a set of high-pressure scenarios. This should encompass methods, technologies, services, and devices combined into a user-friendly, yet comprehensive, toolkit. This toolkit will address the response capacity of health systems. Throughout the project, tenderers must fully implement their approach at the pilot sites.

In **their proposal**, tenderers are requested to describe their DYNAMO Solution. The proposal is rated according to the Weighted Award Criteria described in section 3.4.2 and based on the tender assessment framework.

Phase I: In this initial stage, up to six contractors present their approach and formulate a distinct package for each of the four Pilot Sites. Designs at this juncture are rudimentary with early-stage planning and calculations. Collaboration is key, as contractors and procurers work closely through the Co-Design method, refining details and making pivotal decisions. The main aim here is to assess the feasibility of the proposed solutions, looking at aspects like concept, technology, organisation, regulatory compliance, and safety.

Phase II: Shifting gears to the second phase, up to three contractors delve deeper into their designs, adding layers of detail, and running tests on all user-focused ICT systems. At this point, designs should be detailed, backed by finalised calculations. The usage of the Co-Design method is in high gear, ensuring all parties are on the same page. The end goal for this phase is to move from a basic blueprint to more intricate designs, priming all stakeholders for prompt execution. Furthermore, it offers potential users an opportunity to assess all ICT systems firsthand.

Phase III: Entering the final stretch, two contractors take their solutions to the finish line, deploying them across all Pilot Sites. Here, solutions aren't just conceptualised but are installed, integrated, set into motion, maintained, and monitored for performance.

After the end of the project, the scalable DYNAMO design ensures that any supplier can quickly built up a commercialisation model within a short period after the project. Interested procurers will be able to be included as Preferred Partners or as Follower in the Network which will receive access to a limited public test of the solution. A PPI may facilitate the widespread implementation of the solutions depending on project success and whether service prices are, at this point, commercially competitive or require further support.

Phase I	
Objectives	Perform research and development to: > elaborate the solution design and determine the approach to be taken to develop the innovative solutions > demonstrate the technical, medical, financial, and commercial feasibility of the proposed concepts and approaches to meet the procurement requirements

	> incorporate the recommendations made by the Buyers Group in their assessment of the tenders.		
Output & results	Progress of the work is monitored in status calls. Written reports.		
Milestones	**By when?**	**How?**	**Output & results**
M1.1 Fine-tuned solution design completed	1 month before end of phase (see Section 2.6)		
Deliverables	**By when?**	**How?**	**Output & results**
SD1.1 Improved solution design	1 month before end of phase (see Section 2.6)	Sent by email to the Lead Procurer	Detailed technical description and specifications of the solution
SD1.2 Publishable project phase abstract	End of phase (see Section 2.6)	In the format required by the EU for publication. Sent by email to the Lead Procurer	Written report to be published on the project website
SD1.3 End of phase report	End of phase (see Section 2.6)	Sent by email to the Lead Procurer	Description of the foreground IPRs and measures to protect the IPRs and the results of this Phase. List the names and location of personnel that carried out the R&D activities.
Other	**By when?**	**How?**	**Output & results**
O1. Offer for phase II	1 month before end of phase (see Section 2.6)	Sent by email to the Lead Procurer	

Phase II

Objectives	> Develop, demonstrate, and validate prototypes under laboratory conditions. Development of Dynamo prototype systems v.1: Prototypes at this stage are conceived as non- or partly functional prototypes of key system components. > Development of Dynamo prototype systems v.2: Prototypes at this stage are conceived as functional prototypes, demonstrating component behaviour and system-wide interaction.
Output & results	The prototypes v1 and v2 are subject to testing with end-users. A suitable number of individuals will be involved in each pilot location. V2 prototypes will be presented by suppliers at each procurer site. Testing will take place according to common protocols. Progress of the work is monitored in status calls. Written report and on-site presentations.

Milestones	By when?	How?	Output & results
M2.1 Prototype system v1 ready	5 months before end of phase (see Section 2.6)		
M2.2 Prototype system v2 ready	1 month before end of phase (see Section 2.6)		
Deliverables	**By when?**	**How?**	**Output & results**
SD2.1 Presentation of prototypes of key system components	5 months before end of phase (see Section 2.6)	Presentation to each procurer on a widely available web platform. Also sent by email to the Lead Procurer	Presentation of prototypes of key system components
SD2.1a Protocol of testing v1	4 months before end of phase (see Section 2.6)	Sent by email to the Lead Procurer	Protocol of testing v1
SD2.2 Presentation of functional prototypes, demonstrating component behaviour and system-wide interaction	2 months before end of phase (see Section 2.6)	On-site presentation to each procurer. Sent by email to the Lead Procurer	Presentation of functional prototypes, demonstrating component behaviour and system-wide interaction
SD2.2a Protocol of testing v2	1 month before end of phase (see Section 2.6)	Sent by email to the Lead Procurer	Protocol of testing v2
SD2.3 Publishable project phase abstract	End of phase (see Section 2.6)	In the format required by the EU for publication. Sent by email to the Lead Procurer	Written report to be published on the project website
SD2.4 GDPR compliance report	End of phase (see Section 2.6)	Sent by email to the Lead Procurer.	Presentation of conformance of the solutions with GDPR
SD2.5 End of phase report	End of phase (see Section 2.6)	Sent by email to the Lead Procurer	Description of the foreground IPRs and measures to protect the IPRs and the results of this Phase. List the names and location of personnel that carried out the R&D activities.
Other	**By when?**	**How?**	**Output & results**
O2. Offer for phase III	1 month before end of phase (see Section 2.6)	Sent by email to the Lead Procurer	O2. Offer for phase III

Phase III

Objectives	> Development of pilot systems for an extended test under real-life conditions at all procurer sites > Installation and testing of pilot systems at each pilot site. > Operation maintained in parallel at full quality > Establishment and operation of a help service and maintenance response team, operated by suppliers > Evaluation of pilot systems against a commonly agreed protocol and metrics.
Output & results	1) Development of pilot systems for an extended test under real-life conditions at all procurer sites. 2) Suppliers install the pilot systems at each site in close collaboration with the respective site partner. System introduction covers installation of central components, user trainings, and preparation of user devices, if any, for roll-out. Before the pilot trials, on-site testing is done to reveal problems arising from the particular situation of equipment, the networks used and the organisational environment in which staff work, to eliminate problems in the full pilot. 3) Operation of all systems at each site in parallel is maintained at full quality. 4) Suppliers set up and operate a help service and a maintenance response service to address problems faced by patients, informal carers and healthcare professionals and other staff involved at the sites. Help and support is provided at each site. 5) Progress of the work is monitored in status calls.

Milestones	**By when?**	**How?**	**Output & results**
M3.1 Pilot systems ready	4 months after start of phase	Final development of systems before the pilot.*	Systems are ready for end use.
M3.2 Systems are connected with procurers' systems	4 months after start of phase	Connection of systems with the systems of the procurers through a data interface	Systems are integrated with the procurers' systems.
M3.3 Pilot operations start	5 months after start of phase	All users are trained and recruited.	
M3.4 Pilot operations end	End of phase		

Deliverables	**By when?**	**How?**	**Output & results**
SD3.1 Progress report on system development	2 months after start of phase	Sent by email to the Lead Procurer	Written report
SD3.2 Presentation of pilot system and onsite connection testing results	3 months after start of phase	On-site presentation to each procurer Also sent by email to the Lead Procurer	Written report
SD3.3 Final report (end of phase report) including final system documentation**, business and	End of phase (see Section 2.6)	Sent by email to the Lead Procurer	Written report

commercialisation plan***			
SD3.4 Publishable project phase abstract	End of phase (see Section 2.6)	In the format required by the EU for publication Sent by email to the Lead Procurer	Written report to be published on the project website
SD3.5 Summary of the lessons learned the results achieved by each contractor during the PCP	End of phase (see Section 2.6)	Sent by email to the Lead Procurer	Written report

Note:

* “Final development of systems” incorporates the procurers’ recommendations for Phase III. Further and continuous development of the solutions is expected during the pilot trials, based on procurer and end-user feedback.

** "Final system documentation" above includes all information required for technically qualified personnel not taking part in the PCP implementation to be able to use the results autonomously (without assistance by the contractor) to directly implement a system conforming to the specification of the Phase III prototype.

*** The business and commercialisation plan should explain the proposed approach to commercialising the results of the PCP and bringing viable products or services to market.

End-of-phase reports (SD1.3, SD2.5, SD3.3)

Each end-of-phase report shall contain:

- a project abstract (in the format required by the EU for publication)
- a summary of the main results achieved by each contractor and conclusions from the phase (in the format required by the EU for publication)
- a description of any results generated (including technical results and any videos submitted)
- a section that explains the IPR measures taken by the contractor to protect the results
- a list of names and location of personnel that carried out the R&D activities
- a declaration of the resources expended, broken down as in the offer. Due evidence of the resources deployed shall be appended to the report.
- the measures taken to protect results
- a declaration that at least 50 % of the work was carried out within the EU27 or a country associated to Horizon Europe.

The offer in Phase I for Phase II and in Phase II for Phase III shall be an update of the original tender. All revisions and additions possible through work in the completed phase shall be made. The offer shall therefore include inter alia:

- updated assessment of societal and procurer benefits
- updated exploitation business plan
- updated list of Background
- any new evidence of the feasibility of achievement of technical objectives and benefits to procurer health systems.

In addition, by the end of phase II the contractors should be prepared to demonstrate the developed v2 prototypes to the European Commission as part of regular technical reviews in EU projects. At the end of phase III, contractors shall provide a summary of overall lessons learnt and results achieved from the PCP.

The *final report* shall include an updated assessment of benefits and updated information on the evidence on which this assessment is made, including evidence generated by the contractor in phase III of PCP implementation.

In Phase III each contractor is to provide for the duration of the pilot full specification access to the innovative system (including all necessary hardware for its proper functioning) for testing.

Moreover, testing of the solution might be carried out in parallel in all testing sites listed in the table below and should be reflected in the tenderer's resource planning.

Procurer	Pilot Site	Additional pilot site
ISRAA	Treviso, IT	
AQUAS	Barcelona, ES	
WMCC	Olsztyn, PL	
SCMA	Amadora, PT	
		West Wales, UK

Table 1. DYNAMO pilot sites

In Phase I, end users will not be directly involved in the R&D process, as their inputs have already been collected by the local Procurer's research team. Users will be involved in phases II and III, with recruitment being an overall responsibility of the procurers.

The procuring regions represented by the Buyers Group are responsible for evaluation. Contractors support the evaluation, e.g., by integrating questionnaires into the system, analysing raw data about the use of the interfaces, etc.

2.2 Tender closing time

Tender closing time is 17:00 Treviso local time (CET) on 20 May 2024.

2.3 Procurers and other parties involved in the PCP

This procurement relates to a joint PCP that will be carried out by the Lead Procurer (ISRAA).

The Lead Procurer is appointed to coordinate and lead the joint PCP, and to sign and award the Framework Agreement and the specific contracts for all phases of the PCP, in the name and on behalf of the following Buyers Group:

- Istituto per Servizi di Ricovero e Assistenza agli Anziani (ISRAA), Italy
- Agència de Qualitat i Avaluació Sanitàries de Catalunya (AQuAS), Spain
- Warmińsko-Mazurskie Centrum Chorób Płuc, (WMCC), Poland
- Irmandade da Santa Casa da Misericordia da Amadora (SCMA), Portugal

The Lead Procurer is part of the Buyers Group. All legal names and registration numbers of the members of the Buyers Group can be found in Dynamo's Prior Information Notice.

The following entities are participating in the PCP, but are not Members of the Buyers Group:

- TICBioMed – Tecnologías de la información de la región de Murcia, Spain
- UK Köln – University Hospital Cologne, Germany
- empirica – Gesellschaft für Kommunikations- und Technologieforschung mbH, Germany
- NHS Wales - Hywel Dda University Health Board, Wales, United Kingdom

These entities are granted access to information shared during the PCP, if they need this information to implement the Dynamo Grant Agreement. They are bound by an obligation of confidentiality. They have no rights to results or IPRs from the PCP.

The project will continuously inform other procurers having expressed interest in the project. Suppliers will be given opportunity to present their solutions as events with interested procurers. Interested procurers are not granted any rights.

2.4 Contracting approach

The PCP will be implemented by concluding a **Framework Agreement** with each successful tenderer and **Specific Contracts** for each of the three R&D phases.

A Framework Agreement and a Specific Contract for Phase I are planned to be awarded to a minimum of six contractors.

A call-off will be organised for Phase II, with the aim of awarding three Phase II contracts. Only offers from contractors that successfully completed Phase I will be eligible for Phase II. The procurers will validate the Phase II prototypes preferably through face-to-face testing sessions. These sessions are anticipated to be held on the premises of each procurer's designated pilot site.

A second call-off will be organised for Phase III, with the aim of awarding a minimum of two Phase III contracts. Only offers from contractors that successfully completed Phase II will be eligible for Phase III. Phase III field-testing is expected to take place at the pilot sites of the procurers and an additional pilot site: Treviso (IT), Barcelona (ES), Olsztyn (PL), Amadora (PT), West Wales (UK)

The Framework Agreement sets the conditions for the entire duration of the PCP (covering all the phases). There will be no renegotiation. The Framework Agreement will be signed before the start of Phase I and will remain binding for the duration of all phases for which contractors remain in the PCP. Tenderers that are awarded a Framework Agreement will also be awarded a specific contract for Phase I (evaluation of tenders for the Framework Agreement and Phase I are combined). Tenderers are therefore asked not only to submit their detailed offer for Phase I, but also to state their goals, and to outline their plans *(including price conditions)* for Phases II and III – thus giving specific details of the steps that would lead to commercial exploitation of the R&D results.

The call-offs between Phases I – II and II – III require binding offers for the next respective phase, which are requested with the end-of phase deliverables for the previous phase. As the evaluation takes place at the very end of a phase, both the completion of the phase (successful or not successful) and the offer for the next phase are part of that evaluation.

In the following table a summary of the overall timing of the PCP including its individual phases (excluding evaluation periods) is detailed.

Phase	Start date	End date	Duration
Call for tenders	January 2023	May 2024	5 months
Phase I	August 2024	November 2024	4 months
Phase II	January 2025	June 2025	6 months
Phase III	August 2025	January 2026	6 months

Table 2. DYNAMO PCP phases

2.5 Total budget and budget distribution per phase

The total budget for the PCP is 3,350,000 €.

The maximum budget available for Phase I is 510,000 €

The maximum budget available for Phase II is 1,190,000 €

The maximum budget available for Phase III is 1,650,000 €

The expected number of specific contracts to be awarded under the DYNAMO PCP is six specific contracts for Phase I, three specific contracts for Phase II, and two specific contracts for Phase III.

For Phase I, offers will be accepted until the remaining budget is insufficient to fund the next best tender. The exact number of contracts finally awarded will thus depend on the prices offered and the number of tenders passing the evaluation. As leftover budget from the previous phase will be transferred to the next phase, the total budget available for Phases II and III may eventually be slightly higher than stated here (but the maximum budget per contractor for Phases II and III will remain the same). The lower the average price of tenders, the more contracts can be awarded. However, the total value of the contracts awarded can also be lower than initially expected if there are fewer tenders than expected that meet the minimum evaluation criteria.

Based on procurer assessments for appropriate resourcing of each phase, including reductions due to IPR arrangements, the maximum allowed price for each tender and phase is:

Type	Phase I	Phase II	Phase III
Maximum total budget per phase (Italian VAT included)	510,000 €	1,190,000 €	1,650,000 €
Expected number of contractors to be funded	6	3	2
Maximum budget per contractor (Italian VAT included)	85,000 €	397,000 €	825,000 €
Duration of the phase	4 months	6 months	6 months

The offer is subject to value for money (see section 3.5).

Since all suppliers will be paid by the Lead Procurer (centralised payments), and ISRAA is the Lead Procurer in the DYNAMO PCP, the valid Italian and EU VAT legislation will be applied in the project. These provisions also apply to suppliers from other countries outside of EU VAT legislation.

2.6 Time schedule

Date	Activity
First tender procedure (framework agreement and phase I contracts)	
26.01.2024	Publication of contract notice in TED
13.03.2024	Deadline for questions by tenderers
05.04.2024	Deadline for replies to questions by tenderers

20.05.2024	Deadline for submission of tenders
21.05.2024	Opening of tenders
05.07.2024	Award decision and notification
05.07.2024 – 01.08.2024	Standstill period
17.07.2024	Contracts sent for signature by tenderers
26.07.2024	Deadline for receipt of signed contracts
01.08.2024	Date of signature by Lead Procurer
01.08.2024	Signed contracts sent to tenderers
01.08.2024	Publication of contract award notice in TED
Implementation of phase I, call-off / tendering for phase II	
01.08.2024	Start of phase
30.10.2024	Submission of offer (tender) for next phase
31.10.2024	Opening of offers (tenders) for next phase
29.11.2024	Award decision and notification
30.11.2024	End of phase
12.12.2024	Contracts sent for signature by tenderers
20.12.2024	Deadline for receipt of signed contracts
22.12.2024	Date of signature by Lead Procurer
22.12.2024	Signed contracts sent to tenderers
Implementation of phase II, call-off / tendering for phase III	
01.01.2025	Start of phase
16.05.2025	Submission of offer (tender) for next phase
19.05.2025	Opening of offers (tenders) for next phase
30.06.2025	End of phase
10.07.2025	Award decision and notification
16.07.2025	Contracts sent for signature by tenderers
18.07.2025	Deadline for receipt of signed contracts
24.07.2025	Date of signature by Lead Procurer
24.07.2025	Signed contracts sent to tenderers
Implementation of phase III	
01.08.2025	Start of phase
30.01.2026	*End of phase*

Notes:

- *The time schedule is indicative. The Buyers Group reserves the right to adjust it.*
- *The standstill period for each phase begins from the award decision and notification and lasts until date of signature by the Lead Procurer.*
- *The list does not include co-design procedure to be organised at the start of each phase as well as the payment schedule and monitoring described in section 5.5.*
- *All work shall be completed at the latest two months before end of the DYNAMO Grant Agreement.*

2.7 IPR issues

Ownership of results (foreground)

Each contractor will keep ownership of the IPRs attached to the results they generate during the PCP implementation. The tendered price is expected to take this into account.

Each Contractor is therefore responsible for the management and protection of its IPRs and bears the costs associated with this.

The Buyers Group has the right to:

> access results, on a royalty-free basis, for their own use
> grant (or to require the contractors to grant) non-exclusive licences to third parties to exploit the results under fair and reasonable conditions (without the right to sub-license)
> require the contractors to transfer ownership of the IPRs if the contractors fail to comply with their obligation to commercially exploit the results (see below) or use the results to the detriment of the public interest (including security interests).

Commercial exploitation of results

Combined, the DYNAMO procurers represent attractive national markets, as well as an overall market. They represent four countries.

The contractors are expected to start commercial exploitation of the results at the latest four years after the end of Phase III.

To ensure timely exploitation, contractors must apply for medical device certification as early as possible, if needed.

The contractors are obliged to prepare in good time for exploitation as follows:

> If extension or modification of existing standards, or new standards, are required for or would promote exploitation, contractors must take any opportunity to offer their contributions to the relevant standards bodies.
> To provide brief slide decks and presentations at events targeting other interested procurers recruited by the DYNAMO project and at the Open Pilot Day. This does not imply sharing IPR.
> Support the project's communication efforts to promote (own) R&D results and the DYNAMO project among other private and public procurers.

Given the expected, attractive business case (positive cost-benefit relation), procurers may consider procuring operational systems. The commercial exploitation of the results includes confirming offers to all members of the Buyers Group to deliver an operational system– without additional cost for IPR - at a price equal to or less that the total cost of ownership

documented in the phase III offer "Phase III total offered price". The only acceptable price increase is for third-party components approved to be part of the Results.

Procurers are committed to promoting the research and development outcomes to other procurers and ensuring that the contract's results are widely shared.

The feasibility of the business plan to commercially exploit the R&D results will be assessed as part of the award criteria (see section 3.4).

Declaration of pre-existing rights (background)

The ownership of pre-existing rights will remain unchanged.

In order to be able to distinguish clearly between results and pre-existing rights (and to establish which pre-existing rights are held by whom), a complete list of all Background and planned Sideground must be provided with the Tender, including its ownership and the commercial conditions for use of Background and Sideground for any Member of the Buyers Group a) to use the Results and the proposed solution for their own purposes b) to exploit the Results as provided for in the Framework Agreement.

The estimated price for any use of third-party Background and the fully annualised charge for the tenderers' own Background and Sideground must be fully included in the calculation of total cost of ownership for procurers.

Ownership and obligations regarding Background and Sideground is further specified in the Framework Agreement.

3 Evaluation of tenders

3.1 Eligible tenders, joint tenders, and subcontracting

Participation in the tendering procedure is open on equal terms to all types of operators from any country, regardless of their geographic location, size, or governance structure.

Tenders may be submitted by a single entity or in collaboration with others. The latter can involve either submitting a joint tender (see 3.1.1) or subcontracting (see 3.1.2), or a combination of the two approaches.

Note: There are requirements relating to the place of performance of the R&D services as well as to the share of personnel costs in R&D services.

At least 50 % of the total value of R&D activities covered by the framework agreement must be performed in the EU Member States or Horizon Europe associated countries. The principal R&D staff working on the PCP must be located in the EU Member States or Horizon Europe associated countries.

Single tenderers or members of the group may not participate in more than one tender. The Buyers Group reserves the right to exclude any tender in breach of this provision.

Participation in the open market consultation is not a condition for submitting a tender.

For Phases II and III, participation is limited to tenderers that successfully completed the preceding phase.

3.1.1 Joint tenders

Joint tenders have specific requirements that must be met:

- Every member in a group of tenderers must share equal responsibility for contract performance, known as *joint and several liability*
- The group must mandate one member as the *Lead Contractor* authorised to sign both the Framework Agreement and any specific contracts in their name and on behalf of the group.

To meet these requirements, each of the members of a group of tenderers, except for the *Lead Contractor,* must submit an originally signed Power of Attorney conforming to the template provided (TD4) along with their tender.

The Buyers Group may exceptionally authorise changes in the composition of a group that tendered at the beginning of the PCP procedure (during the proposal selection) and/or the formation of a new group different from the one that tendered at the beginning of the tendering process. Nevertheless, any such authorisation, to be provided in writing at the discretion of the Buyers Group, shall not apply if:

- It implies the entry of new participants different from those tendering individually or jointly at the beginning of the tendering process, or of participants previously withdrawn or excluded from said procedure or in default under the Framework Agreement or under a Specific (phase) Contract
- It leads to a reduction of the number of Specific Contracts in a phase below the minimum numbers set in Section 2.5
- It leads, according to an independent legal report, to IPR/confidentiality issues (i.e. if associated participants selected for Phase I decide to continue as individual entities or to join other consortia)
- The new bidder resulting from the change no longer meets the selection criteria required under section 3.3

- It occurs during the execution of a specific (phase) contract, except in the event of the insolvency of one of the members of the consortium, corporate restructuring operations affecting one or several of the members of the tendering group or the merger, take-over, transformation or assignment of a company or business unit.

3.1.2 Subcontracting

Subcontracting refers to any contract or agreement between the tenderer and any third party whereby that third party agrees to provide services to the tenderer to enable or assist the tenderer to provide all or any part of the services offered to the Buyers Group in the tender.

The selection of a subcontractor to provide more than 10% of the work to be performed under any Specific Contract is subject to the approval of the Buyers Group unless such subcontractor was identified in the tender or in the tenderer's offer for a phase as the entity to deliver the work concerned.

The tenderer remains fully liable to the Buyers Group for the performance of the Framework Agreement and each Specific Contract.

Before subcontracted work begins in any Specific Contract, the tenderer must provide the Buyers Group with an originally signed agreement with the subcontractor including a clear description of the work to be subcontracted and a declaration that the subcontractor:

- agrees to be bound vis-a-vis the tenderer by the provisions of the Framework Agreement and Specific Contract (in particular in relation to IPR) mutatis mutandis
- meets the qualification requirements for the subcontracted services,
- has placed the required resources at the tenderer’s disposal for the full duration of the specific contract
- agrees to be bound by and complies fully with obligations imposed on subcontractors under the DYNAMO Grant Agreement, including those relating to the place of performance, the definition of R&D services, confidentiality, results and IPRs, the visibility of EU funding, conflicts of interest, language, obligation to provide information and keep records, audits and checks by the EU, the processing of personal data, liability for damages and ethics and security requirements
- will not subcontract any of the work so subcontracted.

Addition or replacement of subcontractors

If, subsequently, the tenderer needs to change or add new subcontractors (Phases I through III), these new subcontractors must observe the requirements described in the above section and following the same form. Nevertheless, no change in subcontractor shall be possible if:

- It leads to a reduction of the number of Specific Contracts in a phase below the minimum numbers set out in Section 2.5
- It leads, according to an independent legal report, to IPR/confidentiality issues (i.e., if associated participants selected for Phase I decide to continue as subcontractor for another bidder)
- It prevents the tenderer from meeting the selection criteria required under section 3.3.

Changes and additions to subcontractors named in prior offers require authorisation by the Buyers Group following the same criteria described above for joined tenders.

The approach to subcontracting (selection of subcontractors and management) is to be described in the tender.

3.2 Exclusion criteria

The exclusion criteria are as follows:

Exclusion criteria	Evidence
A) Conflict of Interest (see section 4.2.1)	Declaration of Honour (TD3a)
B) Exclusion grounds as defined in Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 (see section 4.2.2)	

Tenderers that do not comply with these criteria will be excluded.

Bidders shall explicitly assure that they are not subject to any of the exclusion criteria listed above by presenting a duly signed and stamped declaration of honour, using for this purpose the template provided in Declaration of Honour on Exclusion Criteria (TD3a).

In case of joint tenders, all members of the consortium or group of bidders must accredit their compliance with the above-mentioned criteria by providing a signed Declaration of Honour on Exclusion Criteria (TD3a).

In case of subcontracting, all subcontractors must provide a Declaration of Honour on Exclusion Criteria (TD3a) signed by an authorised representative.

Should there be any reasonable doubt as to any of these criteria, bidders may be requested to provide additional information and/or evidence.

Tenders that do not meet the administrative procedures will be excluded.

This is not an exhaustive list of the reasons for exclusion of the offers. Italian laws apply throughout the procurement procedure.

A) Conflict of interest

Tenderers that are subject to a conflict of interest may be excluded. If there is a potential conflict of interest, tenderers must immediately notify the Lead Procurer in writing.

A conflict of interest is any situation where the impartial and objective implementation of the evaluation of tenders and/or implementation of the contract is compromised for reasons relating to economic interests, political or national affinity, family, personal life (e.g., family of emotional ties) or any other shared interest.

Note: If an actual or potential conflict of interest arises at a later stage (i.e. during the implementation of the contract), the contractor must contact the Lead Procurer, who is required to notify the EU and to take steps to rectify the situation. The EU may verify the measures taken and require additional information to be provided and/or further measures to be taken.

B) Exclusion grounds as defined in Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014

Grounds relating to criminal convictions

The Buyers Group shall exclude a bidder if it has been subject of a conviction by final judgement for one or more of the following reasons:

- Participation in a criminal organisation, as defined in Article 2 of Council Framework Decision 2008/841/JHA;
- Corruption, as defined in Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of Member States of the

European Union and Article 2 of Council Framework Decision 2003/568/JHA (34), as well as corruption as defined in the national law of the Lead Procurer or the economic operator;
- Fraud within the meaning of Article 1 of the Convention on the protection of the European Communities' financial interests;
- Terrorist offences or offences linked to terrorist activities, as defined in Articles 1 and 3 of Council Framework Decision 2002/475/JHA, respectively, or inciting or aiding or abetting or attempting to commit an offence, as referred to in Article 4 of the aforesaid Framework Decision;
- Money laundering or terrorist financing, as defined in Article 1 of Directive 2005/60/EC of the European Parliament and of the Council;
- Child labour and other forms of trafficking in human beings as defined in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council.

The obligation to exclude a bidder shall also apply where the person convicted by final judgement is a member of the administrative, management or supervisory body of that bidder or has powers of representation, decision, or control therein.

Grounds relating to the payment of taxes or social security contributions

A bidder shall be excluded from participation in this procurement procedure where the Lead Procurer is aware that the bidder is in breach of its obligations relating to the payment of taxes or social security contributions, and where this has been established by a judicial or administrative decision having final and binding effect in accordance with the legal provisions of the country in which it is established or with those of the country of the Lead Procurer.

Furthermore, the Lead Procurer may exclude from participation in this procurement procedure a bidder where the Lead Procurer can demonstrate by any appropriate means that the bidder is in breach of its obligations relating to the payment of taxes or social security contributions.

This paragraph shall no longer apply when the bidder has fulfilled its obligations by paying or entering into a binding arrangement with a view to paying the taxes or social security contributions due, including, where applicable, any interest accrued or fines.

Grounds of insolvency or professional misconduct

The Lead Procurer may exclude a bidder in any of the following situations:

- Where the bidder is bankrupt or is the subject of insolvency or winding-up proceedings, where its assets are being administered by a liquidator or by the court, where it is in an arrangement with creditors, where its business activities are suspended or it is in any analogous situation arising from a similar procedure under national laws and regulations;
- Where the Lead Procurer can demonstrate by appropriate means that the bidder is guilty of grave professional misconduct, which renders its integrity questionable; Where the Lead Procurer has sufficiently plausible indications to conclude that the bidder has entered into agreements with other economic operators with the intention of distorting competition;
- Where a conflict of interest cannot be effectively remedied by other less intrusive measures;
- Where a distortion of competition from the prior involvement of the bidder in the preparation of this procurement procedure cannot be remedied by other, less intrusive measures;
- Where the bidder has shown significant or persistent deficiencies in the performance of a substantive requirement under a prior public contract, a prior contract with a contracting entity or a prior concession contract which led to early termination of that prior contract, damages or other comparable sanctions;
- Where the bidder has been guilty of serious misrepresentation in supplying the information required for the verification of the absence of grounds for exclusion or the fulfilment of the selection criteria;
- Where the bidder has undertaken to unduly influence the decision-making process of the Lead Procurer, to obtain confidential information that may confer upon it undue

advantages in the procurement procedure, or to negligently provide misleading information that may have a material influence on decisions concerning exclusion, selection or award.

3.3 Selection criteria

The purpose of the selection criteria is to determine whether a tenderer has the financial, economic, technical, and professional capacity necessary to carry out and perform the work.

These selection criteria will be evaluated on a pass/fail basis. “Fail” means that the evidence given does not provide sufficient indication of the tenderer’s expertise, ability and/or equipment to meet project’s objectives. Any tenderer that cannot meet all requirements in this Section will not be selected. The selection criteria are summarised in the following table.

Table 3. Selection criteria

Selection criteria	Evidence
A) Ability to perform R&D up to original development of the first products or services	Description of the capacity, materials and equipment that are available to the tenderer for research, prototyping and limited production and supply of the first set of products or services.
B) Experience with Multi-disciplinary & Cross-organisational Pathway Planning	List of successfully completed projects similar in nature, CVs of key technical personnel highlighting their expertise. Details of technical tools or software in the tenderer's possession. Client feedback.
C) Proven Collaboration with Public Procurers & Stakeholder Management	List of instances where the tenderer successfully engaged with public procurers, emphasising ability to manage diverse stakeholder expectations, navigate bureaucratic processes, and deliver results in a public procurement setting. Case studies or references from past public-sector collaborations.
D) Commercially exploit the results of the PCP, including intangible results, in particular IPRs	Description of the financial and organisational structures that are available to the tenderer for management, exploitation and transfer of IPRs and for generating revenue by marketing commercial applications of the results.

Tenderers that do not comply with these criteria will be excluded.

Detailed instructions on each selection criterion and evidence to be provided are explained in the Administrative Tender Application Template (TD5).

3.4 Award criteria

There are two types of award criteria (on/ off criteria and weighted criteria).

3.4.1 On/off criteria

On/off award criteria can only have the value 0 or 1. The score of the other (weighted) award criteria is multiplied by this value (so that the total score becomes 0 if a tender scores 0 on an on/off award criterion). The on/off award criteria are shown in Table 4 below.

Table 4. On/off award criteria

On/off criteria	Evidence
A) Compliance with the definition of R&D services	Declaration of Honour on On/off Award Criteria (TD3b)
B) Compatibility with other public financing	
C) Compliance with the requirements regarding the place of performance of the contract	
D) Compliance with ethics requirements	
E) Compliance with security requirements	

Tenders that do not comply with these criteria will be excluded.

The offers for each phase will be evaluated against these criteria.

A) Compliance with the definition of R&D services

Tenders that go beyond the provision of R&D services will be excluded.

R&D covers fundamental research, industrial research and experimental development, as per the definition given in the EU R&D&I state aid framework[6]. It may include exploration and design of solutions and prototyping up to the original development of a limited volume of first products or services in the form of a test series. Original development of a first product or service may include limited production or supply in order to incorporate the results of field-testing and to demonstrate that the product or service is suitable for production or supply in quantity to acceptable quality standards[7]. R&D does not include quantity production or supply to establish commercial viability or to recover R&D costs. It also excludes commercial development activities such as incremental adaptations or routine or periodic changes to existing products, services, production lines, processes or other operations in progress, even if such changes may constitute improvements. The purchase of commercial volumes of products or services is not permitted.

The definition of services means that the value of the total amount of products covered by the contract must be less than 50 % of the total value of the PCP framework agreement.

The following evidence is required:

- the financial part of the offer for the framework agreement must provide binding unit prices for all foreseeable items for the duration of the whole Framework Agreement
- the financial part of the offer for each phase must give a breakdown of the price for that phase in terms of units and unit prices for every type of item in the contract, clearly distinguishing the units and unit prices for items that concern products
- the offers for all three phases may include only items needed to address the challenge in question and to deliver the R&D services described in the call for tenders
- the offers for all three phases must offer services matching the R&D definition above
- The EC guidance on PCPs also specifies that “the total value of products offered in phase I respectively phase II must be less than 50 % of the value of the phase I respectively phase II contract and the total value of products offered in phase III must be so that the total value of products offered in all phases (I, II and III) is less than 50% of the total value of the PCP Framework Agreement”

[6] See Point 15 of the Commission Communication on a framework for state aid for research and development and innovation (C(2014) 3282).

[7] See Article XV(1)(e) WTO GPA 1994 and the Article XIII(1)(f) of the revised WTO GPA 2014.

B) Compatibility with other public financing

Tenders that receive public funding from other sources will be excluded if this leads to double public financing or an accumulation of different types of public financing that is not permitted by EU legislation, including EU state aid rules. Compliance needs to be confirmed in a dedicated section of the Declaration of Honour –on on/ off Award Criteria (TD3b).

C) Compliance with requirements relating to the place of performance of the contract

Tenders will be excluded if they do not meet the following requirements relating to the place of performance of the contract:

- At least 50% of the total value of activities covered by the framework agreement must be performed in the EU Member States or Horizon Europe associated countries. The principal R&D staff working on the PCP must be located in the EU Member States or Horizon Europe associated countries.
- At least 50% of the total value of activities covered by each specific contract for each PCP phase must be performed in the EU Member States or in Horizon Europe associated countries. The principal R&D staff working on each specific contract must be located in the EU Member States or Horizon Europe associated countries.

The percentage is calculated as the part of the total monetary value of the contract that is allocated to activities performed in the EU Member States or in other countries associated to Horizon 2020Europe. All activities covered by the contract are included in the calculation, i.e. all R&D and operational activities that are needed to perform the R&D services (e.g. research, development, testing and certifying solutions). This includes all activities performed under the contract by contractors and, if applicable, their subcontractors.

The principal R&D staff are the main researchers, developers, and testers responsible for leading the R&D activities covered by the contract.

The countries associated to Horizon Europe are those listed as associated countries in the Participant Portal Online Manual[8].

The following evidence is required:

- the financial part of the offer must provide binding unit prices for all foreseeable items for the duration of the whole framework agreement and give a breakdown of the price for the current phase in terms of units and unit prices (hours and unit price per hour), for every type of item in the contract (e.g., junior and senior researchers)
- a list of staff working on the specific contract (including for subcontractors), clearly indicating their role in performing the contract (i.e., whether they are principal R&D staff or not) and the location (country) where they will carry out their tasks under the contract
- a confirmation or declaration of honour that, where certain activities forming part of the contract are subcontracted, subcontractors will be required to comply with the place of performance obligation to ensure that the minimum percentage of the total amount of activities that has to be performed in the EU Member States or in countries participating in Horizon Europe is respected

D) Compliance with ethics and research integrity

Tenders will be excluded if they:

- do not comply with

[8] https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/list-3rd-country-participation_horizon-euratom_en.pdf

- ethical principles (including the highest standards of research integrity, notably as set out in the European Code of Conduct for Research Integrity[9], and, in particular, avoiding fabrication, falsification, plagiarism and other research misconduct)
- applicable international, EU and national law

> include plans to carry out activities that are prohibited in all Member States or in a country outside the EU (where those activities are allowed)
> include activities that do not focus exclusively on civil applications
> do not comply with the ethics requirements specified in the Framework Agreement.

If the tender involves activities that raise ethical issues, the tenderer must submit an ethics self-assessment that:

> describes how the tender meets the legal and ethical requirements of the country or countries where the tasks raising ethical issues are to be carried out
> explains in detail how the tenderer intends to address the ethical issues identified, in particular as regards:
    - objectives (e.g., dealing with vulnerable populations and dual-use goods)[10]
    - methodology (e.g., involvement of children and related consent procedure and protection of data collected)
    - the potential impact (e.g., issues relating to the dual use of goods, environmental damage, stigmatisation of particular social groups, political or financial retaliation, benefit-sharing and malevolent use of results).

For information on ethics issues, see the guidance for EU grant beneficiaries How to complete your ethics self-assessment.

Note: Call-offs for phases II and III may request that this information be updated in the offers submitted for these phases.

Before starting the particular task that raises ethical issues, contractors must provide a copy of:

- any ethics committee opinion required under national law; and

- any notification or authorisation for activities raising ethical issues required under national law.

The Framework Agreement contains a provision on ethics.

E) Compliance with security

Tenders will be excluded if they do not comply with EU, national and international law on dual-use goods or dangerous materials and substances.

Tenders themselves must not contain any classified information.

If the output of activities or results proposed in the tender raise security issues or uses EU-classified information, the tenderer must show that these issues are being handled correctly. In such a case, tenderers are required to ensure and to provide evidence of the adequate clearance of all relevant facilities. They must examine any issues (such as those relating to access to classified information or export or transfer control) with the national authorities before submitting their offer. Tenders must include a draft Security Classification Guide (SCG), indicating the expected levels of security classification.

[9] The European Code of Conduct for Research Integrity of ALLEA (All European Academies)) of March 2017.
[10] See Article 2(1) EU export control Regulation No 428/2009.

Note: If necessary for the tender procedure or for performing the contract itself, contractors will be requested to ensure appropriate security clearance for third parties (e.g., for external experts needed to evaluate the proposal).

Call-offs for phases II and III may request that this security information be updated in the offers submitted for that phase.

Before starting the particular task that raises security issues, contractors must provide a copy of any export or transfer licences required under EU, national or international law.

Should there be any doubt as to any of these criteria, tenderers may be requested to provide additional information.

3.4.2 Weighted award criteria

The award criteria are grouped into the following domains:

- **Excellence**: focusing on the understanding of the tender of the DYNAMO challenge, alignment with the DYNAMO vision, maturity, and evidence of effectiveness of the proposed approach, and compliance with the DYNAMO specifications (requirements, use cases and process models)
- **Impact**: with a focus on the extent to which the expected outputs of the tender contribute to the DYNAMO objectives and the procurers' needs for a tool that has the capability to design care pathways for their chosen population segment in the event of their respective crisis scenarios. Value is expected to be created in the whole ecosystem of the procurers, with a specific focus on benefits for patients, the procurers, and the wider health and care systems they are a part of.
- **Implementation**: focusing on the quality and efficiency of the proposed implementation approach, as well as the necessity to involve a variety of stakeholders in the design process (e.g., health and social care practitioners, family carers, specialists, health and care planners, community organisations and citizens).

Award criteria for Phase I [11]	Maximum points	Threshold
Excellence of the proposed solution		
Level of innovativeness and ability to go beyond the state-of-the-art	5	3
Understanding of the DYNAMO concept	5	
Extent to which the solution can be adapted for data sharing and alignment between the diverse ecosystem entities	15	8
Extent to which the proposed solution meets the DYNAMO vision and its requirements documented in the Call	15	8
Evidence of effectiveness in addressing crisis pathway planning for the different high-pressure scenarios	10	
Total for excellence	*50*	*25*
Impact of the proposed solution		
Value of benefits for procurers and their employees including planners	15	8

[11] The basis for evaluation in the Call for Tenders evaluation are the written tenders. The evaluation of the call-offs takes into account, in addition to the updated offers from the Call for Tenders, also the experience and outcomes achieved in that phase, distributed across the different award criteria.

Award criteria for Phase I [11]	Maximum points	Threshold
Total cost of ownership of the solution including economic impact for health and care organisations	5	2
Sustainability of supplier business case including demonstrating scalability and commercialisation	5	
Soundness of the approach to data interfacing with procurer IT systems	10	5
Total for impact	*35*	*18*
Implementation of the proposed solution		
Quality and completeness of the work-plan as well as detail of tasks, methodology, milestones, and deliverables (incl. ongoing technical support and advice to procurers)	5	
Feasibility of plan and resources to meet the objectives specified	5	2
Relevance of the proposed way to involve health and care practitioners as well as planners in all aspects of design and development	5	
Total for implementation	*15*	*8*
Overall score for tender	*100*	*60*

Award criteria for Phase II	Maximum points	Threshold
Excellence of the proposed solution		
Level of innovativeness and ability to go beyond the state-of-the-art	5	1
Extent to which the solution can be adapted for data sharing and alignment between the diverse ecosystem entities (beyond health and care organisations)	10	6
Extent to which the proposed solution meets the DYNAMO vision and its requirements documented in the Call	10	6
Evidence of effectiveness in addressing crisis pathway planning for the different high-pressure scenarios	10	4
Total for excellence	*35*	*18*
Impact of the proposed solution		
Value of benefits for procurers and their employees including planners	5	2
Total cost of ownership of the solution including economic impact for health and care organisations	10	5
Sustainability of supplier business case including demonstrating scalability and commercialisation	10	5
Soundness of the approach to data interfacing with procurer IT systems	10	6
Total for impact	*35*	*18*
Implementation of the proposed solution		

Award criteria for Phase II	Maximum points	Threshold
Quality and completeness of the work-plan as well as detail of tasks, methodology, milestones, and deliverables (incl. ongoing technical support and advice to procurers)	10	
Feasibility of plan and resources to meet the objectives specified	10	5
Relevance of the proposed way to involve health and care practitioners as well as planners in all aspects of design and development	10	
Total for implementation	*30*	*15*
Overall score for tender	*100*	*60*

Award criteria for Phase III	Maximum points	Threshold
Excellence of the proposed solution		
Extent to which the solution can be adapted for data sharing and alignment between the diverse ecosystem entities	10	5
Extent to which the proposed solution meets the DYNAMO vision and its requirements documented in the Call	10	6
Evidence of effectiveness in addressing crisis pathway planning for the different high-pressure scenarios	5	2
Total for excellence	*25*	*13*
Impact of the proposed solution		
Value of benefits for procurers and their employees including planners	5	2
Total cost of ownership of the solution including economic impact for health and care organisations	20	11
Sustainability of supplier business case demonstrating scalability and commercialisation	10	
Soundness of the approach to data interfacing with procurer IT systems	5	3
Total for impact	*40*	*21*
Implementation of the proposed solution		
Quality and completeness of the work-plan as well as detail of tasks, methodology, milestones, and deliverables (incl. ongoing technical support and advice to procurers)	15	
Feasibility of plan and resources to meet the objectives specified	15	8
Relevance of the proposed way to involve health and care practitioners as well as planners in all aspects of design and development	5	
Total for implementation	*35*	*18*
Overall score for tender	*100*	*60*

The award criteria are described in more detail below.

Excellence of the proposed solution

Level of innovativeness and ability to go beyond the state-of-the-art

Proposed solutions should be innovative, based on an assessment of the market offers, on-going and upcoming technological developments and research which has relevant to the DYNAMO challenge. In addition, the proposed solutions should demonstrate additional valuable insights into health and care crisis management by means of care pathway design. Elements that make the solution original and innovative should be clearly identified, allowing to differentiate the proposed solution with respect to the known state-of-the-art.

Understanding of the DYNAMO concept

Tenderers need to show good understanding of the DYNAMO concept and focus on the development of a tool to enable care pathway redesign in the event of a crisis situation. The "solution" proposed should align to the needs of the procurers and the end users (the Local Modelling Group as a dedicated crisis response planning team), while ICT systems should be regarded as tools enabling an evidence-supported planning process.

Extent to which the solution can be adapted for data sharing and alignment between the diverse ecosystem entities

Tenderers need to show that the proposed solution will have the capability to inform the crisis care pathway planning process with data available from different entities that may be relevant for each crisis scenario, for instance, by connecting DYNAMO to existing data (IT) systems in each organisational setting but also allows for easy entry of data that is not available in semantic form (e.g., passed on verbally from somebody, taken from a paper report, and the like).

Extent to which the proposed solution meets the DYNAMO vision and its requirements documented in the Call

Tenderers need to show that the vision of the DYNAMO procurers has been well understood and reflected in the proposed approach in the tender. The vision consists of the published materials – requirements, use cases and process models, as well as contextual information (e.g. graphical representations of the socio-technical process flow and data sources for each procurer sites). A clear explanation should be provided to understand how the proposed solution matches the requirements documented in the Call for Tenders. Specific reference can be made to certain requirements, functionalities, and use cases.

Evidence of effectiveness in addressing the different high-pressure scenarios

Novel concepts can be introduced as part of the solution, but there should be evidence available which helps show the effectiveness of the proposed solution, achievable within the duration of the DYNAMO project. The long-term aim of the procurers is to be able to include the solutions as part of an emergency crisis response, therefore the solutions sought in the PCP cannot be of experimental nature (not lower that TRL6). The approaches proposed should reference literature about outcomes of studies and evaluation trials and discuss the results' reliability and the evaluation's rigour.

Impact of the proposed solution

Value of benefits for procurers and their employees including planners

Tenderers should describe the benefits procurers can expect when the proposed solution is in place, e.g. when it comes their employees including planners but also for other ecosystem stakeholders and patients. Benefits for a procurer and their staff may include:

- Availability of population risk stratified data for the evidence-supported design of alternative crisis care pathways for affected patient groups, identifying resource requirements (staff, equipment etc), use of estates (buildings).
- Reliable and robust interfacing with a variety of data sources to support evidence-based planning of cross-organisational crisis care pathways.
- Improved capability to maintain essential services when crisis occurs.
- A single solution to plan and assess alternative care pathways for a diverse range of crisis situations and patient groups
- Multi-channel communication of crisis care pathways and related information facilitates a concerted crisis response across organisations stakeholder groups, and sectors.
- Staff will be informed of their emergency response role and responsibility more quickly.
- Reduced fragmentation of demand for innovative solutions, networking activities and increased opportunities for solution uptake.

Total cost of ownership of the solution

The total cost of deploying the proposed solution includes both payments to system providers, summarised as total cost of ownership, and additional time required by procurer staff, especially the members of the LMG as a dedicated response planning group, but also time required for operations and maintenance, summarised as procurer annual operation costs. Tenderers need to ensure that all additional costs incurred in deploying the proposed solution are considered.

Different figures should be given for different scales of deployment (e.g., intra-organisational deployment (one deploying organisation, several departments, one system environment for deployment) and inter-organisational deployment (several organisations, distributed systems). One-off costs should be depreciated over a maximum of five years. All costs incurred by a procurer from third parties to reap the benefits from the proposed solution must be listed (licensing, maintenance, replacement, insurance, etc.). Costs may include:

- Purchase/Software License
- Implementation costs, set-up costs, including hardware, shipping, installation, and configuration, and initial training
- Operation and maintenance including hosting, training, security updates and upgrades
- Data interfacing costs with existing IT systems
- Adaptation to existing IT systems,
- Operational Efficiency losses and gains
- Costs associated with data import from different sources, including IT systems and non-digital sources
- Costs associated with managing potential risks, such as cybersecurity threats or regulatory compliance issues.
- Potential savings

Sustainability of supplier business case

Tenderers need to explain the proposed approach to commercially exploit the results of the PCP and to bring a viable product or service onto the market. This includes a business strategy for commercialising the solution (including competitors' analysis, market expansion plans, business models, value proposition, capital plan etc.). As far as possible, the business case should be backed up with plausible figures, including estimates if necessary.

Soundness of the approach to data interfacing with procurer IT systems

An important aspect of the process is the interfacing of the solutions with existing IT systems of the procurers and/or other eco-system organisations with relevance to a given high-pressure scenario. Clear interfacing approaches should be provided in the tenders to ensure that the solutions tested in phase III are working seamlessly within the procurers' health and care eco-systems. As a minimum requirement, a connection to existing data systems must be

enabled as a way to securely transfer data files extracted from other systems, in combination with a tool allowing for the pseudonymisation of relevant identifiers (e.g., names, insurance numbers and the like) in a way that still allows for individual level linkage of different datasets where required. Enabling a deeper integration with existing data systems for the automatic extraction of real-time data should be anticipated as a future requirement of individual procurers following the successful piloting of the DYNAMO solution as part of the ongoing PCP project. Above all, the approach to data interfacing must comply with relevant regulatory requirements, e.g. when it comes to the processing of personal data.

Implementation of the proposed solution

Quality and completeness of the work-plan as well as detail of tasks, methodology, milestones, and deliverables

Comprehensive workplan, to include work packages, tasks, methodology, milestones, deliverables and responsibilities, need to be drawn up for all PCP phases.

Feasibility of plan and resources to meet the objectives specified

Details on the resources needed to achieve the work-plan have to be provided for each organisation involved in the tender. Other resources such as travel, and licenses need to also be quantified and provided.

The operational capacity of the suppliers aligned with the plan and resources need to be convincing and address all phases. The scope and intensity of work increases in phases II and III of the PCP, where suppliers will need to build prototypes, interact frequently with users (LMG members) of the procurers, pilot the services in realistic crisis simulation setting, provide support in training, change management, a dedicated helpdesk, etc. Past experiences of the procurers have shown the importance of working with local partners to cover the full scope of the procurement, including localisation of the solution to the local language, regular exchanges in meetings with the suppliers and their users (in many cases, communication with healthcare planners and professionals is done using their mother tongue). The tender plan should have a convincing operational capacity, e.g., reflected already in the consortium composition, or by having a plan and reserved budget for involving local subcontractors while complying with the limit on use of subcontracting.

Relevance of the proposed way to involve health and care practitioners as well as planners in all aspects of design and development

User-centred design is an important aspect. The DYNAMO procurers have consulted users when preparing the Call for Tenders. Users need to be involved in the work of the suppliers as well, including in the prototype and testing phases.

Points system

Award criteria points are awarded based on the following scheme:

Assessment				Description
5-point criteria	10-point criteria	15-point criteria	20-point criteria	
0	0	0	0	Insufficient (fails to address the criterion under examination or cannot be judged due to missing or incomplete information)
1	2	3	4	Poor (the criterion is addressed in an inadequate manner, or there are serious inherent weaknesses)

Assessment				Description
2	4	6	8	Fair (while the criterion is broadly addressed, there are some weaknesses)
3	6	9	12	Satisfactory (the criterion is addressed well, although improvements would have been necessary)
4	8	12	16	Good (the criterion is addressed well, although certain improvements are still possible)
5	10	15	20	Excellent (all relevant aspects of the criterion are successfully addressed; any shortcomings are minor)

3.5 Awarding of contracts

Tenders must score above the weighted award criteria thresholds given, for each threshold. Tenders that do not reach the minimum quality thresholds will be rejected.

The contracts will be awarded to the most economically advantageous tenderers, i.e., the tenders with the highest total scores that score above all thresholds and offering the best quality-price ratio determined in accordance with the formula below.

$$Total\ Score_{Tender\ i} = 90\% * Quality\ Score_{Tender\ i} + 10\% * \left(\frac{lowest\ price\ of\ all\ tenders}{Price_{Tender\ i}} * 100\right)$$

The price applied is to be the **total offered price** relating to the next specific contract (contract for each phase) in the PCP. For the first tender, the price for phase I will be applied.

The maximum score for a tender is 100 points, of which 90 % correspond to the technical quality and 10 % to the financial offer, as shown in the formula above.

Should there be any doubt as to the application of any of these criteria to a tender / offer, tenderers may be requested to provide additional information.

3.6 Evaluation procedure: Opening of tenders & evaluation

Opening of tenders

Tenders will be evaluated in a non-discriminatory manner in accordance with the legal requirements provided for in relevant provisions under Italian regulations.

The Lead Procurer will open the tenders which have been submitted by the deadline mentioned in the time schedule in section 2.6, and register them.

The location will be ISRAA Administrative Headquarter, Borgo Mazzini 48, 31100 Treviso on 30th April 2024 at 9:00 local time.

Upon the request addressed to the Lead Procurer, access to the minutes of the opening of tenders may be requested also by entities which have not submitted a tender.

Organisation of the tender evaluation

The tender evaluation is carried out by an Evaluation Committee, which is appointed by the Lead Procurer after the publication of the call for tender. Each of the four procurers will nominate three or more experts to the Evaluation Committee they wish to represent them. Irrespective of the total number of experts, the expert members of a given procurer form that procurer's Evaluation Team. The Evaluation Committee is therefore made up of four Evaluation Teams.

The experts in the Evaluation Committee should reflect relevant expertise areas – procurement, technical, business, clinical. The nomination is done by forwarding information on the identity, education, professional qualifications, and experience of the relevant nominee to the Lead Procurer. When doing so, the procurers shall use the form provided by the Lead Procurer. It is a duty of each procurer to ensure the person appointed is in accordance with the requirements provided by the law in force and there are no reasons for excluding the candidate.

The Lead Procurer draws up a list of the members of the Evaluation Committee, based on persons appointed by the other procurers.

Note: Each member of the Evaluation Committee will sign in advance a Declaration of absence of conflict of interest and protection of confidentiality and in addition specifically notify the Lead Procurer if there is any conflict of interest with any of the tenderers.

When carrying out their tasks, the Evaluation Committee shall not seek or take instructions from the Lead Procurer, other procurers, any institutions, bodies, offices, or agencies, from any government of a Procurer or from any other body. The Committee shall respect the general principles settled in relevant provisions under Italian regulations, and work in accordance with all the provisions and content of the Contract Notice.

The nomination and appointment of the Evaluation Committee shall take place in good time for meeting deadlines set for the evaluation of tenders.

Note: For phases II and III, no differences in the composition of the Evaluation Committee or in the procedure are expected.

The Lead Procurer will keep duly certified copies of the Declaration of absence of conflict of interest and protection of confidentiality, signed by the Committee members. The Lead Procurer will refuse to accept a nomination if a conflict of interest is stated in the above-mentioned Declaration.

Evaluation

The Evaluation Committee may request clarification or additional evidence if needed. The tenderer concerned will be notified by the Lead Procurer by email. The tenderer will have five (5) calendar days (from the day he receives the notification) to send the clarifications and / or evidence requested. After this deadline, if no answer is received from the tenderer, the offer may be rejected and excluded from the tender evaluation. The tenderer will be informed by the Lead Procurer by email.

The Evaluation Committee will carry out the selection of requests to participate and will evaluate tenders on the basis of exclusion, on/off award, and selection criteria e.g., not meeting formal requirements.

Only tenders that satisfy the provided requirements, that are not excluded on the basis of the exclusion criteria and that meet the selection criteria, are admissible for evaluation under the weighted award criteria.

The Evaluation Committee plans to, within three weeks of the start of the evaluation, issue its reports on selection and award, respectively.

In summary, the Evaluation Committee will carry out the following steps:

- Step 1 — Checking whether the tenderer is not in one of the situations covered by the exclusion criteria
- Step 2 — For tenderers passing Step 1, assessing whether the tenderer has the capacities necessary to perform the contract, on the basis of the selection criteria

- Step 3 — For tenderers passing Step 2, evaluating the tender based on the on/off award criteria
- Step 4 — For tenders passing Step 3, evaluating the tender based on the weighted award criteria
- Step 5 — For tenders passing Step 4, opening the financial offer and validating it is compliant
- Step 6 – Preparing the outcome letters which include justification of the evaluation outcome, including the tender scoring, the tender rank, and a summary report with evaluation comments that should be addressed by the selected tenders in the next PCP phase

The Evaluation Committee will reach its decision by a Simple Majority vote (based on the four (4) procurers and their Evaluation Teams, with each procurer / Evaluation Team having one vote). Should the vote result in a tie, the vote of the Lead Procurer breaks the tie. It is, however, expected that the Evaluation Teams make their best endeavours to reach unanimous decisions as to the content and conclusions of the reports.

Each member of the Evaluation Committee shall carry out their tasks in an independent manner, applying their professional judgement.

For Step 5, the Evaluation Committee will incorporate evaluation comments from all Evaluation Committee members. The DYNAMO Expert Board may be requested to provide input to the comments provided. The Board consists of non-procuring partners and represents leading experts and organisations in their respective fields.

Expert Board members may be requested by the Evaluation Committee to provide comments on weaknesses of the tenders from their respective expert perspective. Inclusion in the evaluation summary reports remains at the discretion of the Evaluation Committee.

Note: Each member of the Expert Board will sign in advance a Declaration of absence of conflict of interest and protection of confidentiality and in addition specifically notify the Lead Procurer if there is any conflict of interest with any of the tenderers.

For phases II and III, no differences in the composition of the Evaluation Committee or in the procedure are to be expected apart from the fact that the evaluation will have only two steps: evaluating the offers based on the on/off and weighted award criteria.

The Buyers Group headed by the Lead Procurer will evaluate the tenders and offers for the call-offs for phase II and III jointly and make a joint award decision.

For each phase and each tender received, the Lead Procurer will send an evaluation form to the Commission or its agency as part of the supplier deliverables to be submitted at the end of the tender evaluation. It will include: the final scores awarded, a qualitative appraisal per evaluation sub-criterion, minutes of the evaluation meeting, the final ranking list, decisions taken, notification of the decisions, any challenge by suppliers and replies to a challenge, if any.

4 Content and format of tenders

4.1 Format

Tenderers shall submit tenders by email not later than the deadline specified in section 2.2. Please send your email to suppliers@dynamo-pcp.eu with all the attachments in PDF, except for TD7 which should be submitted in xlsx format (Excel).

List of tender documents:

- TD1 – Call for tenders
- TD2 –Challenge Brief
- TD3a – Declaration of Honour – Exclusion Criteria
- TD3b – Declaration of Honour – On/off Award Criteria
- TD4 – Power of Attorney (not required for single organisation as tenderer)
- TD5 – Tender Application Template – Administrative section
- TD6 – Tender Application Template – Technical section
- TD7 – Tender template – Financial section
- TD8 – PCP Framework agreement
- TD9 – PCP Specific contract for phase [I][II][III]

The following documents must be submitted as part of the tender: TD3a, TD3b, TD4 (not required for a single organisation as tenderer), TD5, TD6, TD7.

Note: The size of the email with all attachments must not exceed 50 megabytes. Only emails with the attachments will be accepted, hosting and FTP services such as WeTransfer will not be accepted.

Tender content

The following table describes the content of each document that must be submitted as part of the tender.

Document	Description of content
TD3a Declaration of Honour – Exclusion Criteria	Tenderers assure that they are not subject to any of the exclusion criteria, as explained in section 3.2 (in PDF)
TD3b Declaration of Honour – On/off Award Criteria	Tenderers assure that they comply with all on/off criteria, as explained in section 3.4.1 (in PDF)
TD4 Power of Attorney	Tenderers accept joint and several liability and mandate one tenderer to sign contract, as explained in section 3.1.1 (in PDF)
TD5 Tender Application Template – Administrative	Tenderers assure that they comply with the Selection criteria, as explained in section 3.3 (in PDF)
TD6 Tender Application Template – Technical	Tenderers assure that they comply with the Award criteria, structured in technical, commercial feasibility and project management criteria, as explained in section 3.4.2 (in PDF)
TD7 Tender Application Template – Financial	Tenderers submit a detailed financial offer, as stated in section 4.4 (in xlsx format and as signed PDF)

Each PDF attachment of the technical section will should be in word-searchable format. The technical sections which are not word-searchable will not be taken into evaluation.

All offers must indicate their minimum validity period from submission (at least six months).

Tender submission

Tenderers must act with due diligence and in accordance with the diligence of a good businessperson when preparing and submitting a tender in electronic form.

A tender shall be deemed submitted on time if the Lead Procurer receives it before the time limit for receipt of tenders specified in section 2.2. Upon submission of the tender, a confirmation of the submitted tender is sent to the economic operator's e-mail address.

The economic operator may withdraw or modify its tender by the time limit for submission of tenders. If the economic operator withdraws its tender by email, the tender shall be deemed not to have been submitted. If the economic operator modifies its tender by email, the Lead Procurer shall have access to the modified tender.

All costs associated with the preparation and submission of the tender shall be borne by the economic operator itself.

Any questions on the call for tenders, tender documents or tendering process must be sent in accordance with the procedure outlined in section 5.3.

Tenderers that do not comply with the formal and delivery requirements described in this section will be rejected.

Call-offs

More detailed information about the final layout requirements for the phase II and III offers will be provided before each call-off. Templates and guidelines will be made available to clarify expectations, and these resources will be distributed well in advance to give all participants sufficient time to familiarise themselves with our requirements.

4.2 Administrative section

The Administrative Section shall contain information and evidence on the legal capacity, non-disqualification from exclusion criteria, economic and financial standing of the bidder, technical and professional solvency, and fulfilment of the on/off award criteria, to be provided by means of the documents and forms described below:

- The legal capacity and the representation of the bidders shall be proved by a signed Legal Entity Form with its supporting evidence. All tenderers (including all members of the group in case of joint tender) must provide this form. The form is available on: https://ec.europa.eu/info/funding-tenders/procedures-guidelines-tenders/information-contractors-and-beneficiaries/forms-contracts_en
- The tenderer (or the leader in case of joint tenders) must provide a Financial Identification Form with its supporting documents. Only one form per tender should be submitted. No form is needed for subcontractors and other members of the group in case of joint tender. The form is available on: https://ec.europa.eu/info/funding-tenders/procedures-guidelines-tenders/information-contractors-and-beneficiaries/forms-contracts_en
- In the case of a joint tender, the documentation referred to in section 3.1.1 of this Call for tender shall be provided.
- In the case of subcontracting, the documentation referred to in section 3.1.2 of this Call for tender shall be provided.
- The non-subjection of the bidder to any of the exclusion grounds contained in section 3.2 of this Call for tender shall be proved by means of the types of evidence referred to in that section.
- The fulfilment of the bidder of the selection criteria contained in section 3.3 of this Call for tender shall be proved by means of the types of evidence referred to in that section.
- The fulfilment of the bidder of the on/off award criteria contained in section 3.4.1 of this Call for tender shall be proved by means of the types of evidence referred to in that section.

- The documentation to be included in the administrative section may be submitted in English, or in a language other than the previous ones, provided that, in the latter case, the original documents are accompanied by their translation into English and a duly signed and stamped copy is annexed to the bid.
- Should there be any doubt as to any of these requirements, bidders may be requested to provide additional information and/or evidence.

Call-offs

More detailed information for the phase II and III offers will be provided in the call-offs (in particular on the technical implementation plan, updated business plan and list of IPRs).

4.3 Technical section

Tenderers are requested to use the tender template TD6 and follow the instructions therein.

The technical section is limited to 80 pages.

Tenders must include a technical offer, containing:

- a technical plan that outlines
    - the tenderer's idea for addressing all the requirements given in the PCP challenge description, relating both to functionality and non-functional, data, organisational and legal requirements; and
    - technical details of how this would be implemented
    - including an explanation of the methodology, a work plan and details of supplier deliverables and milestones for phase I and
    - must specify the plans for and objectives of the subsequent phases II and III and beyond
- a draft business plan that explains the proposed approach to commercially exploit the results of the PCP and to bring a viable product or service onto the market
- a list of the pre-existing rights (background) relevant to the tenderer's proposed solution, in order to allow IPR dependencies to be assessed
- a risk assessment and risk mitigation strategy
- a reply to the question "Does this tender involve ethical issues? (YES/NO)" and if YES, an ethics self-assessment, with explanations how the ethical issues will be addressed (see section 3.4.1)
- a reply to the question "Does this tender involve activities or results that may raise security issues and/or EU-classified information as background or results? (YES/NO)" and if YES information on how these issues will be addressed (see section 3.4.1).

Tenders failing to meet these requirements will be excluded.

The technical part must provide a detailed technical offer for phase II (including an explanation of the methodology, a work plan and details of deliverables and milestones) and must specify the plans for and objectives of the subsequent phases II and III and beyond (including a plan for commercial exploitation of the results).

Tenderers are requested to use the tender template TD6 and follow the instructions therein.

The information provided in the technical section of the tender will be used to evaluate the tenders, based on the weighted award criteria and the on/off criteria A, D and E.

More detailed information for the phase II and III offers (in particular on the technical implementation plan, updated business plan and list of IPRs) will be provided in the call-offs.

The **technical section is limited to 80 pages**.

4.4 Financial section

The tender must include a detailed **financial offer** (TD7) specifying:

- binding **unit prices** for all items needed for carrying out phase I and for items that are expected to be needed for phases II and III (given in euros, excluding VAT but including any other taxes and duties)
- a **fixed total price** for phase I and an estimated total price for phases II and III, broken down to show unit prices and the number of each unit needed to carry out phase I (given in euros, excluding VAT but including any other taxes and duties).
- For that please use the breakdown of the financial bid template TD7
- As the payments to contractors are centralised through the Lead Procurer.

In addition, the financial section must include:

- a **price breakdown** that shows the price for **R&D services** and the price for **supplies of products** (to demonstrate compliance with the definition of R&D in on/off criterion A)
- a **price breakdown** that shows the **location or country** in which the different categories of activities are to be carried out *(e.g., x hours of senior researchers in country L at y euro/hour; a hours of junior developers in country M at b euro/hour)* (to demonstrate compliance with the requirement relating to place of performance in on/off criterion C)
- the **financial compensation** valuing the allocation of ownership of the **IPRs generated during the PCP** to the tenderer, by giving an absolute value for the price reduction between the price offered in the tender compared to the exclusive development price (i.e. the price that would have been quoted were IPR ownership to be transferred to the procurers) in order to ensure compliance with the EU R&D&I state aid framework.

Note: The unit prices quoted for each category of items (e.g., hourly rates for junior and senior researchers, developers, and testers) remain binding for all phases (i.e., for the duration of the framework agreement).

The financial compensation for IPRs must reflect the market value of the benefits received (i.e., the opportunity that the IPRs offer for commercial exploitation) and the risks assumed by the contractor *(e.g. the cost of maintaining IPRs and bringing the products onto the market)*.

The information provided in the financial section of the tender will be used to evaluate the tenders based on the price award criteria and the on/off award criteria A and C.

Tenders failing to meet these requirements will be excluded.

Call-offs

More detailed information for phase II and III offers will be provided in the call-off. The price for phase II and III offers must be based on the binding unit prices in the tender and the price conditions set out in the Framework Agreement. Where new units/unit prices *(e.g., for new tasks or equipment)* are subsequently added to the phase II or III offers, they will become binding for the remaining phases.

Similar price breakdowns will be requested for the call-offs for phases II and III. The total offer price for phase III will be binding for delivery.

5 Miscellaneous

5.1 Language

All communication (relating to either the tender procedure or the implementation of the contract) must be carried out in English according to the DYNAMO Grant Agreement.

Tenders as well as offers for phase II and III call-offs must be submitted in English.

Supplier deliverables must be submitted in English.

For prototype testing in phase II and pilot testing in phase III the ability to speak the local languages (Italian, Spanish, Polish, and Portuguese) will be an advantage. This relates to tasks such as demonstration of prototypes in front of local end users, continuous communication with key procurer personnel and support staff on the ground, maintaining a helpdesk throughout the pilot phase, etc.

With the submission of their proposals, tenderers accept these requirements.

5.2 Tender constitutes binding offer

A signed tender will be considered to constitute a firm, irrevocable, unchangeable, and binding offer from the tenderer.

The signature of an authorised representative will be considered as the signature of the tender (and will be binding on the tenderer or, for joint tenders, the group of tenderers).

5.3 Unauthorised communication | Questions

The FAQ from the Open Market Consultation can be found on https://dynamo-pcp.eu/faq/. It contains all questions and their answers submitted via the OMC events or via a central supplier email (suppliers@dynamo-pcp.eu).

The Buyers Group might also receive questions from potential bidders during the tender period. The answers to these questions will be published on the project website. It is the responsibility of all prospective Bidders to check the project website for additional information posted during the tender period.

For the call-offs for phases II and III, the answers will not be published, but distributed to all contractors that successfully completed the previous phase.

Note: All other contacts (or attempted contacts) will be considered unauthorised and may lead to the exclusion of your tender.

5.4 Confidentiality

Tenderers must keep confidential any information obtained in the context of the tender procedure *(including EU-classified information*[12]*)*.

[12] Commission Decision 2015/444/EC, Euratom of 13 March 2015 on the security rules for protecting EU-classified information.

5.5 Contract implementation

Successful tenderers will be requested to sign both a Framework Agreement and specific contracts for phases I, II and III *(see the models given in TD8 and TD9)*.

5.5.1 Monitoring

During each phase, contract implementation will be monitored periodically and reviewed against the expected outcomes (milestones, supplier deliverables and output or results) for the phase.

Each contractor will be assigned a main contact person (their supervisor) from the monitoring team appointed by the procurers.

There will be monthly monitoring online meetings between each contractor and the supervisor/monitoring team. The Buyers Group can request a higher frequency of monitoring meetings, where necessary.

The contractor will be asked to discuss the results achieved in the preceding period and present an updated work plan. The monitoring team and supervisor are allowed to visit the contractor's premises to monitor progress. The contractor can also visit the procurer's premises, at its own expense.

The contractors are asked to obtain all information necessary for their performance. The procurers will do their best to provide the contractors with information required. The contractor must cover its own costs and thus foresee personnel and travel budgets in its offer.

The monitoring team and/or supervisor will provide written feedback to contractors after meetings or visits. Detailed information on the role of the supervisor will be provided after award of a specific contract. The role is intended to allow contractors to improve the way in which their solutions address the problem set out in the PCP description.

Monitoring in phase II includes testing of prototypes v1 and v2 with end-users of the procurers. The testing is done as demonstration meetings and feedback is given to the suppliers by the procurers. The demonstration meetings are not subject to evaluation and should be seen as milestones in the PCP process.

5.5.2 Payments based on satisfactory completion of milestones and deliverables of the phase

Payments corresponding to each PCP phase will be subject to the *satisfactory* completion of the deliverables and milestones for that phase.

Satisfactory completion will be assessed by the Evaluation Committee composed of representatives of the Buyers Group.

Satisfactory completion will be assessed according to the following requirements:

- if the work corresponding to that milestone / deliverable has been carried out
- if a reasonable minimum quality has been delivered
- if the reports have been submitted on time
- if the monies have been allocated to the planned objectives
- if the monies have been allocated and the work has been carried out according to the on/off criteria (place of performance, public funding and R&D definition criteria), and
- if the work has been carried out in compliance with the provisions of the contract (including in particular verification if the contractor has duly protected and managed IPRs generated in the respective phase)

- if the feedback provided by the monitoring team has been addressed properly by the contractor making required changes or improvements or giving a sufficient justification for not having made them.

'Reasonable minimum quality' of a report means that:

- the report can be read by somebody who is familiar with the topic, but not an expert
- the report gives insight in the tasks performed in and the results
- the report uses any reasonable template or form provided to the tenderer.

'Reasonable minimum quality' of a demonstration (for phase II or III) means:

- the demonstration can be understood by somebody who is familiar with the topic, but not an expert (for instance, somebody with operational but not technical knowledge)
- the demonstration shows how the innovation works, how it can be used and (if applicable) how it is operated and maintained
- the demonstration is accessible to parties appointed by the procurers unless these are direct competitors of the contractor.

Satisfactory completion in each of the phases does not mean successful completion. (A PCP could, for instance, be satisfactorily completed even if it concludes that the innovation is not feasible.)

The assessment will consider the efforts made by contractors to take into account the feedback from the supervisor or the monitoring team. The Buyers Group aims to approve as 'satisfactory' or reject submitted deliverables within 15 calendar days.

Where the Evaluation Committee judges the completion of deliverables or milestones to be unsatisfactory, the Buyers Group may decide to reduce or withdraw payments for that deliverable and/or may terminate the contract according to Article 17 of the Framework Agreement.

Invoices must be submitted to the Lead Procurer after the Lead Procurer declares satisfactory completion of the deliverables and milestones related to a payment.

Contractors must notify the Lead Procurer in good time of the bank account to which payments are to be made in a document bearing the signature of the authorised signatory of the contractor following procedures reasonably required by the Lead Procurer.

Contractors' invoices must provide a **price breakdown** showing the number of units and resulting price for each of the unit prices defined in the offer in a format agreed with the Lead Procurer (in order to verify compliance with the definition of R&D, on/off award criteria A and C).

5.5.3 Payment schedule

- Payment for phase I: 100 % of the total price offered by the contractor will be accepted for invoicing from the date the Lead Procurer declares satisfactory completion of phase I
- Payment for phase II: 50 % of the total price offered by the contractor will be accepted for invoicing from the date the Lead Procurer declares the satisfactory completion of the phase II D2.1 Presentation of prototypes of key system components. 50 % of the total price offered by the contractor will be accepted for invoicing from the date on which the Lead Procurer declares the satisfactory completion of phase II
- Payment for phase III: 50 % of the total price offered by the contractor will be accepted for invoicing from the date on which the Lead Procurer declares the satisfactory completion of D3.2 Presentation of pilot system and onsite testing results. 50 % of the total price offered by the contractor will be accepted for invoicing from the date on which the Lead Procurer declares the satisfactory completion of phase III.

Payments will be made to the bank account provided by the contractor within 30 days from the date of receipt, by the Lead Procurer, of a correct and approved invoice. The final payment

of phase III will be settled only after the Dynamo project consortium receives a full grant from the European Commission at or after the end of the project.

Any costs, fees or charges resulting from the bank transfer (e.g. bank account outside of SWIFT) are to be paid in full by the recipient.

5.5.4 Eligibility for the next phase based on successful completion of the phase

Eligibility for participation in the next phase will be subject to *successful* completion of the current phase.

Successful completion of a phase will be assessed by the assessment committee against the following requirements:

- if all milestones have been successfully completed
- if the R&D results meet the minimum functionality/performance requirements of the challenge description (i.e. the minimum quality/efficiency improvements which the procurers set forth for the innovative solutions to achieve)
- if the results of the R&D are considered to be promising.

'Promising' means:

- for phase I, that the feasibility is convincing
- for phase II, that the feasibility, the applicability in an operational setting and the potential impact of the product is convincing.

Note: Note the difference between satisfactory completion (requirement for payment) and successful completion (prerequisite for passing from one phase to the next).

5.5.5 Finalisation of phase III: Possible follow-up PPI procurements

A new call for tenders may be launched for a follow-up public procurement of innovative solutions (PPI) to deploy a commercial volume of innovative solutions.

5.6 Cancellation of the tender procedure

The procurers may, at any moment, cease to proceed with the tender procedure and cancel it with or without reason.

The procurers reserve the right not to award any contracts at the end of the initial tender procedure or at the end of call-offs including to reverse award decisions should the tenderer unduly delay the signature or attempt to negotiate the content of the Specific Contract or other significant reasons.

The procurers are not liable for any expense or loss the tenderers may have incurred in preparing their offer or during the period before signature of the Specific Contract.

5.7 Procedures for appeal

The Lead Procurer has incorporated a voluntary standstill period as described in Section 2.6. The standstill period for each phase begins from the award decision and notification and lasts until date of signature by the Lead Procurer.

Any clarification, questions or appeals must be submitted in writing to suppliers@dynamo-pcp.eu before the end of the standstill period.

Any legal claim, petition, or application for judicial review with regard to the Dynamo PCP procedure shall be heard by the competent court, administrative or civil, (please see Article 20 of the Framework Agreement). By submitting a tender, the tenderer accepts the exclusive jurisdiction of Italian courts.

Decisions made during the procurement may be reviewed in administrative procedure at the Administrative Court in Treviso in accordance with Italian law.

Decisions taken regarding the selection of tenders may be challenged only by means of an administrative remedy before the court.

For the resolution of disputes arising from the performance of a framework agreement, tenderers are referred to the framework agreement.