

REQUEST FOR TENDER

MULTI-PARTY FRAMEWORK AGREEMENT

Title:	ATU Quality and Regulation Consultancy in Medical Technologies- Multi Operator Framework Agreement
Contracting Authority:	Atlantic Technological University
Procedure:	Open
eTenders ref:	CFT 8365482
Closing Date for Queries:	3 rd July 2026 14:00 Hours Local Time
Closing Date for Tender Submission:	14 th July 2026 12.00 Noon Local Time
Submissions and Queries via:	eTenders only

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1 Disclaimer

This document issued herewith ("the Document") is for information only and does not constitute, and shall not be interpreted as, an offer for sale, prospectus, or the basis of a contract.

Tenderers are recommended to read the documents thoroughly. While all reasonable steps have been taken to ensure that the information set out in the Document is accurate and up to date, no representation or warranty, express or implied, is or will be made or given in relation to the accuracy or the completeness of any information contained in the Document or otherwise provided by or on behalf of the Contracting Authority (in writing or otherwise) to any interested party or its advisers. No responsibility or liability for any loss or damage arising as a result of reliance on these documents, or for the information contained in these documents or for any omission is or will be accepted by the Contracting Authority or by any of its officers, employees, agents or professional advisers. No officer, employee, agent, or professional adviser of the company has any authority to give or make any representation or warranty, express or implied, in relation to such information. The Contracting Authority's officers, employees, agents, and professional advisers expressly disclaim any and all liability arising out of such documentation or information and any errors or omissions in or from the documents and information.

The Contracting Authority reserves the right to discontinue the procurement process at any time.

2 Note

Please note that information relating to this Request for Tender, including clarifications and changes, will be published on the Irish Government Procurement Opportunities Portal www.etenders.gov.ie. Registration is free of charge and there is no charge for documents. Please note that the Contracting Authority accepts no responsibility for information relayed (or not relayed) via third parties.

The Contracting Authority has provided a Tender Response Document as a separate document for tenderers to use in preparing their response to this tender. This document and format must be used.

3 About the Contracting Authority

3.1 The Contracting Authority

Atlantic Technological University (hereinafter referred to as the “Contracting Authority”) is the authority responsible for this procurement.

Further information is available at our corporate website www.atu.ie

3.2 Small and Medium Enterprise participation

It is the policy of the Contracting Authority to promote participation by Small and Medium Enterprises (SMEs) on a fair and equal basis.

SMEs are encouraged to explore the possibilities of forming relationships with other SMEs or with larger enterprises to meet the financial, economic or technical capacity requirements of the competition, if required.

Tenderers may include individuals, partnerships, limited companies, groupings or any combination of the foregoing with or without legal personality. However, a grouping if successful will be required to establish legal personality to enter the framework agreement / contract.

Tenderers are reminded that they may rely on the resources of other entities to establish the requirements on condition that they can prove to the satisfaction of the Contracting Authority that they will have these resources at their disposal when necessary.

If the tender is from a consortium / joint venture, tenderers must ensure that all the relevant information is provided and where necessary, provide the information requested separately for each party. Relevant information relates to where a tenderer is relying on the resources to qualify (e.g. turnover, manpower, previous experience) and or to deliver contracts. The consortium must appoint a single point of contact who will assume overall responsibility for delivery, and who is authorised to sign the framework agreement / contract on behalf of all consortia members. The Contracting Authority will not act as an arbitrator between members of consortia.

4 Scope of the Framework Agreement

4.1 Type of Framework

The Contracting Authority proposes to engage in a competitive process for the establishment of a Multi-Operator Framework Agreement for the provision of Quality and Regulatory Consultancy Services focused on medical device prototypes. These services will support device development across clinical, regulatory, and commercial planning pathways in accordance with applicable EU and international regulatory requirements.

A framework agreement constitutes a means of establishing overall terms and conditions in accordance with which, for a specified duration, individual contracts may or may not be awarded.

This competition relates to the establishment of a multi-party framework with five Economic Operators, subject to that number meeting the minimum qualification criterion. Thereafter contracts will be awarded in accordance with the rules contained herein.

4.2 Scope of Requirements under the Framework

4.2.1 The Scope of the Framework

The framework agreement will be established on foot of this tender competition, based on a defined basket of services. Framework consultants will be expected to provide expert advice, analysis, and documentation to ensure alignment with EU Medical Device Regulation (Regulation (EU) 2017/745) and related quality system standards such as ISO 13485, ISO 14971, and ISO 14155, as well as other guidance relevant to clinical evaluation and performance assessment.

Services procured under the framework may include, but are not limited to:

- Regulatory strategy and pathway development (CE marking, risk classification, conformity assessment routes)
- Quality management system (QMS) development, implementation, and audit readiness
- Technical documentation preparation and review (Design Dossiers, Technical Files, CERs)
- Clinical evaluation strategy and evidence gap analysis
- Risk management planning and documentation
- Requirements for post-market surveillance (PMS) and vigilance reporting
- Support for interactions with Notified Bodies and Competent Authorities
- Compliance advice on applicable international standards and guidance documents

These services will assist the Contracting Authority's research community and project teams in progressing novel medical device technologies toward regulatory approval, commercialisation, and collaborative research outcomes.

Consultants appointed under the framework will deliver expert guidance and evidence-based insights to ensure regulatory compliance, quality assurance, and clinical readiness across all stages of medical device design, testing, and commercialisation. These services will assist in technology advancement, licensing, and collaborative research projects involving medical devices.

4.2.2 Additional / Call-Off Contracts under the Framework

Additional requirements within the category of Quality and Regulatory Consultancy Services for Medical Device Technology may arise over the duration of the framework, not known at this point in time.

While the Contracting Authority does not guarantee the volume or number of call-off contracts, any additional requirements will be communicated to framework members and awarded in accordance with the operational rules set out in this Request for Tender.

4.3 Anticipated Timeline

The following indicative timeline is envisaged for this procurement:

Issue RFT	As specified on title page
Closing Date for Queries	As specified on title page
Closing Date for Tender Submission	As specified on title page
Clarification/verification meetings (if anticipated)	TBC
Award decision	July/August 2026
Framework Agreement Commencement	August 2026

The dates provided above are estimates at the time of publication of the Request for Tender. The Contracting Authority will endeavour to run the process to this timetable, but this cannot be guaranteed.

4.4 Numbers admitted to the Framework

The framework agreement will be established as a multi-party framework agreement with [five] [5] members, subject to that number meeting the minimum criteria and rules.

4.5 Duration of the Framework Agreement

The framework agreement will be for a maximum period of Five [5] years, subject to annual review and performance

The Contracting Authority confirms that the period of any contracts awarded under the framework agreement may extend beyond the date of expiry of the agreement.

The proposed five-year term is justified by the ongoing and iterative nature of quality and regulatory consultancy support required for medical technologies, where sustained access to specialist expertise is necessary to maintain compliance, manage change, and support repeated procurement and development needs throughout the framework period..

4.6 Estimated Value for the Framework Agreement

It is envisaged that maximum spend under this framework agreement will not exceed €500,000.00 excluding VAT.

It is emphasised, however, that this figure is provided strictly for indicative purposes only as there is no guaranteed expenditure under the framework agreement.

The likely value of contracts to be awarded under the framework will be in the region of €10,000 to €25,000

4.7 Awarding Contracts under the Framework Agreement

Multi-party framework agreement contracts may be awarded as follows:

4.7.1 Mini-Tenders

Through invitation to a mini-tender of all the firms admitted to the framework agreement. On each occasion, a Supplementary Request for Tender will be issued detailing the scope of requirements, the award criteria, a closing date and time and methodology for submission of responses.

4.7.2 Direct Award

The Contracting Authority reserves the right to award a call off contract by direct award to a framework member, in limited and clearly defined circumstances for continuity and consistency.

4.8 Right to tender outside of the Framework

The Contracting Authority intends to use the framework for the procurement of requirements falling within its scope during the specified period; however, it reserves the right to go outside the framework for the procurement of any requirement without reference to the Framework Member(s). Admission to a framework does not guarantee the award of any contract to any Economic Operator, nor does it give the member(s) the right to be consulted in respect of, or tender for, any contract.

4.9 Compliance with the Terms and Conditions of the Framework Agreement

Admission to the framework agreement will be conditional upon acceptance of the Contracting Authority's Framework Terms and Conditions as appended at the relevant Appendix.

Tenderers are required to review these terms and conditions and indicate their acceptance thereof as part of their tender submission. Any reservation with regard to these terms should be submitted as a query in accordance with the procedure described in the Instructions to Tenderers (*Section 6*) of this document.

4.10 Award to Runner Up

If for any reason, it is not possible to admit to the framework agreement one or more of the tenderers invited following the conclusion of this competitive process, the Contracting Authority reserves the right to invite the next highest scoring tenderer(s) to join the framework agreement as appropriate, at any time during the tender validity period.

If it is not possible following the conclusion of the competitive process to award the initial contract to the designated successful tenderer; the Contracting Authority reserves the right to award the initial

contract to the Framework Member with the next highest score based on the original competition, at any time during the tender validity period.

If, following the award of any contract under this framework agreement, the Framework Member cannot, for whatever reason, deliver the required services to the satisfaction of the Contracting Authority; the Contracting Authority reserves the right to award the contract to the next highest-ranked tenderer emerging from the process at any time during the contract tender validity period.

5 Specification of Requirements

5.1 Scope of Requirements under the Framework Agreement

The framework agreement will be established on foot of this tender competition, based on a defined basket of services providing specialist quality and regulatory consultancy support for the development and commercialisation of medical device prototypes.

This framework will provide the Contracting Authority's research community with a structured mechanism to access expert advice and deliverables relating to regulatory strategy, quality management systems, clinical evaluation, risk management, and technical documentation. Consultants appointed under the framework will generate submission-ready and audit-ready deliverables that inform key decisions concerning regulatory pathways (EU/US/global), conformity assessment, quality compliance, and readiness for CE marking.

The scope of services includes, but is not limited to, the provision of quality assurance and regulatory consultancy for medical device prototypes, including:

5.1.1 Regulatory Strategy and Pathway Planning

- **Determine appropriate device classification and conformity assessment route under Regulation (EU) 2017/745 (MDR)**
 - Prepare and maintain regulatory strategy plans, including timelines to conformity and key regulatory milestones.
 - Advise on interactions with Notified Bodies, Competent Authorities, and Ethics Committees
 - Assess international regulatory alignment (FDA 510(k), PMA, UKCA, Health Canada, etc.) where relevant
- **Quality Management and Compliance Systems**
 - Develop, implement, or refine Quality Management Systems (QMS) aligned with ISO 13485:2016
 - Establish Design and Development controls, Document control, and Change management systems
 - Provide internal audit and readiness assessments for ISO 13485 certification
 - Develop Standard Operating Procedures (SOPs) and templates for design, production, and post-market phases
- **Risk Management and Clinical Evaluation**
 - Conduct risk management planning in accordance with ISO 14971:2019, including risk identification, evaluation, and mitigation
 - Prepare and maintain Clinical Evaluation Plans (CEP) and Reports (CER) compliant with MEDDEV 2.7/1 revision 4 and MDR Annex XIV
 - Perform Clinical Evidence Gap Analyses and Literature Reviews supporting performance claim

- Advise on requirements for clinical investigations and post-market clinical follow-up (PMCF)
- **Technical Documentation and Regulatory Submissions**
 - Compile and review Technical Documentation (Annex II and III of MDR) for accuracy and compliance
 - Develop and verify essential requirements checklists and General Safety and Performance Requirements (GSPR) matrices
 - Prepare device labelling, IFU, and UDI documentation in compliance with MDR Annex I
 - Generate regulatory deliverables suitable for submission to Notified Bodies and Competent Authorities
- **Post-Market Surveillance and Vigilance**
 - Design and implement PMS and Vigilance procedures, including PMCF plans and reports
 - Review and analyse PMS data, trend reports, and CAPA outputs
 - Ensure continuous compliance with incident reporting requirements
- **Specialist Advisory Support**
 - Advise on interactions with Notified Bodies and HPRA
 - Interpret new or amended regulatory guidance impacting ongoing or planned submissions
 - Support internal training and capacity development on quality and regulatory compliance topics

5.2 Consultancy Services Minimum Requirements

Call-off contracts under this framework will specify the precise deliverables and milestones for individual projects. However, all regulatory and quality consultancy assignments MUST meet the following minimum requirements.

5.2.1 Methodology and Execution

Primary Regulatory Review:

- Initial regulatory classification and conformity assessment justification referencing MDR Annex VIII
- Verification of applicable harmonised standards and guidance documents

Documentation Review:

- Comprehensive desktop audit of source documentation (design files, risk documentation, usability reports, clinical data)
- Gap analysis against ISO 13485, ISO 14971, and MDR Annex II/III deliverables

Audit Preparation:

- Mock audit or readiness assessment against certification or Notified Body expectations
- Generation of non-conformance reports (NCRs) and corrective action plans (CAPAs)

Sampling and Evidence:

- Sampling of documentation across product families or prototypes to ensure representativeness
- Traceability matrix verification from design input to verification and validation

5.2.2 Core Deliverable Requirements

Each consultancy engagement shall produce a comprehensive, audit-ready report and associated documentation pack, formatted as required by the Contracting Authority.

Below is indication format:

Executive Summary (2–3 pages):

- Summary of device classification rationale and applicable conformity path
- Definitive Go/No-Go recommendation for continued regulatory advancement
- Outline of principal risks and mitigation measures
- Summary of QMS maturity and compliance readiness

Main Report (25–40 pages):

- Detailed overview of regulatory strategy, classification, and applicable standards
- Comprehensive QMS and documentation review findings
- Risk management summary incorporating probability/impact assessment
- Clinical evaluation and evidence gap analysis
- Post-market requirements outline (PMS, PMCF, vigilance strategy)
- Readiness assessment for Notified Body engagement or CE marking application

Appendices:

- Copy of reviewed or generated documents (e.g., Risk Plans, GSPR matrix, QMS flowcharts)
- Corrective and Preventive Action (CAPA) register
- Regulatory gap analysis table
- Standards and guidance references cross-mapped to MDR Annexes
- Ethical compliance documentation (if clinical evaluation included)

5.3 Compliance with EU Law and Irish Law

All services delivered under this Framework Agreement MUST comply with:

- Regulation (EU) 2017/745 – Medical Device Regulation Clinical Evaluation Standards
- Regulation (EU) 2016/679 (GDPR) – Data Protection
- MedTech Europe Code of Ethical Business Practice 2022 – Healthcare Professional Engagement Rules
- Health Products Regulatory Authority (HPRA) Clinical Investigation Standards

5.4 Contractual Compliance Documentation

Framework members **MUST** maintain and provide evidence of compliance where required by the Contracting Authority:

- GDPR Data Processing Agreements
- Participants Consent Register (Anonymised).
- Fair Market Value Documentation for HCP engagement
- Conflict of Interest Declarations

5.5 Confidentiality and Non-Disclosure Requirements

Framework members shall execute a Non-Disclosure Agreement (NDA) with the Contracting Authority prior to commencement of any call-off contract under this Framework Agreement.

Indicative Scope:

1. In respect of Information provided in documentary form or by way of a model or in other tangible form, Information which at the time of provision is marked or otherwise designated to show expressly or by necessary implication that it is imparted in confidence; and
2. in respect of Information that is imparted orally, any information that the Disclosing Party or its representatives informed the Receiving Party at the time of disclosure was imparted in confidence; and
3. in respect of Confidential Information imparted orally, any note or record of the disclosure; and
4. any copy of any of the foregoing; and
5. the fact that discussions are taking place between the Disclosing Party and the Receiving Party.

NDA Execution Process:

1. **Framework Award:** Pre-signed master NDA provided to successful Economic Operators
2. **Call-off Contract:** Project-specific confidentiality annex executed
3. **Team Access:** All personnel (employees, subcontractors) must be NDA-bound
4. **Term:** Minimum 5 years post-project completion or patent filing (whichever later)

Compliance Verification:

- Signed NDAs required before access to proprietary technology data
- Sub-contractor NDAs subject to Contracting Authority approval
- Breach of NDA constitutes immediate termination grounds

All research deliverables containing third-party confidential information must maintain appropriate confidentiality markings and handling protocols.

Non-compliance with NDA requirements results in immediate exclusion from framework participation and potential legal action.

5.5.1 Quality Control

The University requires a robust quality assurance process ensuring all work adheres to brand, accessibility, and ethical standards.

Service provision will be periodically reviewed against agreed performance metrics.

5.5.2 Service Level Agreement

It will be a condition for the conclusion of the framework agreement that the successful framework operator sign up to a specific Service Level Agreement that will govern the delivery of the required services. The precise content of such a Service Level Agreement will be agreed with the successful framework member.

5.5.3 Copyright and Intellectual Property

In accordance with Irish and EU law, all intellectual property and copyright arising from work produced under this Framework shall vest in the Contracting Authority.

The successful tenderer shall:

- Transfer all copyright and intellectual property rights in commissioned design works upon project completion.
- Deliver all original artwork source files to the Contracting Authority.
- Warrant that materials do not infringe third-party rights and comply with applicable copyright statutes and EU directives.

5.6 Quality and expertise of Resources

Tenderer must submit CVs (not to exceed two (2) A4 pages and using the format in the TRD) for each resource proposed, clearly setting out their individual roles and responsibilities. Please complete the CV tables in the Tender Response Document.

The Contracting Authority will be assessing the experience of the resource(s) in terms of coverage of the service requirements. Tenderers who can demonstrate greater relevant experience to services sought are likely to score higher.

Tenderers should note that, as set out in the contract documents, the proposed resource(s) will be required to deliver the services, although the Contracting Authority reserves the right to seek additional personnel in any call-off, having regard to the nature of the particular call-off.

Tenderers should note that Framework Members may, at call off stage, be permitted to supplement their resources with a Consultant/Specialist(s) where, in their opinion, there is a requirement to do so given the nature of the requirements under the call-off. The Consultant / Specialist(s) will be assessed as part of the call off competition. Rates for any agreed supplementary resources must be in line with the rates submitted for the resource types in the Form of Tender where applicable.

5.7 Contract Management

The Contracting Authority requires tenderers to nominate a dedicated contract manager who will act as the main point of contact for the duration of the framework. This person shall have the authority to deal with all matters in relation to contracts and be responsible for the satisfactory delivery of the supplies/services required. The duties of the contract manager will include the following:

- Overall responsibility for a good working relationship with the Contracting Authority
- Provide regular reports on performance as agreed with the Contracting Authority
- Meet as and when required to review and examine performance
- Deal with disputes, complaints or concerns that cannot be adequately resolved
- Proactively discuss with the Contracting Authority ways of improving efficiency regarding service delivery in general and providing suggestions for improvement and cost savings

6 Selection Criteria

The Contracting Authority is using the **Open** procedure for the award of this framework agreement, therefore, while all interested parties may submit a tender, only those demonstrating that they have the required level of financial and technical capacity will have their tender considered. In order to demonstrate a tenderer's qualifications, tenderers are required to provide the information set out below in the Tender Response Document (TRD) which is based on a self-declaration model. However, tenderers are required to provide the minimum information required.

6.1 Use of the European Single Procurement Document

In accordance with Directive 2014/24/EU, tenderers may have compiled accepted as evidence of compliance with *Section 4.3* on condition that all information a European Single Procurement Document (ESPD), either electronically via the eESPD on eTenders or as a separate uploaded attachment with the tender response, which will be self-declared will be provided promptly on request at any time prior to an award decision.

6.2 Relying on the standing of other Entities

SMEs are encouraged to explore the possibilities of forming relationships with other SMEs or with larger enterprises to meet the financial, economic or technical capacity requirements of the competition, if required.

Tenderers are reminded that they may rely on the resources of other entities to establish the requirements on condition that they can prove to the satisfaction of the Contracting Authority that they will have these resources at their disposal when necessary.

If the tender is from a consortium/joint venture, tenderers must ensure that all the relevant information is provided and where necessary, provide the information requested separately for each party. The consortium must appoint a single point of contact who will assume overall responsibility for delivery, and who is authorised to sign the framework agreement / contract on behalf of all consortia members. The Contracting Authority will not act as an arbitrator between members of consortia.

6.3 General Declarations and Financial Capacity Requirements

Tenderers are required to provide information on the following in the Tender Response Document. The criteria and rules outlined below are assessed on a pass/fail basis. Failure to comply with the requirements will result in the tender being considered inadmissible.

General Information

Provide contact and general information on the tendering organisation - company name, address and contact details for individual responsible for this tender and company overview as well as information on sub-contractors and consortium members if applicable.

Declaration

Complete the Declaration of Bona Fides as per Art. 57 of Directive 2014/24/EU as implemented by Regulation SI 284 of May 2016 and as contained in the Tender Response Document.

Complete the Declaration regarding compliance with relevant statutory obligations as contained in the Tender Response Document. Where tenderers are established and operating outside of the jurisdiction of supply, compliance with equivalent legislation as applicable in the country of establishment / operation is required.

Financial and Economic Standing

Tax Compliance	Confirmation that the tenderer / all parties associated with the tenderer are fully tax compliant. Please refer to the tax rules contained in the Tender Response Document.	
Financial Capacity	(a) Confirmation that the tendering party turnover exceeded €50,000.00 in each of the last three financial years, or on or pro-rata if more recently established firms are tendering – however the firm must have been in existence for at least 6 months. (b) Confirmation of financial standing ensuring the tendering party has the financial capacity to pay its debts identified on the current statement of assets and liabilities as being the debts as they fall due. Evidence of both statements will be required prior to the award of any contract.	
Insurance	Confirmation of the following insurances being in place:	
Insurance Type		Required Level
Employer’s Liability		€13 million
Public Liability		€6.5 million
Product Liability		€6.5 million
Professional Indemnity		€1.5 million

Tenderers are required to provide information on the following in the Tender Response Document. The criteria and rules outlined below are assessed on a pass/fail basis. Failure to comply with the requirements will result in the tender being considered inadmissible.

6.4 Technical Capacity Requirements

Personnel and Skills	
Tenderers must provide information which demonstrates access to the minimum number of skilled personnel as indicated below and outlined in the TRD.	
Skillset Required	Minimum Number
Lead MedTech Researcher 5+ years Quality and Regulatory expertise in Medical Technologies	1
Analyst	1
QMS Specialist	1
Clinical Evaluation Expert	1
Previous Experience	
Tenderers must provide information clearly demonstrating successful delivery of three (3) previous comparable experience/projects, involving the features as defined in the TRD.	
Quality Assurance Management System	
Tenderers must provide information which demonstrates a commitment to quality assurance and provide details of quality assurance policies and systems and whether externally certified. Please complete the TRD.	
Environmental Management System	
Tenderers must provide information which demonstrates operation of an appropriate environmental management system whether externally certified or in-house. Please complete the TRD.	
Data Protection	
Tenderers must demonstrate compliance with all General Data Protection Regulations and comply with ATU's GDPR Requirements. The Contracting Authority reserves the right to seek further information to verify compliance.	

7 Award Criteria

Only tenders which meet the Selection Criteria and are confirmed as valid and responsive to the specifications set out in this document will be evaluated against the award criteria. Tenderers should ensure that they have submitted sufficient relevant information to allow their tenders to be assessed under each of the award criteria set out below.

The framework will be awarded on the basis of the most economically advantageous compliant tender taking into account the following award criteria and weightings. Please refer to the Framework Terms and Conditions for details of the award criteria which would apply in the case of mini-tenders under the framework agreement.

Criterion A	Weighting	Maximum Marks	Minimum Marks
	35%	3500	n/a
Title	Cost		
Description	Please complete the form of Tender and pricing schedule in the TRD the framework will be established on a basket of rates.		
Criterion B	Weighting	Maximum Marks	Minimum Marks 50%
	30%	3000	1500
Title	Methodology and Approach for Typical Call Off Contract		
Description	Tenderers must ensure they provide sufficient details to enable the Contracting Authority (ATU) to assess their submission for the delivery of call-off contracts under the Framework Agreement as outlined in Section 5 of this document. Paying close attention to all service areas listed in the Scope of Services, Tenderers must outline how they will approach the delivery of a typical Quality and Regulation call-off contract. Tenderers should describe their proposed end-to-end delivery methodology addressing the following: • Service delivery process, from initial client briefing through gap analysis, deliverable production, to final audit-ready outputs • Resource planning and allocation across all service areas (regulatory strategy, QMS, clinical evaluation, risk management, technical documentation, post-market surveillance) • Quality control procedures ensuring compliance with specified standards and formats. • Typical timelines and milestones for a standard call-off assignment. • A maximum of 10 x A4 pages excluding graphics is permitted under this criterion. This criterion will be assessed in its totality.		

Criterion C	Weighting	Maximum Marks	Minimum Marks 50%
	25%	2500	1250
Title	Quality and Balance of the Proposed Team		
Description	Tenderers must complete the Resource Allocation Schedule for the Core Team, providing details of the resource types proposed to deliver the framework services, including key responsibilities and supporting activities. Tenderers must provide a statement confirming the overall suitability and balance of the proposed resource capability and identifying the core resource types that will deliver services under typical framework call-offs. Tenderers must list the Key Resource Types, including Subject Matter Expert(s), in the template provided. Tenderers must provide relevant experience summaries and specialist knowledge for each proposed resource type, demonstrating how their collective capability covers all framework service areas (regulatory strategy, QMS, clinical evaluation, risk management, technical documentation, post-market surveillance). Tenderers must demonstrate internal resource allocation and management processes, including how work is assigned to appropriate expertise levels and how the team maintains appropriate balance across disciplines. Please use the TRD (Tender Response Document Template provided). This criterion will be evaluated in its totality.		
Criterion D	Weighting	Maximum Marks	Minimum Marks 50%
	10%	1000	500
Title	Sustainability and Value Add Services		
Description	Tenderers must demonstrate how sustainability considerations will be integrated into the delivery of consultancy services under this Framework Agreement. Responses should describe proportionate environmental, social, and economic measures relevant to the nature of quality and regulatory consultancy for medical device prototyping over the lifetime of the framework. Tenderers must also describe any value-add services proposed at no additional cost. These should be specific to the requirements of this competition and should demonstrate how they will enhance the delivery of quality and regulatory consultancy services, support the Contracting Authority's research community, improve responsiveness to changing project needs, and provide measurable benefits beyond the core service offering. Tenderers should address the following in their response:		

	• How sustainability will be embedded in the delivery of the services. • The environmental, social, and economic benefits of the proposed approach. • Any value-add services offered at no additional cost. • How these additional services will improve efficiency, flexibility, knowledge transfer, or overall framework performance. Responses are limited to two (2) A4 pages, excluding graphics. This criterion will be evaluated in its totality. Additional appendices, external links or information beyond the page limit will not be considered. Tenderers MUST use the Tender Response Document (TRD) provided.
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Tenderers should ensure in their tenders that they provide detailed information in respect of all aspects of the framework award criteria as stated above. This will enable the awarding authority to assess fully the extent of their offers.

Tenderers MUST achieve a minimum score of 50% of the available marks for each of Criteria B, C, and D. Any tenderer failing to achieve this minimum threshold in any one of those criteria shall be deemed ineligible for further consideration.

7.1 Methodology for calculating the Cost Score

The following formula will be applied to the cost score:

The lowest cost tender that also meets all the minimum requirements of the qualitative award criteria will receive the maximum score achievable under this criterion. The scores of the other valid tenders will be calculated using the following formula:

Lowest Cost from a Bona Fide tender	A
Cost for the tender being evaluated	B
Maximum Points available for Cost	C
Formula employed	$\frac{A \times C}{B}$

7.2 Methodology for scoring Qualitative Criteria

Score	Category	Description
90 – 100%	Exceptional	An exceptional response demonstrating extensive understanding offering full assurance to client – fully supported with no reservations.
80 – 89%	Excellent	An excellent response demonstrating excellent understanding offering assurance to client – fully supported.
70 – 79%	Very good	A very good response demonstrating very good understanding offering assurance to client – strongly supported.

60 – 69%	Good	A good response demonstrating good understanding offering assurance to client – well supported.
50 – 59%	Acceptable	An acceptable response demonstrating a minimum understanding offering assurance to client - satisfactorily supported.
Less than 50% is unacceptable and considered ineligible from further consideration		

Marks in the score ranges outlined above can be awarded where responses so merit additional marks.

7.3 Post Tender Clarification

At the discretion of the Contracting Authority, tenderers may be invited, in writing, to clarify certain aspects of their tender, particularly where information or documentation to be submitted appears to be incomplete or erroneous. However, all such requests will be made in full compliance with the principles of equal treatment and transparency and avoid any distortion of competition.

7.4 Verification

Award of contract/membership of the framework may be subject to attendance at a verification meeting. It would be essential that the key personnel assigned to this contract should be available and present at this meeting. If required, tenderers will be notified of the date, time, agenda and format for such meetings as soon as possible.

A visit to the tenderer's premises may be required to clarify any questions or queries regarding the tender offer.

7.5 Clarification of Abnormally Low Tenders

If the Contracting Authority considers the tender submission to be commercially unsustainable or otherwise problematic considering the tendered price or any other financial matter (including proposed indicative hours), the tenderer shall be invited to provide clarification to the Contracting Authority in respect of all elements of the tender submission that the Contracting Authority deems relevant. Any failure to satisfactorily comply with such a request, or to satisfactorily address the Contracting Authority's concerns, may, at the discretion of the Contracting Authority, result in the elimination of the tender in question based on it being considered abnormally low.

7.6 Right to Confirm Suitability

Tenderers should note that the Contracting Authority reserves the right to confirm that the financial and technical capacity of the tenderer is valid and unchanged prior to the establishment of the framework and award of any contract.

8 Instructions for Tenderers

8.1 Closing Date for Tenders

The closing date for tender submission is specified on the title page.

It is the responsibility of the tenderer to ensure that their tender is complete and is uploaded / submitted by the designated deadline. Tenders that are received late or via other means will not be considered in this public procurement competition.

It is important to note that only persons who have downloaded and accepted a document can upload a submission.

8.2 Submission of Applications

The Contracting Authority is using the postbox facility on eTenders, and applications must be submitted electronically via the eTenders postbox facility on www.etenders.gov.ie only. Only applications submitted to the electronic postbox will be accepted. Applications submitted by any other means (including but not limited to by email, post or hand delivery) will **not** be accepted.

Applicants must ensure that they give themselves enough time to upload and submit all required documentation before the closing date/time noting the use of the new eTenders platform. Applicants should consider the fact that upload speeds vary. In order to submit a response to the electronic postbox, please note that you must ensure you have submitted the response completely. It is advisable to familiarise yourself with the new platform prior to the closing date.

Below we provide an overview of the key steps. Please note that the Contracting Authority take no responsibility for these steps being the totality of the steps required as different processes may require different actions.

If in doubt, please ensure you contact the eTenders helpdesk as follows:

Email: irish-eproc-helpdesk@eurodyn.com

Phone: +353-818001459

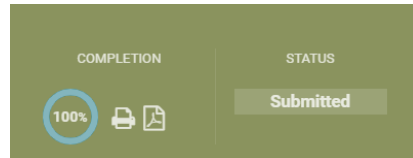
Accessing documents

It is important to note that you must ensure you **ASSOCIATE** your company with this competition in the first instance. To do this you must do the following:

- (a) Log-in to the system
- (b) Locate the competition using the Advanced Search by Contracting Authority or Resource ID
- (c) Click on the hyperlink for the competition which will bring you to the CfT Workspace
- (d) In the Show CfT Menu for the competition click on the "Expression of Interest" in the drop down menu
- (e) Complete the "Association with the CfT" tab
- (f) This will then provide you with a link to "Tender" under the Show CfT Menu

Submitting your Response

In responding to a competition without an electronic ESPD, a number of steps are required. The final step involves clicking on a Submit button and receiving the following status:



If you do not receive a message similar to above, you have not submitted your response.

Please note that the screen may say **OFFLINE**, this is a technical feature of etenders and does not mean you cannot submit. Also please note you may see the percentage field also saying 100% before you submit, this still requires you to go through the submit button.

Please upload your response as a **ZIP FILE** to protect the integrity of the file names.

File Naming Convention: Use short names (max 20 characters, no spaces/symbols) to prevent corruption on eTenders platform.

It is the responsibility of the Applicant to ensure that their application is complete and is uploaded in accordance with the instructions provided on eTenders prior to the deadline as per the front page.

Applications that are received via other means WILL NOT be considered in this procurement competition.

8.3 Queries

The closing date for submitting queries is specified on the title page.

All queries regarding this tender should be through the messaging facility on www.etenders.gov.ie, including any omissions which would prevent tenderers from submitting a comprehensive tender. Please submit queries as soon as possible.

In circulating responses, queries will be edited to avoid disclosing the identity of the querist and will be circulated to all parties who have expressed an interest in the procurement on the eTenders website.

8.4 Extension of the Tender Deadline

The Contracting Authority reserves the right, at its sole discretion, to extend the closing date for receipt of tenders by giving notice in writing (by post or electronic means) to all parties who have expressed an interest in the notice via eTenders no later than six days before the original closing date.

Tenderers will be responsible for any costs incurred by them in the event that they are required to attend clarification or other meetings or make a presentation of their proposals.

8.5 Tender Validity Period

To allow sufficient time for tender assessment a tender validity period of 12 months is required, this period commencing on the closing date by which the tenders are to be returned.

8.6 Discrepancies between Documents

A pdf version of the Request for Tender has been made available on eTenders. This document will be considered as the primary source document in this procurement process, word versions of documents where they are provided are being made available to assist tenderers in responding to the tender competition. Where there is a discrepancy between a pdf version and a word version, the pdf version will take precedence. Tenderers are requested to notify the Contracting Authority immediately of any anomaly. Where applicable the Contracting Authority will issue amended versions.

8.7 Formatting of Tenders / Amending Tender Documents

Tenderers must ensure they use the Tender Response Document (TRD) when preparing their submission.

Tenderers are prohibited from amending any text or content of forms or declarations or templates provided as part of this tender competition in their tender responses. Where amendments have been identified, the Contracting Authority may at its discretion eliminate the tenderer from further consideration. Likewise, failure to use the template documentation provided particularly in relation to costing / pricing may result in tenders being eliminated.

8.8 Collusive Tendering

If any tendering party is found to have, at any time, offered to give or to have agreed to offer or give to any person, any bribe, gift, gratuity, commission or consideration of any kind as an inducement or reward for taking or forbearing to take any action in relation to the obtaining of its tenders, or for showing or forbearing to show any favour or disfavour to any person in relation to its tenders, the bid submitted by such tendering party shall be automatically disqualified and the circumstances surrounding such action shall be referred to the appropriate authority.

8.9 Confidentiality

After the official opening of tenders, information relating to the examination, clarification, evaluation and comparison of tenders and recommendations will not be disclosed to tenderers or other persons not officially concerned with such process until the award decision with the successful tenderer has been announced and in conformity with national laws.

Tenderers shall treat the details of all documents supplied to them in connection with this contract as private and confidential and shall not disclose the contents to a third party without the permission of the Contracting Authority.

Any effort by the tenderer to influence the Contracting Authority or their staff in the process of examination, clarification, evaluation and comparison of tenders and in decisions concerning the award of the contract may result in the rejection of that tender.

8.10 Clarification of Tenders

The Contracting Authority is entitled, but not obliged, to seek clarification of tenders, including pricing breakdowns in the course of the evaluation process. No change in the price or substance of the tender shall be sought, offered or permitted. To assist in finalising the tender evaluation, selected tenderers may be invited to attend clarification meetings with the Contracting Authority.

8.11 Correction of errors

Detailed pricing of all tenders will be examined for errors that might alter the tender pricing as determined from the figures on the tender form or as between the hard copy and electronic versions of the tender (if applicable). In general, the following approach will be applied to manifest errors - where there is a discrepancy between the unit price and the total amount derived from the multiplication of the unit price and the quantity, the unit price as quoted will normally govern.

The amount stated in the tender form will be adjusted by the Contracting Authority in accordance with the above procedure and, with the agreement of the tenderer, shall be considered as binding upon the tenderer. Without prejudice to the above, a tenderer not accepting the correction of their tender as outlined may have their tender rejected.

Where the Total Quote function has been activated on eTenders and a discrepancy arises between the amount in the Total Quote box and the tender submission, the amount in the tender submission shall take precedence.

8.12 Change in the composition of a Tender

Where a change in composition of a tender arises, this must be notified in writing to the Contracting Authority and formally approved by them.

The Contracting Authority reserves the right, but is not obliged, to disqualify any tenderer that makes any change to its composition after submission of a tender.

8.13 Interference and Inducement to Purchase

Any effort by the tenderer to unduly influence the Contracting Authority, relevant agency personnel or any other relevant persons or bodies in the process of examination, clarification, evaluation and comparison of tenders and in decisions concerning the Award of Contract shall have their tender rejected. The presumptions (including as to any gift, consideration or advantage) and other provisions under the Criminal Justice Act 2018, and all other measures for the time being governing the subject-matter in any applicable jurisdiction, shall be applicable.

8.14 Conflict of Interest

Any conflict of interest involving a tenderer (or tenderers in the event of a consortium bid) must be fully disclosed to the Contracting Authority. Any registrable interest involving the tenderer and the Contracting Authority or employees of the Contracting Authority or their relatives must be fully disclosed in the tender submission or should be communicated to the Contracting Authority immediately upon such information becoming known to the tenderer, in the event of this information only coming to their notice after the submission of a bid and prior to the award of the contract. Failure to disclose a conflict of interest may disqualify a tenderer or invalidate an award of contract, depending on when the conflict of interest comes to light.

8.15 Publicity

Tenderers shall not undertake (or permit to be undertaken) at any time, whether at this stage or after the award of the contract, any publicity activity with any section of the media in relation to this tender/agreement other than with the prior written consent of the Contracting Authority. Such consent shall extend to the content of any publicity. For the purposes of this paragraph, the word “media” includes (but is not limited to) radio, television, newspapers, trade and specialist press, the Internet and email, accessible by the public at large and the representatives of such media.

The Contracting Authority will have the right to publicise or otherwise disclose to any third-party information regarding this process and the agreement.

8.16 Right Not to Award

The Contracting Authority does not bind itself to accept the most economically advantageous tender or any tender. It also reserves the right to accept or reject in whole or in part any or all tenders received, and, in particular, to source the requirement with more than one service provider.

The Request for Tender is issued in good faith; however, the Contracting Authority at its sole discretion shall not be obliged to award a contract or proceed to further stages in the procurement process and reserves the right to cancel the procurement process.

8.17 Notification of Tender Evaluations

All tenderers will be informed of the outcome of their tenders following tender evaluation and any necessary clarifications.

Potential outcomes can be:

- Establishment of Framework/Award of Contract
- Letter of Regret
- Decision not to proceed with the establishment of the Framework

The following information will be provided in the Letter of Regret – name of successful tenderer designate; the applicable standstill period (for EU tenders only); scores of tenderer being notified and that of the successful tenderer; the features and characteristics of the successful tenderer where they scored higher marks in specific criteria.

In the case of EU tenders only, the Contracting Authority will undertake not to award the contract for a period of at least 14 (or whatever period is stated in the notification letters) days from the date of notification of unsuccessful tenderers (‘standstill period’).

8.18 Award Notices

Following the award of contract, an award notice will be dispatched to the Official Journal of the European Union announcing the results of the competition. It should be noted that it is standard practice for the Contracting Authority to include the price of the winning tender or the range of prices of tenders received in the publication of the award notice as required under European procurement rules.

8.19 Policy on Personal Debriefings

Based on the provision of the information to unsuccessful tenderers as outlined above and due to resourcing constraints, the Contracting Authority will not be offering individual debriefing meetings to unsuccessful bidders.

8.20 Copyright

The Contracting Authority will have copyright ownership of any material developed for use by the Contracting Authority under the terms of this tender. The service provider may have a non-exclusive license to use such material but only for its own purposes (to be agreed with the successful tenderer).

8.21 Brand Names, etc.

Please note in relation to this tender document; where reference is made to a particular make, source, process, trademark, type or patent, that this is not to be regarded as a de facto requirement. In all such cases it should be understood that the reference in question is accompanied by the words "or equivalent".

8.22 Environmental Aspects

The Contracting Authority is committed to the principles of environmental management in its activities and it encourages the implementation of sustainability principles in its procurement practices and throughout the delivery of all contracts.

8.23 Knowledge and Skills Transfer

It will be a condition of the contract that opportunities for the transfer of skills and/or knowledge from the successful tenderer's staff to the Contracting Authority staff will be availed of during the course of the contract or prior to the handing over of the finished work/product.

8.24 Currency and Payments

The currency and invoices in which all prices and rates shall be tendered, and which payments under the contract will be paid, shall be euro (€).

All prices and rates quoted should be on the basis of both VAT exclusive and VAT inclusive costs, clearly identifying the applicable rate of VAT.

A schedule of payments will be agreed with the successful tenderer and invoices shall be submitted in accordance with the terms agreed with the Contracting Authority.

8.25 Irish Legislation and Law

Tenderers should be aware that national legislation applies in other matters such as Employment, Working Hours, Official Secrets, Data Protection and Health and Safety. Tenderers must have regard to statutory terms relating to minimum pay and to legally binding industrial or sectoral agreements in the Contracting Authority tenders and in delivering contracts awarded to them. The contract(s) awarded on foot of this tender process will be governed by Irish law.

8.26 Anti-Competitive Conduct

Tenderers should take notice of the Competition Act 2002 (as amended, the “2002 Act”), which makes it a criminal offence for tenderers to collude on prices or any other aspects relating to this procurement competition.

8.27 Accessibility / Dignity at Work

The successful tenderer(s) shall comply with all relevant legislation relating to dignity at work. As a public body and employer, the Contracting Authority is committed to a policy of equality of opportunity for all personnel.

In line with the Disability Act 2005, accessibility requirements should be clearly stated in request for tenders / quotations where applicable. Under Section 27 of the Act the Contracting Authority is required to ensure that both the goods supplied, and services provided to it are accessible to persons with disabilities.

8.28 Withholding Tax

Where applicable, payments shall be subject to Irish ‘Professional Services Withholding Tax’ at the prevailing rate (currently at 20%) as laid down by the Revenue Commissioners in Ireland. Non-residents may be able to reclaim such deducted Tax from the Office of the Revenue Commissioners in Ireland, International Claims Section located currently at Government Buildings, Nenagh, Co. Tipperary, Ireland (Tel: +353 (0) 67 63400).

8.29 Freedom of Information

All responses to this Request for Tender will be treated in confidence and no information contained therein will be communicated to any third party without the written permission of the tenderer except insofar as is specifically required for the consideration and evaluation of the response or as may be required under law, including the Freedom of Information Act 2014, EU and Irish Government Procurement Procedures, or in response to questions, debates or other parliamentary procedures in or of the Oireachtas (the Irish Parliament).

Tenderers are asked to consider if any of the information supplied by them in response to this request for tenders should not be disclosed because of its sensitivity. However, any blanket or all-encompassing request for exemption from disclosure is not acceptable; tenderers must identify explicitly any such information and give relevant reasons for considering it to be economically sensitive or confidential in nature. If this is the case, tenderers should specify the information that is sensitive and the reasons for its sensitivity. The Contracting Authority cannot guarantee that any information provided by tenderers, either in response to this tender or in the course of any contract awarded as a result thereof, will not be released pursuant to the Contracting Authority’s obligations under law, including the Freedom of Information Act 2014, or to those under EU and Irish Government Procurement rules. The Contracting Authority accepts no liability whatsoever in respect of any information provided which is subsequently released, or in respect of any consequential damage suffered as a result of such disclosure.

8.30 Late Payment

The Contracting Authority operates in accordance with EU Directive 2011/7/EU on combating Late Payment in commercial Transactions transposed into national legislation as S.I. 580 of 2012 and amended by S.I. No. 281 of 2016.

8.31 Data Protection

“Data Protection Laws” means all applicable national and EU data protection laws, regulations and guidelines including but not limited to Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (the “General Data Protection Regulation”), the Data Protection Act, 2018 and any guidelines and codes of practice issued by the Data Protection Commission or other supervisory authority for data protection in Ireland from time to time.

The Contracting Authority will be a Controller (where Controller has the meaning given under the Data Protection Laws) in respect of any Personal Data (where Personal Data has the meaning given under the Data Protection Laws) required to be provided by the tenderer in response to this Request for Tender.

The tenderer, as Controller in respect of any Personal Data provided by it in its tender, is required to confirm by way of statement in the “Declarations” section of the accompanying Tender Response Document that all Data Subjects (where Data Subject has the meaning given under the Data Protection Laws) whose Personal Data is provided by the tenderer have consented to the processing of such Personal Data by the tenderer, the Contracting Authority, the Evaluation Team and the supplier of the eTenders website, for the purposes of the participation of the tenderer in this Competition or that the tenderer otherwise has a legal basis for providing such Personal Data to the Contracting Authority for the purposes of its participation in this Competition.

8.32 Responsibility of Successful Party

As a condition of award, it shall be the successful tenderer’s sole responsibility to ensure they have taken account of all obligations under the Contract including factors which might arise based on the withdrawal of the United Kingdom from membership of the EU.

9 Draft Contract Terms and Conditions

Attached as a separate appendix.