Fundació Hospital Universitari Vall Hebron - Institut de Recerca (VHIR)

NUM. EXPEDIENTE: 2025-029 PROTEIN PRODUCTION

DOCUMENT OF TECHNICAL SPECIFICATIONS
NOT HARMONIZED TRADE – OPEN PROCEDURE

PRODUCTION SERVICE OF A BIS-SPECIFIC FUSION PROTEIN (DUACEPT) FOR THE PROJECT 'DUACEPT, A NOVEL BIS-SPECIFIC FUSION PROTEIN TO PREVENT TRANSPLANT REJECTION', FOR THE NEPHROLOGY AND RENAL TRANSPLANT GROUP OF THE FUNDACIÓ HOSPITAL UNIVERSITARI VALL HEBRON - INSTITUT DE RECERCA (VHIR).

Subvencions pel finançament de proves de validació (2024-2026) - SLT036/24/000043, finançat per la Generalitat de Catalunya – Departament de Salut

Generalitat de Catalunya
Departament de Salut

"la Caixa" Foundation

CaixaImpulse
Health Innovation Call 2023

The project leading to these results has received funding and support from the "la Caixa" Foundation under the Grant CI23-20514.

Pg. Vall d'Hebron 119-129 | 08035 Barcelona
Edifici Central
T. 937 37 35 00
contractacio.publica@vhir.org / https://vhir.vallhebron.com/ca

Clause 1. Aim of the tender

The aim of this tender procedure is to contract the production service of a bispecific fusion protein (Duacept) to prevent transplant rejection, under the CAIXAIMPULS 2023 (CI23-20514) and PERIS 2024 (SLT036/24/000043) projects, for the Nephrology and Renal Transplant Group of the Fundació Hospital Universitari Vall Hebron - Institut de Recerca (VHIR).

The project leading to these results has received funding and support from the "la Caixa" Foundation under the Grant CI23-20514, and the Subvencions pel finançament de proves de validació (2024-2026) - SLT036/24/000043, funded by la Generalitat de Catalunya – Departament de Salut.

The projects specifically require contracting the in silico design of gene sequences for the expression of different proteins that ultimately form the bi-specific protein in a functional way, including the cloning and preparation of plasmids, with subsequent expression and purification with quality controls. In addition, in order to characterize the binding and biospecificity of the fusion protein against its specific ligands of the different constructs to be developed, a Surface Plasmon Resonance study will be required. These techniques will be used to evaluate the degree of simultaneous binding to the receptors, as well as the degree of competition for their respective receptors. Bispecific heterodimers constructs should be able to be developed, besides homodimer-like structures.

The service cannot be divided into lots, as all its phases, from the in silico design of gene sequences to the functional characterization of the protein constructs, are closely interconnected and require a comprehensive approach from a single company specialized in performing all the steps described above to ensure methodological consistency and compliance with the project requirements.

Gene design, cloning into suitable plasmids and protein expression are critical steps that must be fully aligned to ensure efficient and reproducible production of the constructs. Subsequent purification with quality controls requires a thorough understanding of the upstream process, as any variation in expression may affect the structure, stability and functionality of the proteins obtained.

In addition, the characterisation of binding and bispecificity by Surface Plasmon Resonance (SPR) requires that the proteins maintain their optimal physicochemical properties, which is achieved by having a single entity controlling all the steps of the process. Remarkably, all these steps are essential for the scalability and manufacturing efficiency of the protein to be tested in different in vitro and in vivo models to confirm its biological power. Dividing this service among several lots and among multiple companies would result in the loss of key information, making traceability difficult, increasing experimental variability and compromising the quality and reliability of the results obtained.

Furthermore, the design of protein constructs is a unique and strategic development for the research group, so it is considered essential that the entire process be carried out by a unique company. This measure aims to preserve confidentiality and avoid fragmentation of the knowledge generated, thus ensuring absolute control over the development and characterization of the constructs.

Throughout this specification, the tasks included within the object of this contract are specifically described, as well as the scope of the proposed service.

Clause 2. Maximum tender budget and estimated value of the contract.

In the present tender procedure, the maximum tender budget and the estimated value of the contract do not match.

The maximum tender budget, corresponding to the duration of the service, amounts to the sum of **"ONE HUNDRED AND FIFTY THOUSAND EUROS" (150.000,00 €)** to which, if the amount corresponding to VAT is added, which is "THIRTY-ONE THOUSAND FIVE HUNDRED EUROS" (31.500,00 €), the total sum amounts to **"ONE HUNDRED EIGHTY-ONE THOUSAND FIVE HUNDRED EUROS" (181.500,00 €)**.

Therefore, for each unit of service to be carried out shall therefore be:

Description	Unit Price
In silico design of heterodimers & Production and purification of up to 12 different protein constructs (100ml).	80.000,00 € (*)
Surface plasmon resonance & cellular binding synapses assessment & other eventual structural molecular analyses up to 12 different protein constructs.	70.000,00 € (*)
Production and purification of one protein construct as well as surface plasmon resonance & cellular binding synapses assessment & other eventual structural molecular analyses to be carried out only in the event of an extension.	12.500,00 € (*)

(*) Price that the tenderer, will be able to improve in the ECONOMIC OFFER – Envelope No. 3.

The maximum budget of the tender is divided as follows:

- 29.000,00 € to be charged to the Caixaimpuls Project CI23-20514 entitled: duacept, a novel bi-specific fusion protein to prevent transplant rejection, internal account: 2023.1244. The project leading to these results has received funding and support from the "la Caixa" Foundation under the Grant CI23-20514.
- 121.000,00 € to be charged to the PERIS Project SLT036/24/000043 entitled: NOVA PROTEÏNA DE FUSIÓ BI-ESPECÍFICA DE SEGONA GENERACIÓ PER

PREVENIR EL REBUIG DELS TRASPLANTAMENTS, account 2024.1225. Project SLT036/24/000043, funded by la Generalitat de Catalunya – Departament de Salut.

- In case of additional modification and or requirement of an extension, the additional costs will be covered by another internal VHIR account of the PI of the project. The production and purification of one protein construct, as well as surface plasmon resonance, cellular binding synapse assessment, and other eventual structural molecular analyses (12.500,00€) would apply only if further experiments are required on the construct identified as the most effective candidate, necessitating additional material and analyses.

The estimated base amount of 150.000,00 € has been determined on the basis of costs associated with previous similar technical activities and current market prices for such specialised work. This budget covers the design and expression of protein constructs, including cloning, plasmid preparation, purification with quality controls, Surface Plasmon Resonance (SPR) studies to characterise binding and biospecificity of the constructs against CD80 and PD-1, assessment of simultaneous binding to both receptors and competition studies, as well as their larger scale production for subsequent use in in vitro and in vivo functional tests.

This amount reflects the resources required to carry out the technical procedures, specialised equipment and the delivery of detailed results.

The estimated value for this tender will be **"TWO HUNDRED TWENTY THOUSAND FIVE HUNDRED EUROS" (220.500,00 €)**, to which, if the VAT amount is added, which is "SIXTY-THREE THOUSAND EUROS" (46.305,00 €), the total sum amounts to **"TWO HUNDRED SIXTY-SIX THOUSAND EIGHT HUNDRED FIVE EUROS" (266,805.00 €)**.

Concept	Amount
Total tender base budget	150.000,00 euros
Possible modifications	30.000,00 euros
Possible extensions	40.500,00 euros
Total	**220.500,00 euros**

In accordance with article 204 of Law 9/2017, it is established the possibility of modifying the contract upwards, and up to 20% of the maximum total tender budget. This amount will be paid to the company in the same way and under the same conditions as regulated in these specifications, upon presentation of the invoice by the successful bidder.

Modifications to the contract may occur in the following cases, as long as they do not modify the object of the contract and are justified according to the development of the project:

- Adjustments in the design of protein constructs based on new experimental data that require optimization of protein expression, stability or functionality.
- Modification of cloning or expression strategies if the initially proposed methods do not offer the required levels of production or quality.
- Increasing the scale of production if a larger amount of purified protein is required for additional studies or experimental replicates.
- Changes in quality controls if additional needs for characterization or validation of the constructs are identified, such as new purity, aggregation or functionality analyses.
- Modification of SPR characterization assays if there is a need to adjust experimental conditions, increase the number of interactions analyzed or include new reference controls.
- Incorporation of additional binding and competition studies in case the development of the project requires it for a more complete characterization of the bi-specificity of the constructs.

In no case shall the estimate of the volume of service provision be binding; the VHIR shall pay the invoices for the service actually provided.

The amount of possible modifications and possible extensions shall be charged to open accounts.

- An amount of 30.000,00 € will be allocated for potential modifications. A sum of 40.500,00 € is reserved for potential extensions. Both eventual additional costs will be covered an internal VHIR account of the PI of the project.

*** The service must comply with all legal requirements at the time of contracting and throughout the contract period.

Clause 3. Duration of the contract.

The provision of this service will have an initial duration of three (3) years, with the possibility of extension for a period of two (2) further years.

The service will begin on the day following the formalization of the contract.

In the event that the extension is agreed by the contracting entity, it will be mandatory for the contractor, in accordance with the established in Article 29 of the LCSP.

Clause 4. Technical characteristics of the service.

The purpose of this tender is to contract a specialised service for the design, cloning, expression and purification of recombinant proteins. The creation of protein constructs is required for their subsequent functional characterization using the SPR technique. This technique will allow assessment of the binding affinity and specificity of Duacept constructs against CD80 and PD-1 receptors, including studies of simultaneous binding and competition between receptors. The service will range from plasmid preparation to detailed analysis of biophysical interactions, ensuring high standards of quality and functionality for the developed products. Bispecific heterodimers constructs made from N-terminal domain to C-terminal domain preserving the binding side free from hindrage should be able to be developed, besides homodimer-like structures.

VHIR will provide the company with the necessary existing sequences of targets, test substances, internal standards and specific information required.

It must provide end-to-end solutions for Duacept development and manufacturing, from concept to commercialisation. It must have a professional staff and state-of-the-art technologies together with scientific expertise to provide the service described.

With multiple proprietary discovery platforms, comprehensive in-house CMC development capabilities, and significant single-use bioreactor capacity, the biddder should offer both flexibility and speed across diverse development programs using a scalable manufacturing model. The CRDMO's unified CMC and development services should be designed to accelerate biologics development and minimize reliance on several external partners.

Its global quality system should be fully aligned with international regulatory standards, with GMP manufacturing certifications from key health authorities including the U.S. FDA, EMA, NMPA, ANVISA, PMDA, and HSA. The company should provide "dual-source" manufacturing options to ensure supply chain flexibility and security.

1. In silico heterodimer design and cloning

1.1. Sequence quality control and gene cloning

- A thorough control of the sequences provided by VHIR will be carried out. The control will include verification of the correct alignment of the sequences with the relevant databases.
- The sequences will be cloned into suitable plasmids by standard molecular cloning methods (such as PCR and ligation) to ensure correct insertion and expression of the constructs.
- The plasmids obtained will be sequenced to verify correct cloning before proceeding to the next steps.

1.2. Protein design and mutations

- The in silico design of the protein constructs will be performed using advanced structural modelling tools, employing Deep Learning algorithms such as

ProteinMPNN (DOI: 10.1126/science.add2187). This design will optimise heterodimer formation.

- The identification of mutations to optimise binding affinity and heterodimer stability will be performed by rational design and molecular simulations. The selected mutations will focus on maximising the interaction between the heterodimers, overcoming the stability of the corresponding homodimers.
- Various computational tools will be used to evaluate the binding energy and possible structural stability of the designs.

1.3. Cloning and plasmid preparation

- The cloning of the constructs will be performed following standard methods to ensure accurate insertion into the selected expression vectors.
- Once cloned, plasmids will be amplified and purified using specific high-throughput kits, ensuring the quality and quantity required for large-scale production.
- Plasmids will be verified by sequencing to ensure the accuracy of the construct before submission.

2. Protein production and purification

2.1. Protein expression

- Production of the protein constructs shall be carried out in suitable expression systems, such as ExpiCHO or bacterial systems, depending on the nature of the proteins and the specific characteristics required.
- The scale of expression should be 100 mL per construct, which will allow sufficient quantities to be obtained for purification and subsequent binding tests.
- Expression shall be carried out under optimal conditions to ensure maximum efficiency and performance of the system used.

2.2. Protein purification

- Recombinant proteins will be purified using affinity chromatography techniques, such as protein A capture, to obtain a high degree of purity and biological activity.
- Standard quality controls shall be performed during the purification process, including analyses such as SDS-PAGE/Caliper-SDS R&NR, SEC-HPLC, Western Blot and endotoxin assays (LAL) to ensure that the proteins are suitable for use in the following assays.
- The quantity, purity and biological activity of the purified proteins shall be verified prior to delivery.

3. Characterisation of binding and bi-specificity by Surface Plasmon Resonance (SPR)

3.1. Protein quality control and preparation for SPR

- Before SPR assays are performed, exhaustive quality controls will be carried out on the proteins produced, which will include the determination of their stability and

conformation by methods such as SEC-MALS (Size Exclusion Chromatography with Multi-Angle Light Scattering) and DSF-QC (Differential Scanning Fluorimetry).

- The characterisation of the proteins will include the analysis of the oligomeric state and the verification of their correct foldability.
- Once the proteins have passed these controls, the SPR system will be set up and validated with positive controls, using commercial proteins such as PD-1 and CD80.

3.2. Study of PD-1 and CD80 binding

- Binding analysis will be performed using the SPR technique to determine the binding affinity (dissociation constant KD) of the constructs to PD-1 and CD80 receptors.
- Full kinetic analysis of the complexes will be performed, evaluating both association (kon) and dissociation (koff) constants to obtain a detailed description of the interaction.
- Dose response assays will be performed using various concentrations of the constructs against the selected receptors to determine the binding capacity and specificity of the interaction.

3.3. Confirmation of bispecificity by simultaneous binding

- SPR bispecificity analysis will be performed to confirm the ability of the constructs to bind simultaneously to PD-1 and CD80.
- One of the receptors (e.g. PD-1) will be immobilised on the SPR sensor chip and the different protein constructs will be sequentially injected, followed by injection of the second receptor (CD80). This analysis will confirm the bispecificity of the constructs and their ability to bind to both targets simultaneously.

3.4. Studies of competition among recipients

- Competition studies will be performed using SPR to assess the ability of the protein constructs to compete with natural ligands or antibodies for binding to PD-1 and CD80.
- The data obtained will be analysed to determine the competitive efficacy of the constructs in comparison to natural ligands.

4. Deliverables and deadline

4.1. Deliverables

Project deliverables must include, but not be limited to, the following documents and reports:

- In silico design report of heterodimers
    - Summary of the results obtained during the in silico design phase, including the selected mutations.
    - Analysis methods used, including molecular simulations and binding energy analysis.
    - Interpretation of the data obtained.
    - Conclusions on the feasibility and efficacy of the designs.

  If it must be delivered in 4 weeks at the latest.

- Protein production and purification report

- Summary of the protein expression results, including the yield obtained.
- Details of the methods used in the purification and the results of the quality controls, such as SDS-PAGE and endotoxin tests.
- Interpretation of the data and conclusions on the purity and amount of proteins obtained.

If it must be delivered in 6 weeks at the latest.

- SPR characterisation report
  - Summary of the results obtained in the binding studies of the constructs to PD-1 and CD80 receptors.
  - Methods used in the SPR analysis, including dissociation constant (KD) studies and kinetic profiles (kon, koff).
  - Study of bispecificity by SPR, confirming simultaneous binding to PD-1 and CD80.
  - Analysis of competition studies with natural ligands or antibodies.

If it must be delivered in 6 weeks at the latest.

- Raw data and metadata files
  - The data files obtained during the whole process, including sequence files, SPR test files and the corresponding metadata files.
  - All files will be available for downloading without additional charges for a minimum period of two months.

4.2. Deadline for delivery

The estimated timeframe for the delivery of reports for each phase will be a maximum of 6 weeks from the completion of each Work Package (WP).

Reports and raw data will be delivered according to the established deadlines, and VHIR will be informed of any significant progress throughout the process.

4.3. Post-delivery support

Continuous support shall be provided to VHIR to resolve any doubt or technical incident that may arise, both by e-mail and telephone, with a maximum response time of 1 working day (Monday to Friday, from 8 a.m. to 2 p.m.).

Clause 5. Location and timetable for the provision of the service.

Location where the service is to be provided: Laboratory of Nephrology and Transplants of the Fundació Hospital Universitari Vall Hebron - Institut de Recerca (VHIR).

Hours of service: Monday to Friday, from 8 a.m. to 5 p.m., Barcelona working calendar.

Clause 6. Billing and payment.

According to Law 25/2013, of December 27, 2013, on the promotion of electronic invoicing and the creation of the accounting registry of invoices in the Public Sector, in its Article 4, "*All suppliers who have delivered goods or provided services to the public administration may issue and send electronic invoices. In any case, they will be obliged to use the electronic invoice and to submit it through the corresponding general entry point...".*

The awarded company will invoice electronically the services actually performed. The DIR3 codes to be able to issue the invoice are the following:

DIR3	ACCOUNTING OFFICE	DIR3	MANAGING BODY	DIR3	PROCESSING UNIT
A09006467	Fundació Hospital Universitari Vall d'Hebron-Institut de Recerca (HUVH IR)	**A09006467**	Fundació Hospital Universitari Vall d'Hebron-Institut de Recerca (HUVH IR)	**A09006467**	Fundació Hospital Universitari Vall d'Hebron-Institut de Recerca (HUVH IR)

In the event that the issuance of the electronic invoice is not feasible for exceptional reasons, the contractor will invoice each service rendered through its corresponding invoice, which must be sent to the following e-mail address: factures@vhir.org

Invoices will be issued for each service provided. Each invoice issued must detail the period to which it corresponds, the breakdown/description of expenses by concept and the internal account that should be charged, as well as indicate the references **"L 2025-029"**.

The effective payment of the executed services will be performed by bank transfer, due 30 days / invoice date.

In no case, the contractor will have the right to the revision of prices pertaining to any concept.

The VHIR's fiscal data that must be included in the invoice are the following:

FUNDACIÓ HOSPITAL UNIVERSITARI VALL D'HEBRON - INSTITUT DE RECERCA
VAT: G-60594009
Passeig Vall d'Hebron, 119-129
08035 Barcelona

In the event that the invoice is not issued in accordance with the criteria established and referenced at the beginning of this clause, payment will not be made and the invoice will be withheld until the requested data is correctly indicated.

In the case of electronic invoicing, this will be rejected until the requested data is correctly indicated.

Once the contract ends, including any extensions that may be executed, VHIR will only accept invoices issued after the end of the contract as long as the period of execution of the same is within the term of the tender.

In the event that the invoice is issued after the end of the contract and in accordance with the above paragraph, VHIR will only pay invoices issued within two (2) months after the end of the contract.

The VHIR will only pay the successful bidder for the services actually provided, without, in any case, the VHIR being obliged to exhaust the estimated value of the contract/bid budget.

Clause 7. Responsible of the contract.

The responsible for the contract is Dr. Oriol Bestard, head of the CaixaImpuls and PERIS projects and Head of the Nephrology and Renal Transplant Group, who will basically be responsible for, among others, the functions of management and supervision of the contracted service, conforming the invoicing issued by the service, monitoring, control and issuing the necessary instructions for the proper execution of the contract; determine whether the service provided complies with the prescriptions established for its execution and compliance and reception of the contract on its completion, and comply with the obligations assumed by the Fundació Hospital Universitari Vall Hebron - Institut de Recerca (VHIR) in this contract.

Clause 8. Confidentiality, Protection of personal data and Intellectual and Industrial Property

Notwithstanding the provisions of the current legislation on intellectual property, protection of personal data and confidentiality, the companies awarded in this call for tenders will expressly commit to not giving the information and / or data provided by VHIR, or any use not provided in this bidding document, and / or expressly authorized by the Head of the Research Grants Office.

The company that awards the contract derived from this bidding will have to extend to their employees the obligations assumed by the awarded company, regarding confidentiality, intellectual property and protection of data.

All rights worldwide will be exclusively granted to VHIR for the maximum time established in applicable laws and / or international treaties for their exploitation through any format and / or exploitation modality, including the exploitation of any discovery, invention, creation, work, procedure, idea, technique, drawing, design, image or any other intellectual or

industrial property right generated, raised or acquired as a consequence of the work carried out by the contracting company (hereinafter "Intellectual Property and / or Industrial"), which derives directly or indirectly from the relationship between VHIR and the company awarded in this tender procedure.

The awarded company must inform VHIR of any discovery, creation, invention, idea or any other element that constitutes or is likely to constitute a right of Industrial and / or Intellectual Property partially or totally developed during the contract period.

In the event that the awarded company discovers or develops any creation of intellectual or industrial property, it will be understood that the discovery or development constitutes confidential information of VHIR.

The awarded company must sign all those public and / or private documents that are necessary, in VHIR's discretion, to allow the accreditation of the ownership of VHIR or the proper protection of the aforementioned Intellectual Property and / or Industrial rights in favor of VHIR or of any designated third party.

The awarded company authorizes VHIR to transform, modify, publish, communicate and exploit the work resulting from the execution of the contract derived from this tender procedure.

Clause 9. Allocation criteria

The following criteria and percentages of evaluation of the tender proposals and the determination of the most economically advantageous will be considered for the evaluation of the tender proposals:

1. Criteria evaluable through automatic formulas	**Maximum 60 points**
• Economic Offer	Maximum 40 points
• Automatic Evaluation Criteria	Maximum 20 points
2. Criteria that can be assessed through value judgments	**Maximum 40 points**

9.1 Criteria that can be assessed through automatic formula…….... up to 60 points

The following criteria will be evaluated by automatic formula. The award criteria for assessing the contents of Envelope No. 3 are as follows:

FINANCIAL OFFER.....up to 40 points

It will be valued automatically for each unitary service, in accordance with the following formula:

$$Pv = \left[1 - \left(\frac{Ov - Om}{IL}\right) x \left(\frac{1}{VP}\right)\right] xP$$

P_v= Bid Score to Rate
P = Economic criteria points
O_m= Best Offer
O_v= Offer to be Valued
IL= Bid Amount
VP= Weighting Value = 1

The automatic formula will be applied to each unit price, and the average score will be established.

> ** If after applying the automatic formula to a submitted bid, the resulting value is negative, you will be directly assigned zero (0) points of the economic part.* ***P(N) = 0.***

AUTOMÁTIC EVALUATION CRITERIA…..…. up to 20 points.

Tenderers must mark the automatic evaluation criteria in Appendix No. 1 of the PCAP, which they must provide in Envelope No. 3, as well as the documentation that accredits this:

- **Work meeting to deliver and discuss the detailed report…… 6 points**
  Work meeting to deliver and discuss the detailed report of the structural and bioinformatics analysis of the protein constructs, with results obtained through in silico modelling and simulations, within a maximum of one week after the delivery of the results: A technical meeting to discuss the results obtained from the in silico analysis, including the predictions of heterodimer interactions and the proposed options will be considered.

- **Reduced time for the delivery of reports…… up to 6 points**
  - **Reduced time for the delivery of in silico design report of heterodimers…….. up to 2 points**
    It will be scored as follows:
    - Under than 4 weeks…….. 0,5 points
    - Under than 3 weeks…….. 1 point
    - Under than 2 weeks…….. 1,5 points
    - Under than 1 week..…….. 2 points

  - **Reduced time for the delivery of the protein production and purification report……..…….. up to 2 points**
    It will be scored as follows:
    - Under than 6 weeks…….. 0,5 points

- Under than 5 weeks…….. 1 point
- Under than 4 weeks…….. 1,5 points
- Under than 3 weeks…….. 2 points

- **Reduced time for the delivery of SPR characterisation report…… up to 2 points**
  It will be scored as follows:
  - Under than 6 weeks…….. 0,5 points
  - Under than 5 weeks…….. 1 point
  - Under than 4 weeks…….. 1,5 points
  - Under than 3 weeks…….. 2 points

- **Availability of raw data and metadata files more than 2 months… up to 8 points**
  Raw data and metadata files will be available for downloading without additional charges more than two months.
  It will be scored as follows:
  - More than 2 months and less than 4 months…….. 2 points
  - More than 4 months and less than 6 months…….. 4 points
  - More than 6 months and less than 8 months…….. 6 points
  - More than 8 months…….. 8 points

9.2 Criteria that can be assessed through value judgments..... up to 40 points.

The following criteria can be assessed through value judgments. The value will be done in compared with the tenders submitted. The highest score will be given to the offer that best fits the technical requirements set out in this document. All other bids will be scored proportionally by comparison. Subsequently, the various proposals evaluated in descending order will be sorted out, and the following formula will be applied to obtain the score,

$$P_{op} = P\ x\ \frac{VT_{op}}{VT_{mv}}$$

P_{op}= Score the offer to value
P= Criteria score
VT_{op}= Technical evaluation of the scored offer
VT_{mv}= Technical evaluation of the best scored offer

It will be necessary to present a technical offer of a **maximum of 10 single-sided pages in Arial 11 font.** In the case of submitting a technical offer of more than 10 pages, it will not be evaluated after page 11.

The following criteria will be evaluated by value judgments. The award criteria for assessing the contents of Envelope No. 2 are as follows:

Report on the technical specifications and characteristics of the service ..... up to 20 points

The bidding company must provide a report that includes the following:

- **Specifications and technical characteristics of the design, cloning and expression of the different protein constructs…….. up to 10 points**
  The following should be detailed:
  - Detailed description of the in silico bioinformatics design methods for the expression of the target proteins.
  - Cloning techniques and plasmid preparation, including DNA quality control to ensure the integrity and correct sequencing of the constructs.
  - Methods for transfection or transformation, including details on efficiency and quality control during the process.

- **The following should be described- Specification of the procedures for the purification and quality control of the expressed proteins…….. up to 10 points**
  The following should be detailed:
  - Description of the protocols used for the expression and purification of proteins, ensuring their purity and functionality.
  - Quality control methods, such as measurement of protein concentration, verification of structure by techniques such as SDS-PAGE and mass spectrometry, and confirmation of the biological activity of the proteins.

Memory on the provision of the service …….. up to 20 points

The bidder shall provide a memorandum including the following:

- **Work plan and organisation during the provision of the service.. up to 5 points**
  The following should be detailed:
  - Detailed description of the work plan for the execution of the service, with estimated timelines for each phase (design and cloning, expression, purification, SPR analysis, etc.).
    The delivery times of the reports should not be inserted in this work plan because it is evaluated in the automatic criteria.

- **System of identification and traceability of constructs and derived products…….. up to 5 points**
  - Description of the system used to identify and track protein constructs, plasmids, and derived products throughout the process, from cloning and expression to purification and SPR analysis.
  - Methods to ensure that each phase of the process is properly documented and that the results are traceable and verifiable throughout the project.

- **Data transfer system and access to results……. up to 5 points**

- Data transfer and access system o Description of the data transfer system, including the security and accessibility of the generated reports, such as data from protein purification and SPR interaction analyses.
- Description of how it will ensure that data will be securely available for as long as necessary.

- **Support plan for the resolution of technical incidents and doubts about the results…… up to 5 points**
  - Description of the mechanisms established to provide technical support during the development of the project.
  - Procedures for the resolution of technical incidents related to cloning, expression, purification, SPR analysis and any other part of the process, in addition to the monitoring and management of any queries or doubts raised by the client regarding the results obtained.

In accordance with Directive 1/2020 on the Application of Evaluation Formulas and Scoring of Economic and Technical Proposals, a threshold is established for each criterion to be evaluated and subsequently scored, which in no case may be less than 50% of the evaluation of each criterion.

Therefore, the minimum scores for each sub-criteria in order to apply the formula will be:

1) **Report on the technical specifications and characteristics of the service:**
   - Specifications and technical characteristics of the design, cloning and expression of the different protein constructs (5 points)
   - The following should be described- Specification of the procedures for the purification and quality control of the expressed proteins (5 points)

2) **Memory on the provision of the service:**
   - Work plan and organisation during the provision of the service (2,5 points)
   - System of identification and traceability of constructs and derived products (2,5 points)
   - Data transfer system and access to results (2,5 points)
   - Support plan for the resolution of technical incidents and doubts about the results (2,5 points).

There are two possible options regarding the function of this threshold, depending on whether none of the bids exceeds it (option 1) or at least one of the technical bids exceeds it (option 2).

- Option 1 - If the evaluation of the bids exceeds the minimum evaluation threshold, all of them obtain as a score the value obtained in the evaluation phase and no bid is excluded from the tender.

- Option 2- If any of the bids exceed the threshold, all the bids are scored and no bid is excluded from the scoring phase, nor from the tender.

In the event that only one bidder submits a tender, the formula presented in the technical criteria will not be applicable by the bidder, the results obtained after the subjective evaluation by the person in charge will be enough.

IMPORTANT NOTE: In order to be awarded the contract, the tenderer must obtain at least **twenty (20) points** in the proposal relating to the criteria quantifiable according to value judgements. Otherwise, the bidder will be excluded.

Barcelona, 25th June of 2025

CONTRACTING ORGANISM
Mr. Montserrat Giménez Prous
Manager
Fundació Hospital Universitari Vall Hebron – Institut de Recerca (VHIR)