

INVITATION FOR PANEL MEMBERSHIP

Title:	Establishment of a Panel for Laboratory Testing Services of preclinical contract research organizations (CROs)
Contracting Authority:	RSCI University of Medicine and Health Sciences
Procedure:	Panel under Competitive Procedure with Negotiation on the basis that the service comprises a Title III Service in accordance with Directive 2014/24/EU.
Duration of Panel	The panel will be established for six (6) years with the option for additional annual advertising during that period to recruit certain skills if required. Applications can be received at any time over the life of the Panel, any party who fails to qualify may re-apply at any time.
eTenders Ref	3902110
Issue Date:	03.07.24
Closing Date for Queries:	Open call- panel to remain open until at least 31/07/2030
Contact for Queries	Messaging facility on www.eTenders.gov.ie
Submissions via:	eTenders only – you must upload your response as a ZIP FILE to protect the integrity of the file names
Please note that information relating to this Application, 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 cannot accept responsibility for information relayed (or not relayed) via third parties.	

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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.

Applicants 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. Summary

Contracting Authority	RCSI University of Medicine and Health Sciences
Nature of Procurement	Establishment of a Panel for Laboratory Testing Services of preclinical contract research organizations (CROs)
Type	Title III Services
Procedure	Panel under Competitive Procedure with Negotiation using the Dynamic Purchasing System tool on eTenders. Applicants should note that this Competition is being run under Regulation 74 of the European Union (Award of Public Authority Contracts) Regulations 2016 (the "Regulations"), and accordingly is subject only to limited aspects of the Regulations.
Stage in Procedure	This is the pre-qualification stage for inclusion on the panel.

3. About the Panel

3.1 Numbers Admitted to the Panel

There is no maximum limit to the number of Applicants that can be admitted to the Panel.

There is an initial closing date for applications as per the dates above which will allow for processing of applications in an efficient manner. However, the Panel will remain open for applications for its entire duration. All subsequent applications after the initial call will be processed at periodic intervals.

3.2 Duration of the Panel

The panel will be established for **six (6) years**.

There will be an initial call for applications as per the dates above which will be subject to an initial deadline to allow for processing of applications. However, the panel will remain open for applications for its duration. All subsequent applications after the initial call will be processed at periodic intervals.

Contracts may extend past the life of the panel.

3.3 Estimated Value of the Panel

The maximum estimated expenditure over the life of the panel is €1.2 million.

The level of expenditure cannot be guaranteed in any given year. The likely value of individual contracts to be awarded under the panel may be in the region of €25,000 to €150,000. However, this is for indicative purposes only and not guaranteed. It is emphasised, however, that this figure is provided strictly for indicative purposes only as there is no guaranteed expenditure under the Panel

3.4 Admission to the Panel

Admission to the panel will also be subject to the Applicant passing the Pass / Fail Criteria A1 to A5 and also achieving **the minimum scores** or higher applying to the **Weighted Criteria B1 and B2** as set out in Appendix A. Applicants who meet the minimum qualifying requirements will be placed on the Panel

subject to verification of self-declared information. For inclusion onto the Panel, Applicants must also agree to the terms and conditions of the Panel, a copy of which will be provided on admission to the panel and which will include items relating to:

- Maintenance of Insurance Levels
- Confidentiality and Conflict of Interest Declarations
- Compliance with all National and EU Regulations or Equivalent

3.5 Awarding Contracts under the Panel

Qualifying for the panel, does not constitute an award of a contract nor does it indicate that any contract will be awarded. Given that the typical value of contracts will exceed €25k, all requirements will be met by inviting at least three firms to submit a quotation. The panel members shall be invited to tender on the basis of a specification and a clear set of award criteria as well as applicable terms and conditions.

Please note that contracts may include single or multiple projects.

In the case of mini tenders, panel members shall be invited to tender, and contracts will be awarded to the most economically advantageous tender evaluated through the application of some or all of the following award criteria:

Criterion		Range
1	Technical Merit of Team Proposed	0% – 50%
2	Approach and Methodology for Delivery Services	0% – 50%
3	Timeframe for delivery of services	0% - 50%
4	Sustainability	0% – 50%
5	Ultimate Cost or Budget Plan	0% – 100%

3.6 Right to Negotiate

It should be noted that the Contracting Authority reserves the right to award the contract directly following receipt of initial tenders without recourse to negotiations with individual tenderers.

Where rates offered are considered to be outside of the budget the Contracting Authority reserves the right to negotiate with tenderers on each occasion.

Where negotiation meetings take place, all aspects of the tender submitted may be discussed, including costs. Those tenderers will be afforded an opportunity to submit a Best and Final Offer (BAFO), which will be assessed against the award criteria.

3.7 Right to use Different Types of Contracts and Contracting Models

The contracting authority reserves the right to award a contract, contract with options, or a single party framework on foot of the panel competition.

3.8 Right to Contract outside of the Panel

The contracting authority also reserves the right to contract with individuals outside of the panel for special projects.

3.9 Reliance on the Capacity of other Entities

Applicants are reminded that they may rely on the resources of other entities in order to meet criteria and/or deliver elements of the contract requirements on condition that they can prove to the satisfaction of the RSCI that they will have these resources at their disposal when necessary.

Therefore, an Applicant may consist of a grouping of any number of economic operators¹ where a group come together in whatever form i.e. consortium, joint venture, subcontractors etc. to submit an application in response to this Pre-Qualification Questionnaire (PQQ)² and regardless of the legal relationship between them, the Contracting Authority will deal with all matters relating to this competition through the entity (the “Prime Applicant”) who will carry overall responsibility for the performance of the contract only, if successful irrespective of whether or not tasks are to be performed by a subcontractor or other consortium member.

The Prime Applicant must clearly and comprehensively set out the name, title, telephone number, postal address, and email address of the nominated contact personnel authorised to represent the Applicant and to whom all communications shall be directed and accepted until this competition has been completed or terminated. Correspondence from any other person (including from any subcontractor) **will not** be accepted or responded to.

All Prime Applicants relying on the capacity of other entities must:

- a. Identify in Section A of the PQQ as the Prime Applicant for the grouping with whom the Contracting Authority will communicate and with whom any subsequent contractual arrangements will be made if successful.
- b. Identify in Section A of the PQQ the relevant 3rd parties upon whose capacity the Prime Applicant is relying upon to meet criteria and/or deliver elements of the contract and identify the relevant criteria and elements of the contract.
- c. Ensure Section A of the PQQ including all subsections are completed and submitted for all relevant 3rd parties upon whom the Prime Applicant is relying on to meet criteria and/or deliver elements of the contract if awarded.
- d. In all applications, the Prime Applicant must nominate the reference contracts for inclusion in the assessment and selection process. The number of reference contracts for which details are to be provided will be nominated in section B of the PQQ of the Prime Applicant. If more reference contracts are provided than required only the first listed reference contracts to the number specified (e.g. 3 reference contracts) will be considered. Where relying on the experience of others, at least one of the references provided should include reference to the relevant experience.

Where the Applicant consists of a grouping of economic operators and the Applicant is subsequently successful at tender stage the Contracting Authority may require the members of the Applicant to

¹ ‘Economic operator’ means any natural or legal person or public entity or group of such persons and/or entities, including any temporary association of undertakings, which offers the execution of works and/or a work, the supply of products or the provision of services on the market; (Art 2(10) of Directive 2014/24/EU).

² Pre-Qualification Questionnaire / Application Form are the same document.

enter into a formal arrangement that can support the provision of collateral warranties to the Contracting Authority for the Applicant members' performance, etc. of the contract.

3.10 Contract Management

Performance of service providers will be continually monitored over the term of any contract awarded under the panel. If a service providers performance is deemed unsatisfactory and the short comings cannot be addressed, then they will lose that contract and it will be awarded to the next highest scoring submission under the mini competition. Removal from a contract can result in the service provider being removed from the panel, which will continue with the remaining members. Quality of service, lead times & user satisfaction will be the main criteria for measuring performance. It is expected that the successful Tenderer(s) will take a proactive role in monitoring performance with a view to making appropriate recommendations where necessary.

The Contracting Authority requires tenderers to nominate a dedicated contract manager who will act as the main point of contact for the duration of contracts awarded under the panel. This person shall have the authority to deal with all matters in relation to contracts and be responsible for the satisfactory delivery of the event management services for community, and cultural events in the public domain 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
- Ensure the relevant invoicing arrangements agreed are implemented

3.11 Sustainability

[we should put in a blurb here on commitment]

4. Selection Criteria

4.1 Summary of Criteria

The table below summaries the requirements for information for those interested in applying for membership of the panel. To apply, you are required to complete the Appendix A Application Form which is available as a separate Word File.

Ref	Pass/Fail Criteria	Pass Requirement
A1	Applicant Summary	Applicants must complete this section. If the Applicant is a grouping, then a separate questionnaire must be completed for each group member.
A2	Tax Compliance	Applicants must provide information regarding their tax compliance. Please note rules on tax compliance. Applications must complete the self-declaration (A2-A4)
A3	Financial Standing	Confirmation of financial standing ensuring the applicant 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. Applications must complete the self-declaration (A2-A4) Evidence will be required prior to confirmation as a member of the panel.
A4	Insurance	Applicants must provide information regarding the insurances in place and are asked to note that the levels required must be in place for the firm(s) being awarded this contract. Applications must complete the self-declaration (A2-A4)
A5	A6 Institutional Authorisation for Pre-Clinical Research Organisations	Establishments must demonstrate that they are registered with and authorised by the competent authority in accordance with Article 20(1) of the Directive (2010/63/EU) and Regulation 35 of S.I. No. 543 of 2012, as amended by S.I. No. 434 of 2013, S.I. No. 174 of 2014, S.I. No. 552 of 2016 and S.I. No. 553 of 2018 (hereafter referred to as the Regulations) or if outside of the EU but within the GPA, must be certified to equivalent standards by a local competent body.
A6	Declaration of Bona Fides	Applicants must complete, sign and date this Declaration. Non-compliant Applicants under any of the headings will be automatically disqualified.

Ref	Weighted Criteria	Max points available	Assessment	Min points required
B1	Previous Contracts	6,000	Applicants should refer to instances within the last five years which demonstrate that they have successfully delivered services of a comparable nature, scope, scale and complexity on one (1) occasion. The contract referenced for consideration should provide comprehensive information to enable the Contracting Authority to determine their comparability to the requirements of this procurement as detailed in Section 6.	3,000
B2	Quality, Health, Safety and Welfare	3,000	Applicants must demonstrate compliance and have systems in place to ensure compliance and to promote best practice and continual improvement in terms of quality, health, safety and welfare. Reference to commitment to the Three Rs Guiding Principles or equivalent would also be relevant in this response. The Contracting Authority reserves the right to seek further information to verify compliance.	1,500
B3	Sustainability	1000	Applicants must describe their organisation/company-wide systems or measures in place which promote sustainability and reduce any harmful impact on the environment associated with delivering the relevant services in addition to any initiatives that support the circular economy and/or social and community inclusion.	n/a
TOTAL		10,000	N/A	n/a

4.2 Qualitative Scoring Methodology for Weighted Criteria B1 and B2

Applicants should note that they must achieve a minimum rating of 50% for the individual qualitative criteria (B1 and B2) above to avoid elimination from the competition. Qualitative criteria will be scored using the following baseline scoring system and an Applicant may be awarded any score between 0 and 100% under criterion (B1 and B2).

Score	Meaning	Interpretation
90 – 100%	Outstanding	An outstanding 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 suitable 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%	Unacceptable	A poor response demonstrating limited to no understanding with insufficient or no details and a risk of non-delivery. This is an unacceptable response and will be classified as a fail.

NOTE: As this competition relates to a Panel, those who fail in their application will be notified of the reasons and are fully entitled to re-apply having addressed the improvements needed.

5. About the Contracting Authority

RCSI University of Medicine and Health Sciences, was established in Dublin in 1784 and is focused on medical and health sciences education. RCSI also conducts cutting-edge research aimed at translating discoveries into clinical practice to enhance patient care. Our mission is to 'Educate, nurture and discover for the benefit of human health'. RCSI is an independent, not-for-profit university which remains committed to institutional independence, service, academic freedom, diversity and humanitarian concern. Our independence enables us to chart our own course in service of excellence in human health. Key research areas include cancer, neuroscience, population health, regenerative medicine, and vascular biology. Through its innovative research and global collaborations with healthcare institutions, industry, and academic organizations, RCSI advances medical knowledge and healthcare standards worldwide. The university's collaborative research environment drives innovation and positions RCSI as a leader globally. RCSI has ranked number five in the world for SDG3 'Good Health and Well-being' in the Times Higher Education University Impact Rankings 2024.

6. Scope of Requirements

RSCI seeks to establish a panel of qualified preclinical contract research organisations (CROs) specialising in disease models to support our early-stage drug discovery and development projects. The chosen CROs will be added to the panel who can provide comprehensive preclinical research services, ensuring rigorous evaluation of potential therapeutic agents in various disease contexts.

6.1 Scope of Work

The successful CROs will be able to offer preclinical services in various areas, including but not limited to the following – applicants may apply if they have expertise one or more of the areas:

1. **Disease Model Development and Validation**
 - Creation and validation of in vitro and in vivo models that accurately replicate human diseases.
 - Use of genetically modified organisms, cell lines, and tissue samples to model disease conditions.
2. **Pharmacological Testing**
 - Evaluation of pharmacokinetics and pharmacodynamics (PK/PD) of candidate compounds.
 - Assessment of drug absorption, distribution, metabolism, and excretion (ADME)
3. **Efficacy Studies**
 - Investigation of therapeutic potential using disease models.
 - Quantitative measurement of treatment effects on disease progression, symptoms, and biomarkers.
4. **Safety and Toxicology Testing**
 - Comprehensive safety assessments to identify potential toxic effects.
 - Data provision on safe dosage ranges and possible adverse effects.
5. **Mechanistic Studies**
 - Exploration of disease mechanisms and therapeutic agent modes of action.
 - Identification of biomarkers for disease progression and treatment response.
6. **Custom Research Services**
 - Tailored study designs to meet specific research objectives and regulatory requirements.
 - Adaptation of protocols based on client needs and emerging data.

Applicants will be considered in situations where they are qualified to provide one or more of the six services outlined above. It is not mandatory to be capable of providing all six services.

7. Instructions to Applicants

7.1 Queries

An application means the submission by an Applicant of a completed Qualification Questionnaire and associated appendices.

Every effort has been made to ensure that this Document contains all the necessary information for the completion of applications. The Contracting Authority does not warrant or represent that this Document, or any other information given to Applicants, is accurate or complete. No liability is accepted for any error, misstatement or omission (negligent or otherwise) in this Document, or any other information given to Applicants.

Requests for additional information and clarification on any matters must be made by via e-mail to the messaging portal on eTenders on www.etenders.gov.ie. All clarifications/additional information will be issued via the eTenders website (www.etenders.gov.ie) and will be made available to all potential Applicants who have noted their interest on the etenders website.

All queries should be submitted on or before the date on the front cover to enable clarifications to be issued to all interested Applicants prior to the deadline date for the receipt of applications.

7.2 Completing the Qualification Questionnaire

When completing the Qualification Questionnaire contained in Appendix 1 to this Document, Applicants should note the following conditions:

All questions must be completed in full and without reference to other documents or other parts of the Qualification Questionnaire.

All questions should be answered with relevance to the subject matter of this competition. For the avoidance of doubt, it is emphasized that the information requested in the Qualification Questionnaire is aimed solely at determining the suitability and choice of Applicants for entry to Panel. In order to ensure that entry to the panel is fair and consistent to all Applicants, you are instructed to respond to the technical questions by giving details of your skill and experience, accurately, honestly and succinctly.

Where a 'Rule' is associated with a particular criterion, Applicants must satisfy the requirements of the rule in order to remain eligible for consideration in the competition.

Applicants are permitted to add lines to the pro-forma tables and boxes set out within the Qualification Questionnaire if required.

The Pre-Qualification Questionnaire must be completed in English or Irish and where copies of original documents are provided in languages other than English or Irish, a complete and accurate English

translation should be provided, or the documents will not be considered during the evaluation process.

All financial information should be denominated in Euro (€), except where financial information is being provided in a certified or audited supporting document such as a set of financial statements in which case it is sufficient for the information to remain in its original currency.

Failure to provide a sufficient level of detail, or to explain adequately any relevant matters, may result in such data or information not being taken into account during the evaluation process.

Applicants for qualification 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 in order to enter into the contract.

Applicants are reminded that they may rely on the resources of other entities in order to establish the suitability 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 application is from a consortium / joint venture, Applicants 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 supplier who will assume overall responsibility for delivery, and who is authorised to sign a contract on behalf of all consortia members. The Contracting Authority will not act as an arbitrator between members of project consortia.

The Contracting Authority reserves the right, subject to procurement regulations and directives, to request clarification of any matter set out in your responses to the Qualification Questionnaire or to request additional information from a Service Provider after the date for submission of completed Qualification Questionnaires has expired.

This document is not a contract, or part of a contract, or an offer to make a contract. The procuring entity has no obligation to enter into a contract with any Applicant.

Applicants are strictly prohibited from discussing any aspect of their application to the Qualification Questionnaire with other Applicants or otherwise exchanging information or colluding in respect of the project. Any Applicant who fails to comply with this requirement may be disqualified.

The Contracting Authority is not responsible for and will not pay for any expense or cost incurred or loss suffered by an Applicant in the preparation or submission of its application or otherwise. Further, The Contracting Authority is not responsible for any travel or accommodation costs incurred by the Applicant unless previously agreed in writing by The Contracting Authority. Each Applicant is fully responsible for the entirety of all expenses and/or costs it incurs in the presentation or submission of an application or in participating in this process and competition.

7.3 Submission of Applications

Applications must be submitted electronically via the eTenders electronic tender facility on www.etenders.gov.ie only. Only Applications submitted through the electronic tender facility will be

accepted. Applications submitted by any other means (including but not limited to by email, post or hand delivery) will not be accepted.

Please note that the eTenders electronic tender facility closes at the stated date and time precisely. It is the responsibility of Applicants to use the tender facility correctly, which includes taking responsibility for the safe and timely delivery of the tender.

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

The Contracting Authority will not be responsible if an economic operator fails to upload their documentation or if the uploaded file(s) is/are corrupted and cannot be read by RSCI.

In order to facilitate assessment, Applicants are kindly requested to submit a single attachment inclusive of the completed questionnaire(s)/ tender(s) and all related appendices.

Economic Operators should note the following when making their submission:

- There is a maximum upload limit of 500MB per submission.
- After submitting a response, the response may be modified and re-submitted as many times as may be necessary until the CfT deadline has expired.
- The 'Submit' button will be disabled automatically upon the expiration of the response deadline.

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.

Should you experience difficulty when uploading documents or have any queries regarding the tender submission, please contact the eTenders helpdesk directly via phone +353 818001459, Email irish-eproc-helpdesk@eurodyn.com or select 'Contact Us' on the home page.

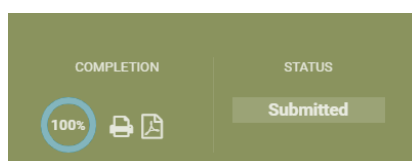
Accessing documents

In order to download all documents associated with a particular Call for Tender, Economic Operators must express an interest in the Call for Tender by associating a user from your organisation with the CfT. It is important to note that you must ensure you ASSOCIATE your company with this tender competition. 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 respond to a tender without an electronic ESPD, a number of steps are required. The final step involves clicking on a Submit button and receiving the following status:



7.4 Opening and Evaluation of Applications

Applications will be evaluated in accordance with the selection criteria, minimum rules and weightings specified in the Qualification Questionnaire.

Applications will be opened in a closed meeting after the closing date for receipt of Applications in the presence of such persons as The Contracting Authority, at its absolute discretion, considers appropriate. Applicants will not be present at the opening of applications.

7.5 Clarification of Applications

While not being obliged to seek clarifications from Applicants, the Contracting Authority reserves the right, at its absolute discretion, to ask Applicants for clarification or elaboration of their applications to assist in its evaluation of applications.

However, it is stressed that the Contracting Authority does not seek clarification where any of the pass requirements set out in the Qualification Questionnaire have not been met.

Therefore, Applicants should pay particular attention to ensure that their applications contain all the required information as even small administrative errors (such as failure to sign or date a declaration) will not be clarified by the Contracting Authority where the required information forms part of the pass requirement.

7.6 Interference

Any effort by the Applicant 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 Applications and in decisions concerning the award of the contract shall have their Application rejected.

In accordance with Section 38 of the Ethics in Public Office Act 1995 any money, gift or other consideration from a person holding or seeking to obtain a contract will be deemed to have been paid or given corruptly unless the contrary is proved

7.7 Inducement to Purchase

The Contracting Authority shall be entitled to disqualify an Applicant in one of the following circumstances:

- (a) if the Applicant has offered or given or agreed to give to any person any gift or consideration of any kind as an inducement or reward for doing or forbearing to do or for having done or forborne to do, any action in relation to the obtaining or execution of this contract award procedure or showing or forbearing to show favour or disfavour to any person in relation to

- this contract award procedure or any other contract award procedure with The Contracting Authority, or
- (b) if like acts have been done by any other person employed by the Applicant or acting on its behalf (whether with or without the knowledge of the Applicant).

7.8 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 Euros (€). All prices and rates quoted should be **exclusive of VAT**.

A schedule of payments will be agreed with the successful panel member. The Contracting Authority operates in accordance with the European Communities (Late Payment in Commercial Transactions) Regulations 2012. The method of payment used by The Contracting Authority is normally Electronic Funds Transfer.

7.9 Conflict of Interest

Any conflict of interest involving an applicant (or applicants in the event of a consortium bid) must be fully disclosed to The Contracting Authority. Any registrable interest involving the applicant and The Contracting Authority or employees of The Contracting Authority or their relatives must be fully disclosed in the submission or should be communicated to The Contracting Authority immediately upon such information becoming known to the applicant, in the event of this information only coming to their notice after the submission of a bid and prior to admittance to the panel. The terms 'registrable interest' and 'relative' shall be interpreted as per Section 2 of the Ethics in Public Office Act, 1995. Failure to disclose a conflict of interest may disqualify an applicant or invalidate an award of contract, depending on when the conflict of interest comes to light.

7.10 Freedom of Information Act

Applicants should be aware that, under the Freedom of Information Act 2014, information provided by them during this Competition may be liable to be disclosed. Applicants are asked to consider if any of the information supplied by them in response to this request should not be disclosed because of its sensitivity. If this is the case, applicants should specify the information that is sensitive and the reasons for its sensitivity. The Contracting Authority cannot guarantee that any information provided by applicants, either in response to this request or while 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, EU and Irish Government Procurement Procedures or in response to questions, debates or other parliamentary procedures in or of the Oireachtas (the Irish Parliament). 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.

7.11 Tax Clearance Certificate

It will be a condition of award of contract that the successful panel member shall, for the term of such contract(s), comply with all EU and domestic tax laws. Applicants are referred to www.revenue.ie for further information. Prior to the award of any contract arising out of this competition, the successful Applicant shall be required to supply its Tax Clearance Access Number and Tax Reference Number, where relevant, to facilitate online verification of their tax status by The Contracting Authority. By supplying these numbers, the successful Panel member, acknowledges and agrees that The

Contracting Authority has the permission of the successful panel member to verify its tax cleared position online. <mailto:nonrestaxclearance@revenue.ie>

7.12 Withholding Tax

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: 353-1-6733533).

7.13 Irish Legislation and Law

Applicants should be aware that national legislation applies in other matters such as Employment, Working Hours, Official Secrets, Data Protection and Health and Safety. Applicants must have regard to statutory terms relating to minimum pay and to legally binding industrial or sectoral agreements in delivering contracts awarded to The Contracting Authority.

The contract[s] awarded on foot of this process will be governed by Irish law.

7.14 Correction of Errors

In general, the following approach will be applied to manifest errors:

- Where there is a discrepancy between the hard copy and the electronic copy of the submission, the hard copy will take precedence.
- Where there is a discrepancy between amounts in figures and words the amount in words shall apply.
- 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.

7.15 Change in the Composition of an Applicant

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

7.16 Notification of Evaluations

All Applicants will be informed of the outcome of their proposals following evaluation and any necessary clarifications. Potential outcomes can be:

- a) Letter of Intent of admittance to panel.
- b) Letter of Regret providing reasons for rejection and notifying suppliers that they can reapply for membership of the panel.

7.17 Policy on Personal Debriefings

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

7.18 Replacement Personnel

Notification must be sent in writing as soon as possible to The Contracting Authority on any proposed change of nominated personnel, such change to be subject to the written approval of The Contracting Authority. Replacement personnel must be of equal or better standing than the existing personnel in terms of qualifications and experience.

7.19 Copyright

The service provider will have copyright of all materials developed for programme delivery, but will provide the Contracting Authority with a perpetual licence to use such material but only for its own purposes (to be agreed with the successful panel member).

7.20 Brand Names, etc.

Please note in relation to this 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".

7.21 European Single Procurement Document

Under the 2014 Directives, suppliers may have compiled an ESPD which will be accepted as evidence of compliance with Section A of the Questionnaire. However, the Contracting Authority requires evidence via completed submission of Section B relating to Technical Capacity. Mere confirmation **will not be** sufficient under these headings.

Progression to panel will be conditional upon identified Applicants providing evidence of self-declared information to the Contracting Authority when requested. Failure to provide appropriate evidence within the required timeframe specified will result in the Applicant being deemed inadmissible for the panel but may apply again over the life-time of the panel.

APPENDIX A:



PANEL APPLICATION DOCUMENT (provided as a separate word document)

Please read this document in conjunction with the Invitation for Panel Membership document

Contracting Authority:	RCSI University of Medicine and Health Sciences	
Procedure:	Panel under Competitive Procedure with Negotiation on the basis that the service comprises a Title III Service in accordance with Directive 2014/24/EU.	
Duration of Panel	The panel will be established for six (6) years with the option for additional annual advertising to recruit certain skills if required. Applications can be received at any time over the life of the Panels, any party who fails to qualify may re-apply at any time.	
Name of Applicant		
Areas of Interest (please tick as many areas as relevant to your organisation – note that during the life of the panel you can request amendment to your qualification where specialist areas change.	1. Disease Model Development and Validation	
	2. Pharmacological Testing	
	3. Efficacy Studies	
	4. Safety and Toxicology Testing	
	5. Mechanistic Studies	
	6. Custom Research Services	

SECTION A - PASS/FAIL CRITERIA

A1. APPLICANT SUMMARY

Weighting: Pass/Fail only

Pass requirement: Applicants must complete this section.

Applicant Company Name:				
Address:				
Eircode/Postcode:				
Contact Person:				
Position:				
Office Telephone:				
Email:				
Website:				
Date of Establishment, if applicable				
VAT Registration No:				
Legal Structure – Company (Ltd), Partnership, Sole Trader, any other				
Overview of Organisation including services, supplies offered, and markets served				
Please confirm if you are an SME (Small and Medium Enterprise) as defined in Commission Recommendation 2003/361/EC*	Yes		No	
*Definition as per 2003/361/EC The company of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR50million, and/or an annual balance sheet total not exceeding EUR43million.				

A1b Relying on the Capacity of other Entities (see Section 3.9 above for instructions)
 Applicants can rely on the capacity of other entities. If the Applicant wishes to rely on the capacity of other parties including sub-contractors to meet criteria and/or deliver elements of the contract, full details should be provided below.

Section A of the PQQ must be completed by those parties, and the Prime Applicant must confirm that if successful that those other parties are available to deliver the services when required and may be required to co-sign the formal Services contract.

Is the Applicant a Prime Applicant acting on behalf of a group of economic operators regardless of legal form of grouping?	Yes		No	
--	-----	--	----	--

If yes, please provide the information below on the other parties in A1b and provide details below on the type of grouping e.g. consortium, joint venture, subcontracting etc.

Is the Applicant a party upon whom the Prime Applicant is relying upon as part of their application?	Yes		No	
--	-----	--	----	--

If yes please furnish a completed Section A of this PQQ to the Prime Applicant for submission

A1c Reliance on other Entities - Details and Contributions:

Name	Service to be delivered and/or criterion where Applicant is relying on their resources	Section A including all sub-sections completed			
		Y		N	
		Y		N	
		Y		N	

Confirmation that relevant information is provided for all entities upon whose capacity the Applicant is relying upon and their agreement to participate has been secured.	Y		N	
--	---	--	---	--

Self-Declaration Form (A2-A4)**A2Tax 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

Applicant 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

A3 Financial Capacity**Financial Year**

If turnover figures for 2024 are unavailable, please use 2023, 2022 and 2021.

2024**2023****2022****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)

Yes

No

I confirm that I will supply evidence of financial standing, by way of auditor's letter, ensuring the applicant 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

A4 Insurances

I confirm that we have the following insurances in place and agree to upgrade to the specific levels where a contract award decision is pending.

Insurance Type	Level in place	Details of Excess	Expiry Date
Employer Liability	€13 million		
Public Liability	€6.5 million		
Professional Indemnity	€1 million (this may need increase for a specific contract)		
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 in the award of a contract		Yes	
		No	
I confirm that if successful, where the levels required under the contract 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.			
Authorised Signatory:			
Name in Block Capitals:			
Position			

A5 Institutional Authorisation for Pre-Clinical Research Organisations

Weighting: Pass/Fail

Minimum requirement to remain eligible in the competition:

Establishments must demonstrate that they are registered with and authorised by the competent authority in accordance with Article 20(1) of the Directive (2010/63/EU) and Regulation 35 of S.I. No. 543 of 2012, as amended by S.I. No. 434 of 2013, S.I. No. 174 of 2014, S.I. No. 552 of 2016 and S.I. No. 553 of 2018 (hereafter referred to as the Regulations) or if outside of the EU but within the GPA, must be certified to equivalent standards by a local competent body.

Please ensure a copy of the relevant registration number / or certification is provided.

Please duplicate where multiple registration/certifications are provided.

Registration Number	
Copy of Certificate Provided – confirmation	Yes / No

A6 - Declaration of Bona Fides (Under Public Sector Directive 2014/24/EU - Article 57)**Weighting:** Pass/Fail**Pass requirement:** Applicants must complete, sign and date this Declaration. The Contracting Authority reserves the right at its discretion to exclude a non-compliant applicant 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).

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?	Yes	No
		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 applicant undue advantages in the procurement procedure; or • negligently provide misleading information that may have a material influence on decisions concerning exclusion, selection or award.		
Declaration re Statutory Obligations			
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.		
Article 5K Declaration			
EU Regulation 2022/576 on restrictive measures in the Context of Russian Actions in the Ukraine			
A.	In the light of Russian actions in the Ukraine, the European Council adopted a new regulation – EU Regulation 2022/576 , aimed at restricting participation in economic activity by economic operators from the Russian Federation. Article 5K of the Regulation prohibits the award or continuation of contracts falling within the scope of the Public Procurement Directives to persons or undertakings related to the Russian Federation. To comply with EU Regulation 2022/576, the Contracting Authority is seeking a declaration from economic operators to this effect.		
B.	I declare that none of the exclusions specified in EU Regulation 2022/576 apply to any party associated with this application.	Yes	No
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 Applications and I am signing on behalf of:			
Name of Economic Operator:			
Authorised Signatory:			
Name in Block Capitals:			
Position:			

SECTION B - WEIGHTED CRITERIA

B1 Previous Experience

Weighting: Maximum Score 6000 marks/Minimum score 3000

Minimum requirement to remain eligible in the competition: Applicants should refer to instances within the last five years which demonstrate that they have successfully delivered services of a comparable nature, scope, scale and complexity on one (1) occasion. The contract referenced for consideration should provide comprehensive information to enable the Contracting Authority to determine their comparability to the requirements of this procurement as detailed in Section 6.

This criterion will be evaluated on the totality of your submission. A maximum page limit of 6 A4 pages using a font size of 11 applies. The Contracting Authority reserves the right to seek further information to verify compliance.

The contracts listed should be chosen to demonstrate your firm's skills, efficiency, experience and reliability in the relevant areas of expertise. 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, Applicants must ensure that they provide sufficient information to allow the Contracting Authority to judge the similarity of these contracts to the services required.

Relying on the Capacity of other Entities:

If this application is not from a single entity, then the referenced contracts should reflect the totality of the contributions of all parties involved including relevant third parties (identified at A2b) above to the successful delivery of each contract where applicable as part of each question for each contract.

Reference Contract #1

Client Name:				
Contact Name:				
Contact email:				
Delivery Date:	From		To	
Contract Value:	€		Period value refers to	
Nature of project and models used				
List any journal publications (if relevant)				
Were any welfare refinements to the procedures made through the duration of the project?				

Were all the project timelines/milestones met? If not explain reasons	
Was project delivered within budget? If not explain reasons	
Please provide any additional information considered relevant.	

B2 Quality, Health and Safety and Welfare

Weighting: Maximum Score 3000 marks/Minimum score 1500.

Minimum requirement to remain eligible in the competition: Applicants must demonstrate compliance and have systems in place to ensure compliance and to promote best practice and continual improvement in terms of quality, health, safety and welfare. Reference to commitment to the Three Rs Guiding Principles or equivalent would also be relevant in this response. The Contracting Authority reserves the right to seek further information to verify compliance.

This should include:

- Adherence to Good Laboratory Practice (GLP) and other regulatory standards to ensure high-quality and reliable data.
- Adherence to with all the relevant health, safety and welfare standards to include Directive 2010/63/EU, Regulation (EU)2019/1010 and the 'Three Rs' (or equivalent).
- Policies, procedures and protocols for; continuous professional development, continuous improvement of practice as part of quality assurance and the implementation of EURL ECVAM recommendations.
- Measures in place to ensure a collaborative approach is taken with RCSI, pharmaceutical and biotechnology companies, academic institutions and government agencies.

This criterion will be evaluated on the totality of your submission. A maximum page limit of 6 A4 pages using a font size of 11 applies. The Contracting Authority reserves the right to seek further information to verify compliance.

ENTER RESPONSE HERE

B3 Sustainability

Weighting: Maximum Score 1000 marks

Minimum score: n/a

Minimum requirement to remain eligible in the competition: Applicants must describe their systems or measures in place at organisational level that which will promote sustainability and reduce any harmful impact on the environment associated with delivering the relevant services including initiatives that support the circular economy and social and community inclusion.

This criterion will be evaluated on the totality of your submission. A maximum page limit of 4 A4 pages using a font size of 11 applies. The Contracting Authority reserves the right to seek further information to verify compliance.

ENTER RESPONSE HERE