



OLLSCOIL NA
GAILLIMHÉ
UNIVERSITY
OF GALWAY

Dynamic Purchasing System (DPS) QUESTIONNAIRE INVITATION FOR DPS MEMBERSHIP

Contracting Authority:	University of Galway
Title:	GALW/CMNHS1218/2025 - Clinical Trials Services Establishment of DPS for the delivery of Clinical Trial Service in 2 Lots as follows: Lot 1: Clinical Research Full Service Clinical Research Services: Device Trials (Partial or Full Service including financial invoicing) Clinical Research Services: Pharma Trials (Partial or Full Service including financial invoicing) Lot 2: Clinical Research Services: Validation and Compliance services for clinical trials
Procedure:	DPS under Restricted procedure
Stage in procedure	This is the first stage of this competitive procedure whereby any interested party may submit a response to this Questionnaire in order to be considered for inclusion on the DPS.
Duration of DPS:	The DPS will be established for ten (10) years.
eTenders Reference (Resource ID):	7840295
Issue Date:	1 st April 2026
Closing Date and Time for Queries:	15 th April 2026, at 12:00 noon (Irish time)
Deadline for submission of Completed Applications <i>for initial work</i>:	1 st May 2026, at 12:00 noon (Irish time)
Ultimate Deadline for submission of Applications for any subsequent work under the DPS:	30 th March 2036, at 12:00 noon (Irish time)
Submission of Queries:	Messaging facility on www.etenders.gov.ie only.

Submission of completed DPS applications

Post-box facility on www.etenders.gov.ie only.

Notes:

- Please note that information relating to this Application, including clarifications and changes, will be published on the Irish Government Procurement Opportunities Portal 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.
- For responding to this DPS, please complete Appendix A (DPS Questionnaire Response Document) which is available on eTenders.
- Please upload your response as a **ZIP FILE** to protect the integrity of the file names.

Contents

Title:	1
1. 1. Disclaimer	3
2. Use of a DPS Questionnaire (Appendix A)	4
3. About the Contracting Authority	5
3.1 The University's Supplier Charter	6
4. Stage in the Procurement procedure	6
5. Scope of Requirements.....	7
5.1 General Requirements.....	7
5.2 Duration of the DPS.....	12
5.3 Numbers to be Admitted to the DPS.....	12
5.4 Estimated Value of the DPS.....	12
5.5 Admission to the DPS.....	12
5.6 Awarding Contracts under the DPS.....	13
5.7 Right to tender outside of the DPS.....	13
5.8 Award Criteria for Future Mini Competitions.....	13
5.9 Fees and Inclusive Rates	15
6. Instructions to Candidates	15
6.1 Queries.....	15
7. Completing the DPS Questionnaire Response Document (Appendix A)	15
7.1 Submission of Applications.....	16
1.1.1 Accessing Documents	17
1.1.2 Submitting your Response	17
7.2 Initial Closing Date for Applications.....	18
7.3 Evaluation of Applications	18
7.4 Clarification of Applications.....	18
7.5 Interference	18
7.6 Inducement to Purchase	18
7.7 Currency and Payment.....	19
7.8 Conflict of Interest.....	19
7.9 Freedom of Information.....	19
7.10 Tax Compliance	19
7.11 Irish Legislation and Law	20

7.12 Change in the Composition of a Candidate	20
7.13 Notification of the Evaluation	20
7.14 Policy on Personal Debriefings.....	20
8. DPS Questionnaire Summary	20
Appendix A – DPS Questionnaire Response Document.....	22
A1. General Information.....	23
A2. Declaration of Bona Fides, Statutory Obligations (under Article 57 of Public Sector Directive 2014/24/EU), Art. 5K Regulation 2022/576/EU, and GDPR	25
A3. Tax compliance	28
A4. Financial capacity	30
A5. Insurances	31
A6. Previous Experience	32
A7. Personnel and Skills.....	38
A8. Health and Safety Management System	38
A9. Quality Assurance Measures.....	40

1. 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.

Candidates 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. Use of a DPS Questionnaire (Appendix A)

The Contracting Authority have provided a DPS Questionnaire Response Document (Appendix A) as a separate document for Candidates to use in preparing their response to this tender. This document and format must be used. Candidate should note that personalisation of the Appendix A is not allowed, and they must not add their branding/colours to the Appendix A.

Please note that in addition to this DPS Questionnaire Document and the Appendix A, any Clarification documents issued by the Contracting Authority during the qualification submission period forms part of the DPS documentation. Candidates must ensure they regularly monitor eTenders and review any Clarification documents published.

The Contracting Authority will not click on any web links in Appendix A responses, so Candidates cannot assume that any material contained in web links will be viewed. Where Candidates submit additional material such as brochures or appendices, they must specifically highlight the information they consider is relevant to their application and clearly explain which criterion it relates to. The Contracting Authority is under no obligation to parse through such material seeking information relevant to the response.

As this is a DPS, candidates who miss the initial deadline may apply at any time during the life of the DPS. Candidates who fail to qualify will be notified of the areas where they failed and are entitled to reapply at any time.

It is recommended to upload your response as a **Zip file** in order to protect the integrity of file names.

3. About the Contracting Authority

University of Galway (herein after referred to as the “Contracting Authority” or University) has been inspiring minds since 1845 as a research-led university. University of Galway is one of the oldest and largest universities in Ireland. We are at the heart of a distinct and vibrant region, renowned for its unique culture, creative industries, medical technologies, marine ecology and economy, and our innovation.

University of Galway is a global [perspective](#), and our university contributes greatly to the diversity and dynamism of Galway, the most international city in Ireland. Through our teaching and research, we attract and develop talent from around the world to address global challenges.

With over 19,000 students, University of Galway has a long-established reputation of teaching and research excellence in the Colleges of Arts, Social Sciences, and Celtic Studies; Business, Public Policy and Law; Engineering and Science, and Medicine, Nursing & Health Sciences. With a complement of over 2,700 (full-time equivalent) staff, University of Galway (Contracting Authority) is one of the largest employers in Galway and makes a significant contribution to the economic, social, and cultural fabric of the city.

University of Galway’s vision is to be a driver of transformational change for our people, our region and our world. We will think globally by inspiring, celebrating and advancing the critical role that our University has in delivering sustainable development. We act locally by empowering our people, investing in our purpose and engaging with the distinctive needs of our region.

We create a distinctively values-based culture, which has excellence, ambition and the wellbeing of our communities at its core. Our vision will be guided by our university values of respect in our actions, excellence in our work, openness in our outlook and sustainability in our approach. Distinguished by kindness and a commitment to equality, this culture will empower our people to thrive. We will harness our distinctive strengths and creative energy to deliver significant and sustainable societal impact.

Our university is at the heart of a distinctive city and region, renowned for its culture, creativity, technology and innovation. Drawing on these distinctive strengths will set us apart internationally. We aim to stimulate creative potential of our students, staff, alumni and wider community to advance our teaching, research, innovation and engagement in and for the world.

Learn more at www.universityofgalway.ie/.

The Institute for Clinical Trials at University of Galway is Ireland’s first dedicated institute for clinical trials, established to transform patient care by rapidly translating scientific advances into improved treatments and health outcomes.

The Institute for Clinical Trials at University of Galway brings together a network of Clinical Trial Units (CTUs) dedicated to operationalising clinical trials. Among these, the CORRIB Research Centre for Advanced Imaging and Core Laboratory and the HRB Clinical Research Facility Galway (CRFG) are cornerstone CTU entities, and clinical trial centres of excellence for the design, operation and execution of clinical research in the University of Galway.

Established in 2008, the **HRB Clinical Research Facility Galway** is a joint venture between Galway University Hospitals (GUH), HSE West Northwest and University of Galway, Ireland. It is uniquely located at a triangular intersection between Galway University Hospital and the Clinical Science Institute at University of Galway and provides the infrastructure, physical space, facilities, expertise and culture needed to optimally support bioscience research. The CRFG focus on studies aimed at understanding a range of diseases and translating this knowledge into regulatory approved advances in patient care.

The **CORRIB Research Centre for Advanced Imaging and Core laboratory** (CORRIB) is established in 2020 and is a centre of excellence for innovation, research, collaboration and education in Cardiovascular research in the University of Galway, Ireland in collaboration with several medical and biomedical institutions and centres at University of Galway and provides cutting-edge imaging methods and decades of cardiovascular imaging expertise to assess the imaging component of these trials and registries to ensure they are reproducible and yield the best outcomes. [<https://www.universityofgalway.ie/corrib-corelab/>]

The CORRIB research centres' main focus is applied clinical translational research, and the CORRIB centre operates in diverse cardiovascular areas to deliver an ambitious research programme of multisite multinational clinical trials. This clinical research program presents an unrivalled opportunity to work alongside such pioneers and global experts in cardiovascular imaging, clinical trials, and innovation in medicine, in an ambitious programme of cardiovascular clinical research in a university that values innovation and collaboration.

Both CORRIB and CRFG operate as integrated CTU units under the Institute for Clinical Trials, facilitating clinical trial readiness, operational excellence, and innovation. They provide essential services such as protocol development, regulatory submissions, study monitoring, data management, and statistical analysis. Their combined expertise enables the Institute to deliver impactful clinical research, foster interdisciplinary collaboration, and support the translation of scientific advances into improved patient outcomes.

Other potential groups under the University of Galway may avail of this tender.

3.1 The University's Supplier Charter

We value the relationships we have with our suppliers, and our Supplier Charter sets out how we require those relationships to be based on our Values of Openness, Respect, Excellence and Sustainability.

All University suppliers and/or service providers shall adhere to the Supplier Charter, available to view and download [here](#).

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

4. Stage in the Procurement procedure

This is a DPS conducted under the

- Restricted Procedure

This is the first stage of the procedure whereby all interested parties may submit a response, but only those meeting the selection criteria will be deemed eligible for admission to the DPS.

5. Scope of Requirements

5.1 General Requirements

There are various services required for a full service CRO, with a speciality in managing clinical trials and post-market clinical follow-up studies. Any prospective service provider should have a track record in Clinical Research Management experience. Specific experience in clinical trials in the field of Cardiology is required for Cardiology trials. The service provider should be able to provide clear demonstration of clinical trial planning, design, set-up and execution, conforming to relevant international best-practice standards (ISO 14155:20 Clinical investigation of medical devices for human subjects — Good clinical practice and/ or article 2 in the EU Regulation on Medical Devices 2017/745, Clinical Trials Regulation (EU No 536/2024) .

The above are essential requirements for any prospective service providers.

The Service Providers may support academic investigator-initiated studies sponsored by the University or studies sponsored by external academic or commercial sponsors where the university has delegated sponsor duties. The service provider will be required to work alongside the Sponsor, the Chief Investigators and the Institute for Clinical Trials, Corrib Corelab and CRFG coordination personnel and other potential groups in the University of Galway. Remote arrangements can be facilitated. Onsite engagement may be required in the relevant unit.

The DPS will consist of 2 Lots:

Lot 1: Clinical Research Partial or Full Service

1A: Clinical Research Services: Device Trials (Partial or Full Service including financial invoicing)

The services of a full-service Clinical Research Organisation are required to provide clinical research support services as required to support scaling the internal expertise and internal team activity as required with the Research centre undertaking clinical trial research. The service provider will have with a speciality in managing device clinical trials and post-market device clinical follow-up studies from study set up phase through to close out. Full service can include all or some aspects and services required with the full-service execution for the trial lifecycle depending on the trial requirements:

- **-Project management, coordination:**

Work alongside the research centre during trial set up, execution and close out as required to delivery clinical research study coordination and project management services including but not limited to coordination of study documentation during set up, regulatory and ethic approval management, site feasibility and selection processes, site contracting process, site initiations and site training, site

management, study management and all associated services during execution phase and study close out phase.

- **- Site management:**

Work alongside the research centre during trial to ensure that all participating sites are fully prepared, compliant, and supported throughout the study. This includes overseeing site selection and feasibility assessments, managing site initiation and training, coordinating regulatory document collection and approvals, and ensuring timely activation of sites. The CRO must monitor site performance, facilitate ongoing communication, and provide guidance to site staff on protocol adherence, data entry, and safety reporting. Proactive resolution of site issues, regular site visits or remote monitoring, and maintenance of essential documents are essential to uphold Good Clinical Practice (GCP) and regulatory standards. The CRO is responsible for ensuring sites meet recruitment targets, maintain high data quality, and deliver patient care in accordance with the protocol, while fostering a collaborative and responsive relationship with investigators and site teams.

- **- Programming and data management:**

Work alongside the research centre during trial set up, execution and close out as required to delivery clinical research database development, database administration and data management services including but not limited to coordination of all data management related documentation during set up including study database set up activities, database testing and validation tasks for eCRF finalization, data management and processing for all study data during study execution and any other data management related services during execution phase and study close out phase.

- **- Safety management:**

Work alongside the research centre during trial set up, execution and close out as required to deliver clinical research device vigilance and safety management services including but not limited to coordination of all study safety documentation during set up including safety database, safety management and processing for all study related safety events during study execution including regulatory and ethics reporting as required, management of clinical event adjudication process and any other safety management related services during execution phase and study close out phase.

- **- Statistical support:**

Operational and strategic biostatistical support for Clinical research activities. Including Protocol design support and statistical analysis plan support for clinical research trials working closely with academic team and coordination team including data management.

Maintenance of statistical database for the clinical studies, drafting and updating relevant statistical standard operating procedures.

Statistical support/advice for the academic/scientific projects of the academic team (e.g. supporting statistical analysis of various imaging analysis).

Working with investigators and the research centre to develop and disseminate statistical methods and techniques that add to the intellectual understanding of the field and the wider scientific and clinical community.

Support the preparation of peer review.

- **Quality and regulatory support:**

Quality and regulatory operational support may be required on occasion as a support/scale up requirement to support internal quality and regulatory resources in the delivery of clinical research

trials with a view to providing and delivering on quality assurance measures as required by the sponsor and coordination centres' programme.

Includes service support for audits and inspections-audit readiness activities and remediation support including CAPA support.

Regulatory gap analysis and quality system update support as required by applicable regulations and standard updates.

- **Medical writing,**

Working alongside the research centre to provide expert development, review, and management of all essential study documents throughout the trial lifecycle. This includes drafting and updating study protocols, investigator brochures, informed consent forms, patient information sheets, and clinical study reports (CSRs), as well as preparing regulatory submission documents and safety narratives. The CRO's medical writers must ensure that all documentation is scientifically accurate, clear, and compliant with global regulatory standards (e.g., ICH-GCP, FDA, EMA), facilitating ethical review, regulatory approval, and effective communication of study results. Medical writing also encompasses the preparation of scientific publications, abstracts, and educational materials to disseminate findings to stakeholders and the broader research community. The CRO must maintain rigorous quality control, editorial review, and timely delivery of documents, supporting the successful conduct and completion of the clinical trial.

Financial invoicing support if applicable

Working alongside the research centre to establish robust systems for managing all financial aspects of the study. This includes generating accurate and timely invoices for services rendered, tracking payments and expenses, and maintaining comprehensive financial records in accordance with contractual agreements and regulatory requirements. The CRO must coordinate with sponsors and sites to ensure transparency in billing, resolve any discrepancies, and provide regular financial reports. Administrative responsibilities also encompass document management, scheduling, correspondence, and support for regulatory submissions. Effective financial and administrative management ensures the trial operates smoothly, remains compliant, and meets all contractual and budgetary obligations.

1B: Clinical Research Services: Pharma Trials (Partial or Full Service including financial invoicing

The services of a full-service Clinical Research Organisation are required to provide clinical research support services as required to support scaling the internal expertise and internal team activity as required with the Research centre undertaking clinical trial research. The service provider will have with a speciality in managing IMP/ATMP clinical trials and post-market clinical follow-up studies from study set up phase through to close out. Full service can include all or some aspects and services required with the full-service execution for the trial lifecycle depending on the trial requirements:

- **-Project management, coordination:**

Work alongside the research centre during trial set up, execution and close out as required to delivery clinical research study coordination and project management services including but not limited to coordination of study documentation during set up, regulatory and ethic approval management, site feasibility and selection processes, site contracting process, site initiations and site training, site

management, study management and all associated services during execution phase and study close out phase.

- **- Site management:**

Work alongside the research centre during trial to ensure that all participating sites are fully prepared, compliant, and supported throughout the study. This includes overseeing site selection and feasibility assessments, managing site initiation and training, coordinating regulatory document collection and approvals, and ensuring timely activation of sites. The CRO must monitor site performance, facilitate ongoing communication, and provide guidance to site staff on protocol adherence, data entry, and safety reporting. Proactive resolution of site issues, regular site visits or remote monitoring, and maintenance of essential documents are essential to uphold Good Clinical Practice (GCP) and regulatory standards. The CRO is responsible for ensuring sites meet recruitment targets, maintain high data quality, and deliver patient care in accordance with the protocol, while fostering a collaborative and responsive relationship with investigators and site teams.

- **-Programming and data management:**

Work alongside the research centre during trial set up, execution and close out as required to delivery clinical research database development, database administration and data management services including but not limited to coordination of all data management related documentation during set up including study database set up activities, database testing and validation tasks for eCRF finalization, data management and processing for all study data during study execution and any other data management related services during execution phase and study close out phase.

- **- Safety management:**

Work alongside the research centre during trial set up, execution and close out as required to deliver pharma clinical research and safety management services including but not limited to coordination of all study safety documentation during set up including safety database, safety management and processing for all study related safety events during study execution including regulatory and ethics reporting as required, management of clinical event adjudication process and any other safety management related services during execution phase and study close out phase.

- **-Statistical support:**

Operational and strategic biostatistical support for Clinical research activities. Including Protocol design support and statistical analysis plan support for clinical research trials working closely with academic team and coordination team including data management.

Maintenance of statistical database for the clinical studies, drafting and updating relevant statistical standard operating procedures.

Statistical support/advice for the academic/scientific projects of the academic team (e.g. supporting statistical analysis of various imaging analysis).

Working with investigators and the research centre to develop and disseminate statistical methods and techniques that add to the intellectual understanding of the field and the wider scientific and clinical community.

Support the preparation of peer review.

- **Quality and regulatory support:**

Quality and regulatory operational support may be required on occasion as a support/scale up requirement to support internal quality and regulatory resources in the delivery of clinical research

trials with a view to providing and delivering on quality assurance measures as required by the sponsor and coordination centres' programme.

Includes service support for audits and inspections-audit readiness activities and remediation support including CAPA support.

Regulatory gap analysis and quality system update support as required by applicable regulations and standard updates.

- **Medical writing,**

Working alongside the research centre to provide expert development, review, and management of all essential study documents throughout the trial lifecycle. This includes drafting and updating study protocols, investigator brochures, informed consent forms, patient information sheets, and clinical study reports (CSRs), as well as preparing regulatory submission documents and safety narratives. The CRO's medical writers must ensure that all documentation is scientifically accurate, clear, and compliant with global regulatory standards (e.g., ICH-GCP, FDA, EMA), facilitating ethical review, regulatory approval, and effective communication of study results. Medical writing also encompasses the preparation of scientific publications, abstracts, and educational materials to disseminate findings to stakeholders and the broader research community. The CRO must maintain rigorous quality control, editorial review, and timely delivery of documents, supporting the successful conduct and completion of the clinical trial.

Financial invoicing support if applicable

Working alongside the research centre to establish robust systems for managing all financial aspects of the study. This includes generating accurate and timely invoices for services rendered, tracking payments and expenses, and maintaining comprehensive financial records in accordance with contractual agreements and regulatory requirements. The CRO must coordinate with sponsors and sites to ensure transparency in billing, resolve any discrepancies, and provide regular financial reports. Administrative responsibilities also encompass document management, scheduling, correspondence, and support for regulatory submissions. Effective financial and administrative management ensures the trial operates smoothly, remains compliant, and meets all contractual and budgetary obligations.

Any additional Clinical Research Services that relate to the subject matter

Lot 2: Clinical Research Services: Validation and Compliance services for clinical trials and clinical research associated computerised systems.

Work with the Research Centre to ensure that all clinical research associated computerised systems and associated clinical research software packages are introduced, maintained and operating in accordance with GCP, GAMP 5 requirements, Lab Policies and Procedures and regulatory requirements with a keen focus on Data Integrity.

Work with the team on the introduction of new software including validation impact assessment under change control processes and any required validation activities including

preparation of validation related documentation, standard operating procedures, reports, test scripts and change controls with regards to computer systems validation.

Support audit readiness and audit compliance activities relating not only to computer system compliance but also to broader clinical research processes. This includes contributing to internal and external audit preparation, execution, and follow-up activities where validation, compliance, or data integrity considerations are involved.

Any additional Clinical Research Services that relate to the subject matter

5.2 Duration of the DPS

The DPS will be established for six (6) years with an option to extend same for a further period of one (1) year, up to four occasions subject to a maximum overall term of ten (10) years, subject to satisfactory performance, business needs and budgetary constraints the DPS will be continually open for access. Should the DPS cease to operate, all members will be notified via www.etenders.gov.ie and an award notice will be published notifying the termination of the DPS. This will not affect the delivery of any contracts awarded under the DPS.

5.3 Numbers to be Admitted to the DPS

There is no maximum limit to the numbers of Candidates that can be admitted to this DPS.

5.4 Estimated Value of the DPS

The level of expenditure cannot be guaranteed in any given year. However, the estimated total value of any purchases pursuant to the DPS is approximately €5,000,000 (excl. VAT) over the Term.

It is emphasised, however, that these figures are provided strictly for indicative purposes only as there is no guaranteed expenditure. Please see below estimated value breakdown by Lot:

5.5 Admission to the DPS

- (i) Admission to the DPS will be subject to the Candidate passing all of the criteria on the basis of meeting all minimum qualifying requirements.

Candidates can apply for one, some or all Lots.

- (ii) On receipt of an application, Candidates will be contacted to confirm receipt. As soon as possible a notification letter will issue to Candidates confirming either
 - (a) their success in being admitted to the DPS, or
 - (b) their failure to be admitted and the reasons for their rejection.

Unsuccessful Candidates are entitled to reapply at any time.

- (iii) Admission to the DPS for each Lot will be conditional upon the successful Candidates agreeing to the terms and conditions of the DPS, a copy of which will be provided on admission to the relevant DPS, and which will include requirements for the successful Candidates to provide evidence of and commit to maintain
 - Tax Clearance status
 - Insurances of the types specified
 - Compliance status with regard to the Art. 57 obligations relating to corruption, fraud, money laundering, etc.

Note: UoG reserves the right to seek updated information over the life of the DPS and to verify any aspect of their qualification prior to the award of any contract.

5.6 Awarding Contracts under the DPS

Qualifying for membership of the DPS, does not constitute an award of a contract nor does it indicate that any contract will be awarded. When contracts arise over the duration of the DPS they may be awarded through a mini tender to all qualified members of the DPS.

For each mini-tender, DPS members shall be invited to tender based on a clearly defined specification. Contracts will be awarded to the most economically advantageous tender evaluated using the specific award criteria, which will be made known to those invited to participate in the mini-tender.

For contracts under €50K the minimum time limit for receipt of mini tenders can be between 5 and 10 working days from the date on which the invitation to tender is sent.

For contracts over €50K the minimum time limit for receipt of mini tenders shall be at least 10 working days from the date on which the invitation to tender is sent.

5.7 Right to tender outside of the DPS

The Contracting Authority intends to use the DPS for the procurement of requirements falling within its scope during the specified period; however, it reserves the right to go outside the DPS for the procurement of any requirement without reference to the DPS Member(s), however the requirement will be tendered in accordance with the appropriate rules.

Admission to a DPS does not guarantee the award of any contract to any Economic Operator, nor does it give the member(s) the right to be consulted in respect of, or tender for, any contract.

5.8 Award Criteria for Future Mini Competitions

The DPS Client shall specify their own requirements and award criteria (including sub-criteria) in future mini tenders conducted under the DPS. The following are examples of requirements and award criteria/sub-criteria that may be applied (and which DPS Members may be required to demonstrate they fulfil) in future mini-tenders to provide Applicants with an overview of future potential requirements and criteria in future Mini-Competitions at Stage 2. Applicants are reminded that while they are required to submit a response to and fulfil *Appendix A – DPS Questionnaire Response Document*, Applicants are **not** required to submit a tender proposal in response to the requirements and criteria below nor pricing at this Stage 1 of the Competition, which will instead be required in response to future Stage 2 mini-tenders conducted under the DPS.

AWARD CRITERIA	WEIGHTING RANGE
1. Quality of Approach and Service Methodology. May Include: Planning and Service Methodology Risk Analysis Proposed Resources Understanding of Client Brief	0% - 75%
2. Quality of Team Proposed Relevant skills and specific experience of the proposed project team who would be assigned to the notional project. Their contribution to the project would be, their precise role, and responsibilities for the notional contract project 3.Contract Management May include: Contract Management Methodology Managing Change Performance Management 4. Proposals on incorporating of Environmentally Sustainable and /or social considerations	0%-75%
4. Cost	0% - 30%
TOTAL	100%

The Contracting Authority is seeking to promote social considerations, including diversity and wider social inclusion, through this DPS arrangement. Accordingly, the DPS Client may, at its

discretion, include “Proposals on the incorporation of Social Considerations” as an award criterion in future Stage 2 Mini-Competitions conducted under the DPS.

5.9 Fees and Inclusive Rates

Candidates should note that all fees will be determined on a contract-by-contract basis and will be paid on an all-inclusive rate. Additional payments for travel and subsistence will not be made under any circumstances.

6. Instructions to Candidates

6.1 Queries

An application means the submission by a Candidate of a completed Appendix A 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 Candidates, is accurate or complete. No liability is accepted for any error or omission (negligent or otherwise) in this document, or any other information given to Candidates.

Requests for additional information and clarification on any matters must be made by via 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 Candidates who have noted their interest on the eTenders website.

Applicants who bid relying on a subcontracting relationship with another entity must prove the relationship has been in existence before the issue date on this tender document. Documentation of this nature is required to be presented as part of the response.

Furthermore, the Previous Experience section A6 must therefore provide at least 1 reference contract where the subject of a previous tender was provided by both parties in the subcontracting relationship.

All queries should be submitted in accordance with that time and date as indicated on the title page to enable clarifications to be issued to all interested Candidates in sufficient time prior to the deadline date for the receipt of applications.

7. Completing the DPS Questionnaire Response Document (Appendix A)

When completing Appendix A for the relevant Lot(s) applied for, which are attached to the eTenders notice as separate documents, Candidates should note the following conditions:

- (a) All questions must be completed in full and without reference to other documents or other parts of the DPS Questionnaire or Appendix A.
- (b) All questions should be answered with relevance to the subject matter of this competition. For the avoidance of doubt, it is emphasised that the information requested in Appendix A is aimed solely at determining the suitability and choice of Candidates for entry to the DPS. To ensure that entry to the DPS is fair and consistent to all Candidates, you are instructed to respond to the technical questions by giving details of your skill and experience, accurately, honestly and succinctly.
- (c) Where a 'Rule' is associated with a particular criterion, Candidates must satisfy the requirements of the rule to remain eligible for consideration in the competition.
- (d) Candidates are permitted to add lines to the pro-forma tables and boxes set out within Appendix A if required.
- (e) 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.
- (f) Failure to provide a sufficient level of detail or to explain adequately any relevant matters may result in such data or information not being considered during the evaluation process.
- (g) Candidates are reminded that they may rely on the resources of other entities 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.
- (h) Candidates 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 may be required to establish legal personality to enter a contract.
- (i) 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 DPS Questionnaire or to request additional information from a Service Provider after the date for submission of completed DPS Questionnaires has expired.
- (j) 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 a contract with any Candidate.
- (k) The Contracting Authority is not responsible for and will not pay for any expense or cost incurred or loss suffered by a Candidate 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 Candidate unless previously agreed in writing by the Contracting Authority. Each Candidate 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.

7.1 Submission of Applications

The Contracting Authority is using the postbox facility on eTenders, and applications must be submitted electronically via the eTenders postbox facility on www.etenders.gov.ie only. Only

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

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

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

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

Email: irish-eproc-helpdesk@eurodyn.com

Phone: +353-818001459

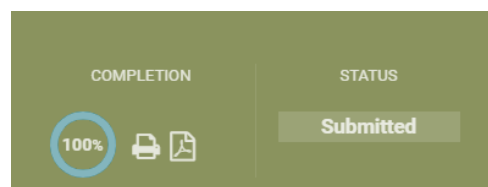
1.1.1 Accessing Documents

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

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

1.1.2 Submitting your Response

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



If you do not receive a message similar to above and an email directly to the inbox of the person who submitted the response, **you have not formally submitted your application.**

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

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

It is the responsibility of the Candidate to ensure that their application is complete and is uploaded in accordance with the instructions provided on eTenders prior to the deadline if they wish to be considered for the initial work to be awarded under the DPS. **Applications that are received late or via other means WILL NOT be considered for the initial work to be awarded under the DPSs.**

7.2 Initial Closing Date for Applications

Applications will be accepted throughout the lifecycle of the DPS at any stage.

The closing date for submission for consideration for initial work is specified on the title page.

Candidates must ensure that they give themselves enough time to upload and submit all required documentation before the closing date/time. Candidates should consider the fact that upload speeds vary. For submissions, the Candidate can upload a total of 2.00 GB of files, with any individual file being up to 250MB. To submit a document to the electronic post-box, please note that you must click "Submit Response". After submitting you can still modify and re-send your response up until response deadline. Candidates should be aware that the 'Submit Response' button will be disabled automatically upon the expiration of the response deadline.

It is the responsibility of the Candidate to ensure that their application is complete and is uploaded by the designated deadline. Applications that are received late or via other means **will not** be considered in this public procurement competition.

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

7.3 Evaluation of Applications

Applications will be evaluated in accordance with the selection criteria and rules as specified in the Appendix A – DPS Questionnaire Response Document.

7.4 Clarification of Applications

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

7.5 Interference

Any effort by the Candidate 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.

7.6 Inducement to Purchase

The Contracting Authority shall be entitled to disqualify a Candidate in one of the following circumstances:

- (a) if the Candidate 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 Candidate or acting on its behalf (whether with or without the knowledge of the Candidate).

7.7 Currency and Payment

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

A schedule of payments will be agreed with the successful DPS member. The Contracting Authority operates in accordance with the European Communities (Late Payment in Commercial Transactions) Regulations 2012.

7.8 Conflict of Interest

Any conflict of interest involving a Candidate (or Candidates in the event of a consortium bid) must be fully disclosed to the Contracting Authority. Any registrable interest involving the Candidate 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 Candidate, in the event of this information only coming to their notice after the submission of a bid and prior to admittance to the DPS. 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 Candidate or invalidate an award of contract, depending on when the conflict of interest comes to light.

7.9 Freedom of Information

Candidates should be aware that, under the Freedom of Information Act 2014, information provided by them at any stage during this Competition may be liable to be disclosed. Candidates 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, Candidates should specify the information that is sensitive and the reasons for its sensitivity. The Contracting Authority cannot guarantee that any information provided by Candidates, 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 because of such disclosure.

7.10 Tax Compliance

It will be a condition of award of contract that the successful DPS member shall, for the term of such contract(s), comply with all EU and domestic tax laws. Candidates are referred to www.revenue.ie for further information. Prior to the award of any contract arising out of this competition, the successful Candidate may be required to supply its Tax Clearance Access Number and Tax Reference Number, if not already available, to facilitate online verification of their tax status by the Contracting Authority. By supplying these numbers, the successful DPS member, acknowledges and agrees that the Contracting Authority has the permission of the successful DPS member to verify its tax cleared position online.

7.11 Irish Legislation and Law

Candidates should be aware that national legislation applies in other matters such as Employment, Working Hours, Official Secrets, Data Protection and Health and Safety. Candidates 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.

7.12 Change in the Composition of a Candidate

The Contracting Authority reserves the right, but is not obliged, to disqualify any Candidate that makes any change to its composition after submission of a DPS Questionnaire. However, Candidates are entitled to reapply on basis of a new membership structure in the case of consortiums or groupings. It should be noted that lead Candidate cannot submit under more than one application.

7.13 Notification of the Evaluation

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

- (a) Letter of Intent of admittance to DPS
- (b) Letter of Regret

Note: Unsuccessful Candidates may reapply at any time.

7.14 Policy on Personal Debriefings

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

8. DPS Questionnaire Summary

Ref.	Pass/Fail Criteria	Pass Requirements
A1	General Information	Candidates must complete this Section. If the Candidate is a grouping, then a separate questionnaire must be completed for each group member.
A2	Declaration of Bona Fides, Statutory Obligations (under Article 57 of Public Sector Directive 2014/24/EU), Art. 5K Regulation 2022/576/EU, and GDPR	Candidates must complete, sign and date this Declaration. The Contracting Authority reserves the right at its discretion to exclude a non-compliant Candidate under each heading.
A3	Tax Compliance	Candidates are required to complete a Self-Declaration Tables . Candidates should note that if invited to tender, they will be required to provide the evidence self-declared prior to receipt of Request for Tender.
A4	Financial Capacity	
A5	Insurance	
A6	Previous Experience	Candidates must refer to instances within the last five (5) years which demonstrate that they have successfully delivered services of a comparable nature and scale on three (3) occasions. The contracts listed should be chosen to demonstrate the firm's skills, efficiency, experience and reliability in the relevant areas of expertise. In completing the table for each reference contract, Candidates must provide sufficient information to enable the Contracting Authority to assess whether the services have been successfully delivered, and their comparability to the requirements of this contract.
A7	Personnel and Skills	Candidates 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. Candidates are reminded that they may rely on the resources of other entities on condition that they are fully described, and that Candidates 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.
A8	Health & Safety	Candidates must provide information which demonstrates operation of Health & Safety systems and procedures in line with all relevant Safety, Health & Welfare at Work legislation. The Contracting Authority reserves the right to seek further information to verify compliance. Evidence of compliance will be required as condition of contract award.
A9	Quality Assurance Measures	Candidates must provide information on the measures, standards, policies and oversight in place to ensure the delivery of a quality service in line with internationally recognised clinical research standards. Any Quality Management, Best Practice and Standards Adherence measures cited must be pertinent to the subject matter of this procurement process and relevant to the Candidate responding to this DPS Questionnaire. The purpose of this question is to ascertain the Candidate's approach and capability as regards delivering a quality service. This can be demonstrated by providing details of an in-house Quality Management System

(QMS) and/or by providing details of *relevant* and *pertinent* independent third-party certified quality certifications. “Relevant” in this sense means that the locations from which it is proposed to deliver some, or all of the services are included on the certificate; “pertinent” implies the services certified are substantive when considering the subject matter of the proposed procurement.

PLEASE COMPLETE THE SEPARATE APPENDIX A DPS QUESTIONNAIRE RESPONSE DOCUMENT FOR EACH LOT APPLIED FOR.

DPS QUESTIONNAIRE RESPONSE DOCUMENT

(Please read in conjunction with the DPS Questionnaire)

Title:	Establishment of DPSs for the delivery of XXX services in XX Lots as follows: • Lot 1: XXX • Lot 2: XXX	
Name of Candidate/Lead Candidate:		
This application refers to:	One Individual	☐
	Multiple Individuals	☐
	If multiple individuals, indicate number:	
Contact Email:		
Contact Phone Number:		
This Application refers to: <i>please check relevant Lot(s)</i>	Lot 1: XXX	☐
	Lot 2: XXX	☐
Closing Date for Queries:		
Closing Date / Time for receipt of Completed Applications for initial work:		

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?	☐	☐
Please detail the contributions 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.		
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 third-party is clearly identified throughout the response
		☐

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.

		☐

Multiple Participation of Sub-Contractors

University of Galway is aware that given the specialised nature and limited availability of some of the requirements, a sub-contractor could potentially be supplying equipment and/or services to more than one applicant. Equally, an applicant may not know at this stage, i.e. prior to submission of a formal tender, which sub-contractor is best suited to provide the relevant equipment and/or services. Applicants should therefore, in their responses, include a completed questionnaire for any and all potential sub-contractors it may wish to subsequently consider for the provision of any substantive part of the tender. However, for the avoidance of doubt, should a sub-contractor be named by more than one applicant, that sub-contractor whilst legitimately participating in the tender process for more than one applicant will not be allowed to participate directly in any stage or discussion process for any applicant. In such circumstances, all clarifications/discussions/negotiations will be carried out with the Lead Contractor and any sub-contractors not part of another tender.

As an Applicant we fully understand and accept this approach. Yes ☐ No ☐

A2. Declaration of Bona Fides, Statutory Obligations (under Article 57 of Public Sector Directive 2014/24/EU), Art. 5K Regulation 2022/576/EU, and GDPR

Weighting: Pass/Fail

Pass requirement: Candidates must complete, sign and date this Declaration.

The Contracting Authority reserves the right at its discretion to exclude a non-compliant Candidate under each heading.

Note: Where a consortium is successful at tender stage, each member of the consortium may be required to complete this Declaration of Bona Fides.

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).

Please check the relevant box (Yes/No):

		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?		
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 2.1a to 2.1i will be excluded.

Please check the relevant box (Yes/No):

2.1	Have any of the following situations applied, within the past three (3) years, or currently apply, to your organisation?	Yes	No
2.1a	The Economic Operator 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	The Economic Operator 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	The Economic Operator is guilty of grave professional misconduct which renders its integrity questionable;	☐	☐
2.1d	The Economic Operator has entered into agreements with other Economic Operators aimed at distorting competition;	☐	☐
2.1e	The Economic Operator 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	The Economic Operator 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	The Economic Operator 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	a. The Economic Operator 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 b. The Economic Operator has withheld such information or is not able to submit supporting documents required under Article 59 of Directive 2014/24/EU; or	☐	☐
2.1i	The Economic Operator 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.	☐	☐

Declaration regarding Statutory Obligations

Please check the relevant box (Yes/No):

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)

In the light of Russian actions in the Ukraine, the European Council adopted a new regulation – [Regulation 2022/576/EU](#), 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.

Please check the relevant box (Yes/No):		Yes	No
I declare that none of the exclusions specified in EU Regulation 2022/576 apply to any party associated with this tender.		☐	☐

Declaration regarding compliance with European General Data Protection Regulation (GDPR)		
Please check the relevant box (Yes/No):	Yes	No
I declare to comply with Privacy and data protection requirements of the (EU) General Data Protection Regulation (GDPR) No. 679/2016.	☐	☐
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:		

A3. Tax compliance

Choose any of the options below:

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	Yes	No
	☐	☐
To this end, please confirm:		
Candidate's Name:		
Candidate's Tax Reference Number (PPSN):		
Access Number:		

OR

Option 2:		
I confirm that I hold a current valid Tax Clearance Certificate (generally relates to Non-Residents ²)	Yes	No
	☐	☐
To this end, please confirm:		
Registration Number:		
Certificate Number:		

² Note for Non-Residents: Please note that a declaration of tax compliance is requested at the selection stage and applying for a tax certificate from the Irish Revenue Commissioners is required. Candidates have three options: a) To confirm and declare having a current and valid Tax Clearance Certificate in place and that tax affairs are in order; b) To confirm holding a valid paper tax clearance certificate; c) To confirm having applied for a Tax Clearance Certificate details of which will be made available as soon as available. Details are available from <https://www.revenue.ie/en/starting-a-business/tax-clearance/apply-for-tax-clearance-certificate/index.aspx>. Please note that there are no costs involved in this application process. If you possess a local tax certificate based on your country of operation this will be considered, however, you must commit to apply and have access to a tax clearance verification from the Irish Revenue Commissioners prior to award decision.

OR

Option 3:

I confirm that I have applied / intend to apply for Tax Clearance status or a Tax Clearance Certificate which will be made available on request.	Yes	No
	☐	☐

AND

Tax Compliance of Third Parties

I confirm that where requested I will ensure that all relevant Third Parties associated with this tender will be in a position to comply with the Tax Compliance obligations.	Yes	No
	☐	☐

A4. Financial capacity			
Please confirm the following by checking the relevant box ('Yes'/'No'):		Yes	No
		☐	☐
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 such other form of documentary evidence that is satisfactory to the Contracting Authority for each party involved in meeting the turnover requirement.		☐	☐
I confirm that I will supply evidence of financial standing, by way of auditor's letter, ensuring the Candidate Party(s) has/have the financial capacity to pay its debts identified on the current statement of assets and liabilities as being the debts as they fall due.		☐	☐
Please provide turnover figures below. If turnover figures for 2025 are unavailable, please use 2024, 2023 and 2022			
Turnover in Financial Year 2025	Turnover in Financial Year 2024	Turnover in Financial Year 2023	
€	€	€	
Month end (e.g. July):	Month end (e.g. July):	Month end (e.g. July):	
I confirm that I am relying on turnover of a third party identified in Section A1 to meet some or all the turnover requirements.		Yes	No
		☐	☐
Name(s) of Third Party/Parties:			
Turnover of third party in Financial Year 2025	Turnover of third party in Financial Year 2024	Turnover or third party in Financial Year 2023	
€	€	€	
Month end (e.g. July):	Month end (e.g. July):	Month end (e.g. July):	

A5. Insurances

The Policies must be placed with a reputable insurance company with a secure financial rating approved by AM Best, Moody or equivalent finance house.

- The successful tenderer shall upon demand provide to the University evidence that the said policy or policies are in full force and effect and shall provide certified extracts reasonably acceptable to the University. Such insurance shall in no event be cancelled or allowed to lapse by the Tenderer during the term of the Contract.

- The successful tenderer shall ensure that Professional Indemnity Insurance is in force for the duration of the Contract and maintain this cover for a further 6 years once the contract has been completed.

- The successful Tenderer shall ensure that any sub-contractors who they engage to carry out the Contract have sufficient insurances in place. The Contractor shall have a system in place to check and validate the insurances of any sub-contractors and ensure they satisfy the requirements of the Tender, including a specific indemnity in favour of University of Galway in relation to the Employers, Public and Products Liability Policies.

Insurance types and minimum required levels:

- Employer's Liability: €13 million
- Public Liability: €6.5 million
- Product Liability: €6.5 million
- Professional Indemnity: €1 million
- Cyber Insurance: €1 million

I confirm that we have the following insurances in place:

Insurance Type:	Level in place	Details of Excess	Expiry Date
Employer's Liability	€		
Public Liability	€		
Product Liability	€		
Professional Indemnity	€		
Cyber Insurance	€		

Please confirm the following:

	Yes	No
If you are using third parties for delivering the services, please confirm they are insured:	☐	☐
I confirm that we 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	☐	☐
I confirm that if successful, where the levels required under the contract or framework are higher than those currently in our possession, we will be in a position to put the required forms and levels of insurances required in place promptly.	☐	☐

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:	

A6. Previous Experience

Weighting: Pass/Fail

Minimum requirement to remain eligible in the competition: Candidates must refer to instances within the last five (5) years which demonstrate that they have successfully delivered services of a comparable nature and scale on three (3) occasions. The contracts / client engagements listed should be chosen to demonstrate the firm's skills, efficiency, experience and reliability in the relevant areas of expertise.

In completing the table for each reference, Candidates must provide sufficient information to enable the Contracting Authority to assess whether the services have been successfully delivered, and their comparability to the requirements of this DPS.

Note #1: All required fields should be completed in full. If the information requested on the value of contracts or identity of clients is considered confidential, Candidates must ensure that they provide sufficient information to allow the Contracting Authority to judge the similarity of these contracts to the services required.

Note #2: Where the Candidate is a grouping relying on the resources of others to meet the previous experience requirement, a minimum of one of the projects must be from the third party identified above under Section A1.

Note #3: Candidates must note that they are to provide contact details for referees for each reference project. The Contracting Authority has the right to contact the referees to verify the information being provided, without further reference to the Candidate. It is the responsibility of Candidates to satisfy themselves that the nominated contact person is in a position to provide a reference if contacted by the Contracting Authority. Candidates should also note that the Contracting Authority may at its discretion contact all referees or referees for the Candidates that will be invited to tender only.

Note #4: The Contracting Authority may require supporting documentation to verify the details provided by the Candidate and Candidates must provide such supporting information without delay when requested by the Contracting Authority. However, where the Candidate is unable, for a valid reason, to provide the requested documentation, the Candidate must inform the Contracting Authority of the reason as to why the documentation cannot be supplied and, if the Contracting Authority considers the reason given to be valid, provide such other suitable alternative documentation to prove, to the satisfaction of the Contracting Authority, that they have the required capacity to deliver the services.

Note #5: Candidates must note the Contracting Authority may deem a Candidate inadmissible based on the feedback received from the referees indicated in the application, where applicable.

Note #6: Where applicant is relying on a subcontracting relationship at least 1 reference contract is required where the subject of a previous tender was provided by both parties in the sub-contracting relationship

Reference Contract #1

Client Name:	
Sector the client operates in:	
Public or Private sector client:	☐ Public sector client ☐ Private sector client
Contact Name:	
Contact email:	
Period of delivery (from/to):	
Contract Value (or range if precise contract value is confidential):	

The contract value above refers to the following period:	
Information in relation to % of contract the Lead Candidate was responsible for:	
If third parties were involved, are they party to this application?	☐ Yes ☐ No
Insert name(s) of third party/parties (if applicable):	
Outline the role of third parties on the contract& provide details of the contractual arrangement between the two parties	
Taking account of the features of the contract / scope of the framework agreement, please provide information in relation to the following, demonstrating comparability with the contract being awarded under this procurement. Note: a) Mere affirmation as a response is not sufficient. b) Where a particular statement is not relevant to the reference contract in question, a response of 'Not Relevant' is appropriate. c) Responses should reflect what the Candidate actually did for the reference contract, not what the Candidate might have done or could do.	
1. Outline how this contract is comparable with the subject matter of the DPS being tendered.	
Candidate's response:	
2. Details of the type of Clinical services provided.	
Candidate's response:	
3. Contracts must demonstrate executed activities associated with that lot	
Candidate's response:	
4. Demonstrate how the services were supported during the life of the reference contract	
Candidate's response:	
5. Any other relevant information:	
Candidate's response:	

Reference Contract #2	
Client Name:	
Sector the client operates in:	
Public or Private sector client:	☐ Public sector client ☐ Private sector client
Contact Name:	
Contact email:	
Period of delivery (from/to):	
Contract Value (or range if precise contract value is confidential):	
The contract value above refers to the following period:	
Information in relation to % of contract the Lead Candidate was responsible for:	
If third parties were involved, are they party to this application?	☐ Yes ☐ No
Insert name(s) of third party/parties (if applicable):	
Outline the role of third parties on the contract& provide details of the contractual arrangement between the two parties	
Taking account of the features of the contract / scope of the framework agreement, please provide information in relation to the following, demonstrating comparability with the contract being awarded under this procurement. Note: a) Mere affirmation as a response is not sufficient. b) Where a particular statement is not relevant to the reference contract in question, a response of 'Not Relevant' is appropriate. c) Responses should reflect what the Candidate actually did for the reference contract, not what the Candidate might have done or could do.	
1.Outline how this contract is comparable with the subject matter of the DPS being tendered.	
Candidate's response:	
2.Details of the type of Clinical services provided.	
Candidate's response:	
3.Contracts must demonstrate executed activities associated with that lot	
Candidate's response:	

4. Demonstrate how the services were supported during the life of the reference contract
Candidate's response:
5. Any other relevant information:
Candidate's response:

Reference Contract #3	
Client Name:	
Sector the client operates in:	
Public or Private sector client:	☐ Public sector client ☐ Private sector client
Contact Name:	
Contact email:	
Period of delivery (from/to):	
Contract Value (or range if precise contract value is confidential):	
The contract value above refers to the following period:	
Information in relation to % of contract the Lead Candidate was responsible for:	
If third parties were involved, are they party to this application?	☐ Yes ☐ No
Insert name(s) of third party/parties (if applicable):	
Outline the role of third parties on the contract& provide details of the contractual arrangement between the two parties	
Taking account of the features of the contract / scope of the framework agreement, please provide information in relation to the following, demonstrating comparability with the contract being awarded under this procurement. Note: a) Mere affirmation as a response is not sufficient. b) Where a particular statement is not relevant to the reference contract in question, a response of 'Not Relevant' is appropriate. c) Responses should reflect what the Candidate actually did for the reference contract, not what the Candidate might have done or could do.	
1.Outline how this contract is comparable with the subject matter of the DPS being tendered.	

Candidate's response:
2. Details of the type of Clinical services provided.
Candidate's response:
3. Contracts must demonstrate executed activities associated with that lot
Candidate's response:
4. Demonstrate how the services were supported during the life of the reference contract
Candidate's response:
5. Any other relevant information:
Candidate's response:

A7. Personnel and Skills

Weighting: Pass/Fail

Minimum requirement to remain eligible in the competition: Candidates 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.

Candidates are reminded that they may rely on the resources of other entities on condition that they are fully described, and that Candidates 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.

Skillset	Number of Full Time Equivalents (FTE)	Number of FTEs provided by 3rd Parties	Minimum Number Required
Project Manager			1
Quality Manager			1
Total			

I confirm that I have attached an organisation chart to my submission:



A8. Health and Safety Management System

Weighting: Pass/Fail

Minimum requirement to remain eligible in the competition: Candidates must provide information which demonstrates operation of Health & Safety systems and procedures in line with all relevant Safety, Health & Welfare at Work legislation. The Contracting Authority reserves the right to seek further information to verify compliance. Evidence of compliance will be required as condition of contract award.

Do you comply with the Safety Health & Welfare at Work Act 2005? Or equivalent	Yes	No
	☐	☐
Name of manager responsible for Health & Safety:		
Health & Safety 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
	☐	☐

A9. Quality Assurance Measures

Weighting: Pass/Fail

Minimum requirement to remain eligible in the competition: Candidates must provide information on the measures, standards, policies and oversight in place to ensure the delivery of a quality service in line with internationally recognised clinical research standards. Any Quality Management, Best Practice and Standards Adherence measures cited must be pertinent to the subject matter of this procurement process and relevant to the Candidate responding to this DPS Questionnaire. The purpose of this question is to ascertain the Candidate's approach and capability as regards delivering a quality service. This can be demonstrated by providing details of an in-house Quality Management System (QMS) and/or by providing details of *relevant* and *pertinent* independent third-party certified quality certifications. "Relevant" in this sense means that the locations from which it is proposed to deliver some, or all of the services are included on the certificate; "pertinent" implies the services certified are substantive when considering the subject matter of the proposed procurement.

Third-party certification(s)

Note: please duplicate where multiple third-party certified systems are operated

Please provide the following details (if the Candidate has multiple relevant certifications, please provide the requested information for all such certifications and duplicate table as required):

Reference title of certification:		
Name of Organisation Certified:		
Name of certified party:		
Name of accreditation body:		
Date of certification:		
Scope of certification:		
Locations to which certification refers:		
Date of first certification:		
Date of most recent renewal:		
Name of person responsible for quality management:		
Confirmation that a copy of third-party certificate(s) has/have been attached to the PQQ submission:	Yes	No
	☐	☐

In house quality management, best practice, standards adherence measures
If you do not have an externally certified system, please provide details of the processes and procedures for ensuring Quality Management in the delivery of the services relevant to this Framework Agreement. Please detail what policies, practices and oversight you have currently in place, and what steps you take to verify and continuously improve your quality management. Please provide up-to-date examples.
Candidate's response: