



Ollscoil
Teicneolaíochta
an Atlantaigh

Atlantic
Technological
University

TENDER RESPONSE DOCUMENT

**PIF 268/25 - CFT ID 8365482 Request for Tender for the Establishment
of a Multi Party Framework Agreement for Quality and Regulation
Consultancy in Medical Technologies**

Tender deadline 12:00 Noon on 14th July 2026

Company Name	
Contact Name	
Contact Email Address	
Phone Number	
Postal Address	

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1 Instruction for Completion

All Responses in this Tender Response Document are subject to the rules, conditions and stipulations as set out in the RFT Document.

This document **MUST** be used for the submission of tenders. Tenderers must follow the instructions contained in this document in relation to attachments, word limits, etc.

Tenderers should ensure they have read the Request for Tender before they attempt to complete this Tender Response Document.

If you consider that the Tender Response Document is missing any sections which would prevent you from preparing a comprehensive response, please contact the Contracting Authority as soon as possible.

Where there is a discrepancy between the contents / instructions in this document and the Request for Tender, the Request for Tender will take precedence.

Tenderers must follow the instructions contained in this document in relation to attachments, links, and format for submission, etc.

In the event that suppliers are co-operating to deliver the service, a separate Tender Response Document will be required for **each** co-operating party with a statement identifying the lead party and explicitly defining the roles and responsibilities of each entity.

2 Tenderer Information

2.1 General Contact Information

A1. General information		
Weighting: Pass/Fail		
Pass requirement: Candidates must complete this Section. If the Candidate is a grouping, then a separate questionnaire must be completed for each group member.		
Organisation Name:		
Contact Name:		
Position:		
Address:		
Telephone (Office):		
Telephone (Mobile):		
Email:		
Website:		
Companies Registration Number (or equivalent based on country of establishment)		
Country of Establishment if outside Ireland		
Date of Establishment:		
Legal Status (Company, Sole Trader, etc.):		
Please answers the following questions with 'Yes' or 'No':	Yes	No
1) Is the Candidate a Small and Medium-size Enterprise (SME) as defined in the European Commission's Recommendation 2003/361/EC ¹ ?	☐	☐
2) Is the Candidate a consortium / group of Economic Operators?	☐	☐
3) Is the Candidate a Lead Candidate acting on behalf of a group of economic operators regardless of legal form of grouping?	☐	☐
4) Is the Candidate relying upon another entity including sub-contractors to meet some/or all of the qualification requirements under the selection criteria?	☐	☐
5) Is the Candidate only relying on the other entity(s) to deliver services under the framework(s)?	☐	☐
6) Does the Lead Candidate confirm that if successful those other parties are available to deliver the services when required and may be required to co-sign the formal Contract?	☐	☐
Details of other parties:		
If the answer to any of the above questions 4 and 5 is 'Yes', full details of the other parties relied upon must be provided below by the Lead Tenderer. Please note that where this entity is being relied upon, this must be clearly identified, where relevant, throughout the Tender Response.		
Please detail the contributions of other parties:		

¹ SMEs are enterprises which employ fewer than 250 persons, and which have an annual turnover not exceeding €50 million, and/or an annual balance sheet total not exceeding €43 million.

Name of Entity	Selection criterion where Candidate is relying on their resources to qualify: <i>and/or</i> Service to be delivered by third party:	Check the box to confirm the third-party is clearly identified throughout the response
		☐
		☐
		☐

3 Response to the Selection Criteria

3.1 Tenderer's Statement

Tenderers shall complete and return the following form of Tenderers' Statement printed on the Tenderers' headed notepaper and signed by the Tenderer. Tenderers are asked to scan the signed document and return it with their tender submission via the electronic post-box.

TENDERERS' STATEMENT

TO: Atlantic Technological University (the "Contracting Authority")

RE: 25/268B CFT ID 8365482 Request for Tender for the Establishment of a Multi Party Framework Agreement for a Quality and Regulation Consultancy Services in Medical Technologies.

Having examined your Request for Tenders (the "RFT") including the Instructions to Tenderers, the Selection and Award Criteria, the Requirements and Specifications, and the Terms and Conditions of the Services Contract, we hereby agree and declare the following:

1.	We understand the nature and extent of the Services to be delivered as described at Section 5 of the RFT Document.
2.	We accept all of the Terms and Conditions of the RFT, the Framework Agreement, Services Contract and the Confidentiality Agreement and agree if awarded a Contract to execute the Framework Agreement at Appendix 3 , the Services Contract at Appendix 3 and the Confidentiality Agreement at Appendix 3 and the Data Processing Agreement at Appendix 3 to the RFT.
3.	We accept all the Selection and Award Criteria as set out in Sections 4 and 5 of the RFT.
4.	We agree to provide the Contracting Authority with the services in accordance with the RFT and our Tender.
5.	We agree that, if awarded any Contract, we shall, in the performance of such Contract, comply with all applicable obligations in the field of environmental, social and labour law.
6.	We confirm that we have complied with all requirements as set out in the RFT.
7.	The costs submitted by the tenderer shall be the maximum price chargeable by the Framework Member during the initial two (2) years of the Framework Agreement. Price changes thereafter, if applicable, any price adjustments for subsequent years (e.g., Years 3, 4 and 5) shall be strictly limited to increases linked to the Consumer Price Index (CPI), as published by the Central Statistics Office of Ireland.
8.	We shall, if awarded any Contract under the RFT, have in place on the Effective Date of the Contract all insurances (if any) as required by section 6.3 of the RFT.
9.	We confirm that all Data Subjects whose Personal Data is provided in our Tender have consented to the processing of such Personal Data by us, the Contracting Authority, the Evaluation Team and the supplier of the etenders.gov.ie website, for the purposes of our participation in this Competition or that we otherwise have a legal basis for

	providing such Personal Data to the Contracting Authority for the purposes of our participation in this Competition and that we will provide evidence of such consent and / or legal basis to the Contracting Authority upon request.	
SIGNED		Company
(Authorised Signatory)		
Print name		Address
Date		

3.2 Declaration of Bona Fides – Pass/Fail Criterion

Declaration of Bona Fides & Statutory Obligations (Under Public Sector Directive 2014/24/EU - Article 57)			
Weighting: Pass/Fail Pass requirement: Tenderers must complete, sign and date this Declaration. The Contracting Authority reserves the right at its discretion to exclude a non-compliant tenderer under each heading. This must be completed by each group member.			
Economic Operators will be excluded from the procurement process if, within the past five (5) years, there is evidence of a conviction relating to a specific criminal offence listed below (see 1.1) or if they have been the subject of a binding legal decision which found a breach of legal obligations to pay tax or social security contributions (see 1.2) (except where this is disproportionate e.g. where only minor amounts are involved).			
		Yes	No
1.1	Has the Economic Operator or a member of their proposed consortium, (if applicable), Director, or Partner or any other person who has powers of representation, decision or control, been convicted of any of the following offences?	Please indicate your answer by marking 'X' in the relevant box	
1.1a	participation in a criminal organisation, as defined in Article 2 of Council Framework decision 2008/841/JHA;		
1.1b	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(1) of Council Framework Decision 2003/568/JHA as well as corruption as defined in Irish Law or the jurisdiction in which the Economic Operator is established;		
1.1c	fraud within the meaning of Article 1 of the Convention on the protection of the European Communities' financial interests;		
1.1d	the subject of a conviction for terrorist offences or offences linked to terrorist activities or for inciting or aiding or abetting or attempting to commit an offence;		
1.1e	the subject of a conviction for money laundering or terrorist financing;		
1.1f	the subject of a conviction of child labour and other forms of trafficking in human beings;		
1.2	Non-payment of taxes or social security obligations Has it been established by a judicial or administrative decision having final and binding effect in accordance with Irish law or the legal provisions of the country in which the Economic Operator is established (if outside Ireland), that the Economic Operator is in breach of obligations related to the payment of tax and social security contributions? If the response to 1.2 above is in the affirmative, please provide further information on the decision and the amounts involved.		

An Economic Operator who answers 'Yes' in any of the situations set out in paragraphs 2.1.a to 2.1.i will be excluded.

2.1	Please indicate if any of the following situations have applied, within the past three (3) years, or currently apply, to your organisation. The Economic Operator:	Yes	No
		Please indicate your answer by marking 'X' in the relevant box	
2.1a	has, in the performance of any public contract, failed to comply with applicable obligations in the field of environmental, social and labour law applying at the place where the works were carried out or the services provided, as established by EU law, national law, collective agreements or by international, environmental, social and labour law listed in Annex X of Directive 2014/24/EU;		
2.1b	is bankrupt or the subject of insolvency or winding-up proceedings, its assets are being administered by a liquidator or by the court, or has entered into an arrangement with creditors, suspended its business activities or is in any analogous situation arising from a similar procedure under national laws and regulations;		
2.1c	is guilty of grave professional misconduct which renders its integrity questionable;		
2.1d	has entered into agreements with other Economic Operators aimed at distorting competition;		
2.1e	has a conflict of interest within the meaning of Article 24 of 2014/24/EU that cannot be effectively remedied by other, less intrusive, measures;		
2.1f	confirms that it has had prior involvement in the preparation of the procurement procedure which has resulted in a distortion of competition, as referred to in Article 41 of 2014/24/EU, that cannot be remedied by other, less intrusive, measures;		
2.1g	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.		
2.1h	- is 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; or - has withheld such information or is not able to submit supporting documents required under Article 59 of Directive 2014/24/EU; or		
2.1i	has undertaken to: unduly influence the decision-making process of the contracting entity, or		

	• obtain confidential information that may confer upon the tenderer undue advantages in the procurement procedure; or • negligently provide misleading information that may have a material influence on decisions concerning exclusion, selection or award.		
Name of Economic Operator:			
Authorised Signatory:			
Name in Block Capitals:			
Position:			

3.3 Declaration re Statutory Obligations – Pass/Fail Criterion

Declaration on Statutory Obligations			
Weighting: Pass/Fail Pass requirement: Tenderers must complete, sign and date this Declaration. The Contracting Authority reserves the right at its discretion to exclude a non-compliant tenderer under each heading. This must be completed by each group member.			
We confirm that we are fully compliant with the following legislation, or equivalent legislation in our country of establishment / operation:		Yes	No
(i)	Employment Equality Acts 1998-2011		
(ii)	Equal Status Acts 2000-2011		
(iii)	National Minimum Wage Act 2000 as amended		
(iv)	Organisation of Working Time Act 1997 as amended		
(v)	Safety, Health and Welfare at Work Act 2005 and Safety, Health and Welfare at Work (General Application) Regulations 2007		
(vi)	Disability Act 2005		
(vii)	General Data Protection Regulation 2016/679		
(viii)	We have procedures in place to ensure that our subcontractors, if any are used for this contract, apply the same standards.		
This Declaration is made for the benefit of the Contracting Authority I certify that the information provided in this declaration is accurate and complete to the best of my knowledge and belief. I understand that the provision of inaccurate or misleading information in this Declaration will lead to my organisation being excluded from participation in this and future tenders and I am signing on behalf of:			
Name of Economic Operator:			
Authorised Signatory:			
Name in Block Capitals:			
Position:			

3.4 General Data Protection Regulation Requirements – Pass/Fail Criterion

General Data Protection Regulation			
Weighting: Pass/Fail Pass requirement: Tenderers must demonstrate compliance with the General Data Protection Regulation Requirements.			
Requirement		Yes	No
(i)	If we are identified as the successful tenderer, I confirm that we shall sign a Data Processing Agreement which will govern the processing of personal data as part of this contract. The Data Processing Agreement agreed between the Parties shall be governed by, and construed in accordance with, the laws of Ireland and the Parties irrevocably agree that the courts of Ireland shall have exclusive jurisdiction to hear and determine any suit, action or proceedings, and to settle any disputes, which may arise out of or in connection with the Agreement and, for such purposes, irrevocably submits to the exclusive jurisdiction of such courts.		
(ii)	If we are identified as the successful tenderer, and are engaging sub-processors, I confirm we shall contractually impose data protection obligations on sub-processors no less protective than set out in the Data Processing Agreement and remain fully liable to ATU for the sub-processor's compliance with our own obligations under the Agreement.		
(iii)	It is the intention of the Contracting Authority that personal data processed shall reside solely in the European Economic Area (EEA) and not be transferred to / accessed from a country outside the EEA. However, if data is stored/processed outside the EEA, for example for hosting, back-up, 24-hour support purposes – including remote access – tenderers will be asked to specify whether an adequacy decision exists in relation to the third country where the processing will take place. I confirm that if we are identified as the successful tenderer and no adequacy decision exists, we will sign the 2021 EU Standard Contractual Clauses AND verify, where appropriate, in collaboration with the Contracting Authority, whether the laws and practices of the third country ensures adequate protection, under EU law, of personal data transferred pursuant to standard data protection clauses, by providing, where necessary, additional safeguards to those offered by those clauses.		
(iv)	If we are identified as the successful tenderer, we shall provide cooperation and assistance to the Contracting Authority in preparing a Data Protection Impact Assessment (DPIA), where necessary, and make necessary documentation available to the Contracting Authority which outlines the technical and organisational measures employed to protect personal data.		

(v)	I can confirm that the solution proposed will allow for the Contracting Authority's data to be completely erased from the cloud system (or exported to a system of the Contracting Authority's choice) after the contract term.		
(vi)	As the successful tenderer, I confirm that we accept that the Contracting Authority shall not accept any liability clauses where Data Processors are indemnified against fines or claims under the GDPR.		
Please provide a narrative on your approach to GDPR:			
This Declaration is made for the benefit of the Contracting Authority I certify that the information provided in this declaration is accurate and complete to the best of my knowledge and belief. I understand that the provision of inaccurate or misleading information in this Declaration will lead to my organisation being excluded from participation in this and future tenders and I am signing on behalf of:			
Name of Economic Operator:			
Authorised Signatory:			
Name in Block Capitals:			
Position:			

3.5 Financial Information – Pass/Fail Criterion – Tenderers MUST Complete All Sections

4.5.1 Tax Compliance		
Option 1: I confirm and declare being tax compliant. The Contracting Authority can verify your tax clearance status through Revenue's online facility at http://www.revenue.ie/en/online/tax-clearance.html To this end, please confirm:	Yes	
	No	
Tenderer Name:		
Tax Reference Number (PPSN):		
Access Number:		
Option 2: I confirm that I hold a current valid Tax Clearance Certificate (generally relates to Non-Residents) To this end, please confirm:	Yes	
	No	
Registration Number:		
Certificate Number:		
Option 3: I confirm that I have applied for Tax Clearance status or a Tax Clearance Certificate which will be made available on request	Yes	
	No	

4.5.2 Financial Capacity			
I confirm that our turnover with regard to provision of Quality and Regulation Consultancy Services exceeded €50,000.00 in each of the last three financial years, or pro-rata if more recently established firms are tendering – however the firm must have been in existence for at least 6 months. Evidence of the foregoing will be required within 7 days of request prior to the award of any contract. If Figures for 2025 are not available please use 2024, 2023, and 2022			
Financial Year Tenderers MUST Complete turnover for the years identified.	2025	2024	2023
Turnover	€	€	€
Month of financial year end			
I confirm that I will provide the following promptly on request at any time prior to the tender list being finalised: (evidence of turnover for the past three financial years by way of auditor's letter or audited accounts)	Yes		
	No		
I confirm that I will supply evidence of financial standing, by way of auditor's letter ensuring the tenderer 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.	Yes		
	No		
4.5.3 Insurances Tenderers MUST confirm current levels in place.			
I confirm that we have the following insurances in place:			
Insurance Type	Level in place	Details of Excess	Expiry Date
Employer Liability	€		
Public Liability	€		
Product Liability	€		
Professional Indemnity	€		
I confirm that the insurance cover includes an 'Indemnity to Principal' clause	Yes		
	No		
I confirm that the Republic of Ireland is included in the territorial and jurisdictional limits of the insurance cover	Yes		
	No		
I confirm that I will provide the following promptly on request at any time prior to the award decision being made: Evidence of insurances in place or Letter from Insurance Broker confirming that the required levels could be put in place if successful	Yes		
	No		
I confirm that if successful, where the levels required under the contract or framework are higher than those currently in our possession, I will be in a position to put the required forms and levels of insurances required in place promptly.	Yes		
	No		

Please note that the Contracting Authority will seek to verify self-declarations regarding financial capacity prior to next stage of the competition.	
Signed:	
Position:	
Date:	

3.6 Previous Experience - Pass/Fail Criterion

Previous Experience
Weighting: Pass/Fail Minimum requirement to remain eligible in the competition: Tenderers should refer to instances within the last five (5) years which demonstrate that they have successfully delivered services of a comparable nature on at least three (3) occasions in total, which collectively demonstrate capability across the framework's service areas (e.g., regulatory strategy, QMS development, clinical evaluation, risk management, technical documentation). At least one (1) contract/assignment must be of comparable scale, with remaining experience demonstrated through equivalent smaller assignments, subcontracts or relevant professional experience. The contracts or assignments referenced for consideration should provide comprehensive information. The contracts or assignments listed should be chosen to demonstrate your firm's skills, efficiency, experience and reliability across quality and regulatory consultancy for medical device prototypes. SMEs, micro-enterprises and sole providers may demonstrate capability through prior consultancy work (corporate contracts, subcontracts, freelance assignments), client references or equivalent evidence proportionate to framework requirement. All fields should be completed in full. In the event that the information requested on the value of contracts or identity of clients is considered confidential, tenderers must ensure that they provide sufficient information to allow the Contracting Authority to judge the similarity of these contracts to the services required.

CLIENT NO. 1	
Company Name:	
Contact name:	
Contact role:	
Contact Tel. Number:	
Contact email address:	
COMPREHENSIVE DESCRIPTION OF CONTRACT DELIVERED INCLUDING:	

Duration of contract including start and completion dates (If completed)			
Role of the Tenderer in this contract E.g., is your firm the sole provider of the Services, is the contract subcontracted?			
Description and scope of the services provided by the Tenderer			
Describe the relevance of this example to the current requirement			
Current Contract Status – on-going, complete			
APPROX. VALUE (€)		DATE(S) DELIVERED	

CLIENT NO. 2	
Company Name:	
Contact name:	
Contact role:	
Contact Tel. number	
Contact email address:	
COMPREHENSIVE DESCRIPTION OF CONTRACT DELIVERED INCLUDING:	

Duration of contract including start and completion dates (If completed)			
Role of the Tenderer in this contract E.g., is your firm the sole provider of the Services, is the contract subcontracted?			
Description and scope of the services provided by the Tenderer			
Describe the relevance of this example to the current requirement			
Current Contract Status – on-going, complete			
APPROX. VALUE (€)		DATE(S) DELIVERED	

CLIENT NO. 3	
Company Name:	
Contact name:	
Contact role:	
Contact Tel. number	
Contact email address:	
COMPREHENSIVE DESCRIPTION OF CONTRACT DELIVERED INCLUDING:	

Duration of contract including start and completion dates (If completed)			
Role of the Tenderer in this contract E.g., is your firm the sole provider of the Services, is the contract subcontracted?			
Description and scope of the services provided by the Tenderer			
Describe the relevance of this example to the current requirement			
Current Contract Status – on-going, complete			
APPROX. VALUE (€)		DATE(S) DELIVERED	

3.7 Personnel & Skills– Pass/Fail Criteria

Personnel & Skills			
Weighting: Pass/Fail Minimum requirement to remain eligible in the competition: Tenderers must demonstrate access to at least the minimum numbers of skilled personnel stated. Please note that the skills outlined may reside in the same person.			
Skillset	Number of Full Time Equivalents (FTE)	Number of FTEs provided by 3rd Parties	Minimum Number Required
Lead MedTech Researcher 5+ years Quality and Regulatory expertise in Medical Technologies			1
Analyst			1
QMS Specialist			1
Clinical Evaluation Expert			1
Total			n/a

Tenderers are reminded that they may rely on the resources of other entities on condition that they are fully described, and that tenderers can prove that they will have these resources at their disposal when required.

Please attach an organisation chart, clearly identifying all relevant departments, divisions, and 3rd parties, if applicable.

3.8 Quality Assurance – Pass/Fail Criteria

Quality Assurance				
Weighting: Pass/Fail Minimum requirement to remain eligible in the competition: Tenderers should provide information on the measures in place to ensure the delivery of a quality service, for example by way of an externally certified system, or an equivalent in-house quality control process or system.				
Do you operate a Quality Management System?	Yes		No	
Manager responsible for Quality:				
Quality management	Externally Certified		In-house	
If externally certified, please provide the following information:				
Name of Certification Body:				
Date of most recent certification:				
Scope of Certification:				
I confirm that evidence of compliance will be provided promptly on request.	Yes		No	

3.9 Environmental Management Systems – Pass/Fail Criteria

Environmental Management Systems				
Weighting: Pass/Fail Minimum requirement to remain eligible in the competition: Tenderers must demonstrate compliance with all the relevant Environmental legislation and guidelines. The Contracting Authority reserves the right to seek further information to verify compliance.				
Do you comply with all relevant Environmental legislation?	Yes		No	
Manager responsible for Environmental Systems:				
Environmental management	Externally Certified		In-house	
If externally certified, please provide the following information:				
Name of Certification Body:				
Date of most recent certification:				
Scope of Certification:				
I confirm that evidence of compliance will be provided promptly on request.	Yes		No	

4 Sub-Contracting

ATU understands that there may be elements of the contract or framework which may need to be subcontracted or outsourced by suppliers. Please indicate if you propose to use any sub-contractors for the delivery of any element of this contract. **[In this instance, sub-contractors will be an organisation/institution(s) which you may propose to subcontract for elements of the system or service delivery.]**

Do you propose to use any sub-contractors?	
Envisaged Scope of the services to be carried out by the sub-contractor	
Name(s) and contact details of other members of grouping.	Company Name: Company Address: Contact Name: Contact Telephone: Contact Email:
Role of lead member of the grouping	

Role of other members of grouping	

In the event that suppliers are co-operating to deliver the service, a separate Tender Response Document with sections **2.1, 3.2, 3.3, 3.4, 3.5 (if appropriate), 3.6, 3.7, 3.8, and 3.9** completed will be required for **each** co-operating party and returned with their tender submission. Failure to provide the foregoing may result in your tender being deemed inadmissible and being eliminated from further evaluation.

5 Response to the Award Criteria

5.1 Response to Qualitative Award Criteria

Criterion B	Weighting	Maximum Marks	Minimum Marks 50%
	30%	3,000	1,500
Title	Methodology and Approach for 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. Tenderers MUST complete and submit their responses using the Tender Response Document (TRD) Template provided. Appendices and additional documentation will not be assessed where not expressly permitted. This criterion will be evaluated in its totality		
	Tenderer’s Response		

Criterion C	Weighting	Maximum Marks	Minimum Marks 50%
	25%	2,500	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.		

Tenderer's Response

Please use this free text page(s) (i.e. do not type in the box) for your response.

Please list the Key Personnel who you propose will be directly involved in the delivery of the required services. Tenderers can add additional names if required.

Name	Proposed Role (Lead Regulatory Consultant, QMS Specialist, Clinical Evaluation Expert etc.)	Number of Years Experience
Click here and insert name	Click here and insert role	Click here and insert Number of years experience
Click here and insert name	Click here and insert role	Click here and insert number of years experience
Click here and insert name	Click here and insert role	Click here and insert number of years experience
Click here and insert name	Click here and insert role	Click here and insert number of years experience
Click here and insert name	Click here and insert role	Click here and insert number of years experience

Tenderers MUST copy the CV format below and complete for each team member proposed. Note CV's attached in appendices will not be considered.

Format of CV for Core Team Member	
Name	
Role on the team (for example; Lead Regulatory Consultant, QMS Specialist, Clinical Evaluation Expert)	
Relevant qualifications: relevant professional qualifications (institution(s), award(s) conferred, and date(s) obtained)	
Years' experience	

Detail experience **relevant to role on the team**, with examples of specific projects where the relevant experience has been gained. Ensure the relevance of the experience is clearly highlighted. If the details of projects are confidential, ensure sufficient information is included to demonstrate their relevance.

[Please duplicate table for each team member where appropriate]

Criterion D	Weighting	Maximum Marks	Minimum Marks 50%
	10%	1,000	500
Title	Sustainability and Value Add		
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		
	Tenderer’s Response		

5.2 Response to Ultimate Cost Criterion A - Form of Tender

Criterion A	Weighting	Maximum Marks	Minimum Marks
	35%	3,500	n/a
Title	Ultimate Cost		
Description	Tenderers must complete this Section 5.2 of the TRD The response must include all costs involved in the delivery of the requirement.		

To:	Atlantic Technological University
From:	
Subject:	PIF 268/25 - CFT ID 7826886 Request for Tender for the Establishment of a Multi Party Framework Agreement for Quality and Regulation Consultancy in Medical Technologies

I/We have examined the tender documentation and hereby offer to provide the services in accordance with the details contained within the Request for Tender (RFT) document.

Ultimate Cost – Notional Cost	Total Fee proposed (excl. VAT)	Total Fee proposed (incl. VAT)
Total Notional Sum for Evaluation Purposes Only	€	€

Tenderers must complete the tables below - Breakdown of pricing. Numbers entered are **notional quantities** only for evaluation purposes only. Lump sum price should be entered in table above i.e. **Notional Total Cost**

Table 1 – Notional Basket of Services for Evaluation Purposes Only – Maximum Hourly Rates Fixed for Initial Two Years of the Framework Agreement.			
Grade	Hourly Rate Excluding Vat (A)	Notional Hours (B)	Total (C) (AxB = C)
Lead Med Tech Researcher	€	42	€
Analyst	€	6	€
QMS Specialist	€	9	€
Clinical Evaluation Expert	€	3	€
Total Notional Sum for Evaluation Purposes Only			

Note 1: The figures above are notional volumes and provide no guarantee of work to be awarded under this framework agreement. It is being used purely to enable assessment of the notional cost for the framework agreement and ensure certainty of rates for work under the framework.
Note 2: Note to Tenderers where resources are required for a day(s) or part of a day within this timeframe the amount payable will be a pro-rata proportion of the hourly rate; The daily rate will be based on an 7.5 hour day (for example, the daily rate will be 7.5 times the relevant hourly rate).
Note 3: Tenderers must complete all elements of this Pricing Schedule by completing ALL the cost tables above. Amounts must be given in figures to two decimal places. Spaces must not be left blank. The terms “included”, dashes, “NA”, or similar terms, must not be used – figures must be used at all times. If Tenderers do not include a rate for any element, the Contracting Authority will insert a rate of €0 and mark on that basis. This will be the rate applicable to that element if the Tenderer is successful.
Note 4: Pricing under this Framework Agreement shall remain fixed for the initial two (2) years from the Framework commencement date, irrespective of any inflation, cost increases, or market fluctuations during this period.
Any price adjustments for subsequent years (e.g., Years 3,4 and 5 shall be strictly limited to increases linked to the Consumer Price Index (CPI), as published by the Central Statistics Office of Ireland. Central Statistics Office of Ireland. The adjustment shall be calculated using the following formula:
Adjusted Annual Price = Fixed Year 2 Price × (Latest CPI / Base CPI) Base CPI shall be the CPI figure published for the month immediately prior to the Framework commencement date. Latest CPI shall be the most recent CPI figure published prior to the adjustment date (annually on the Framework anniversary). No adjustment shall result in a decrease below the Fixed Year 2 Price
Note 5: Tenderers must provide full pricing transparency in the Pricing Schedule, with no separate charges for account management or ancillary services.

I/We confirm that I/we:

- Have priced our tender on the basis of all rates being inclusive of all out of pocket expenses (i.e. mileage, subsistence, phone, postage, printing etc.) and account / contract management related costs,
 - Will keep this offer for the contract / framework open for acceptance by you for a period of 12 months from the date of deadline for submission of tenders,
 - Agree that you are not bound to accept the most economically advantageous or any tender you may receive,
 - Agree that the rates stated are maximum prices for the initial two (2) years of the framework agreement, from commencement. Costs for the subsequent two years in the initial contract will be adjusted in line with the Consumer Price Index (CPI) (e.g., Years 3 and 4) shall be strictly limited to increases linked to the Consumer Price Index (CPI), as published by the Central Statistics Office of Ireland.
 - Have read and thoroughly examined the RFT,
 - Fully understand the RFT and the Client's requirements,
 - Undertake to treat the details of the RFT, its tender and any subsequent agreements as private and confidential,
 - Acknowledge that acceptance by the Contracting Authority of this tender will not constitute a binding and enforceable agreement and that a legally enforceable agreement will not exist until and unless the contract is awarded / framework agreement has been established between the Contracting Authority and the tenderer,
 - Have availed of all offers for additional information or have otherwise satisfied myself/ourselves as to conditions that may in any manner affect the performance of the contract,
 - Have included all elements necessary for the performance of the specified requirements, which are either expressly stated in the RFT or contained in any supplementary information or which could reasonably be inferred therefrom,
 - Have found no errors, omissions, conflicts or ambiguities in the RFT except those which I/We have brought to the attention of the Contracting Authority before the latest date for submitting queries,
 - Have included for compliance with all statutory requirements applicable in Ireland and those applicable in any country where parts of the contract may be performed that are in force 7 days prior to the deadline for receipt of tenders,
 - Will not, if awarded a contract employ labour in a manner that is discriminatory in relation to gender, civil/family status, sexual orientation, religion, age, disability, race, or membership of the traveller community.
 - Agree that as a condition of award, it shall be our sole responsibility to fulfil the obligations under the Contract, notwithstanding any changes in circulars, laws, regulations, taxation, duties or other factors which might arise following the withdrawal of the United Kingdom from membership of the EU.
-

Signed:	
Name (in Capital Letters):	
On behalf of:	
Address:	
Telephone (Office):	
Telephone (Mobile):	
Email:	
Date:	

6 Checklist

Section	Element	Section Complete/ Evidence Supplied
2.1	Tenderer Information	
3.1	Tenderer's Statement <i>Note: this is to be provided on Tenderers headed notepaper.</i>	
3.2	Declaration of Bona Fides	
3.3	Declaration re Statutory Obligations	
3.4	General Data Protection Requirements Declaration	
3.5	Financial Information	
3.5.1	Tax Compliance	
3.5.2	Turnover	
3.5.3	Insurance Cover	
3.6	Previous Experience	
3.7	Personnel and Skills	
3.8	Quality Assurance	
3.9	Environmental Management System	
4	Sub-Contracting	
5.1	Response to Qualitative Award Criteria	
5.2	Response to Ultimate Cost Criterion	