

Explanatory note: In case of doubt or contradiction between the original in Catalan and the English version of this Specification, the Catalan version will prevail.

**CHARACTERISTICS CHART
Service Negotiated Procedure File**

CONTRACT FILE: 02/2024-SE-PNSPRH

PATIENT RECRUITMENT AND MONITORING SERVICE IN NINETEEN FOREIGN CENTRES WITHIN THE FRAMEWORK OF THE "LIVERATION" RESEARCH PROJECT FOR THE HOSPITAL DEL MAR MEDICAL RESEARCH INSTITUTE FOUNDATION.

A.- PURPOSE OF THE CONTRACT

Description: Patient recruitment and monitoring service in nineteen foreign centres within the framework of the "LIVERATION" research project for the Hospital del Mar Medical Research Institute Foundation, in accordance with the provisions of the tender's Technical Specifications.

This recruitment is carried out within the framework of the following research project:

- *"Unraveling the impact of Radiofrequency in liver surgery: the key to decrease local recurrence? (Liveration)"*.

- This project is funded by the European Commission, within the framework of the Horizon Europe programme. Project 101104360 – LIVERATION.

Obligatory to go to the totality: No.

Lots: Yes. Due to the nature and characteristics of the project, and specifically the need to recruit 570 patients in just 9 months, it is appropriate to divide it into batches, since the recruitment and subsequent follow-up of patients cannot be carried out by a single center, but must be carried out by 19 differentiated European centers. in order to guarantee said recruitment within the indicated period.

Therefore, the bidder will only be invited to participate and present his proposal in a single lot, so the same bidder can only be awarded a single lot.

Mandatory to go to whole batches: Yes.

Obligatory to go to entire sublots: Not applicable.

CPV codes: 73210000-7 "Research consulting services".

B.- ECONOMIC DATA

B1. Determination of the Price of the contract: The price of the service corresponds to the budgetary forecasts determined by the Grant Agreement of the European Union, which have been calculated at € 500.00 per patient recruited and the evaluation of the subsequent intervention and its comparability with other therapeutic alternatives in terms of quality of life and patient experience in real world environments, with a maximum of €15,000.00 per centre. See justification report.

B2. Estimated Value of the Contract for the purposes of applying the award procedure:

ESTIMATED CONTRACT VALUE (VEC): 285.000,00 €

TENDER AMOUNT (excluding VAT): 285.000,00 €

MODIFICATION AMOUNT: 0,00 €

EXTENSION AMOUNT (excluding VAT): 0,00 €

B3. Base tender budget:

TAX BASE: 285.000,00 €

VAT at 21%: 59.850,00 €

TOTAL: 344.850,00 €

The IMIM Foundation is not obliged to exhaust this amount on the basis that invoices, if any, once the contract has ended, could amount to a lower amount than initially planned, as a result of the total or partial use of the service, being limited to the real needs of the IMIM Foundation.

Direct and indirect costs and other possible expenses calculated for the determination of this budget:

In determining the base tender budget, the amounts determined in the European Union Grant Agreement have been taken into account, taking into account direct and indirect costs, and other possible expenses calculated for its determination.

B4. INVOICING TYPE: See Annex 8 of the PCAP.

C.- EXISTENCE OF CREDIT

C1. Certificate of existence of credit: Yes.

C2. Multiannual file: Yes.

Distribution of annuities (if applicable): Yes. See Annex 8 of the PCAP.

D.- DELIVERY PERIOD/DURATION OF THE CONTRACT, RECEIPT AND TRIAL PERIOD

Duration of the planned contract: The recruitment of patients by each of the centers will be carried out within a period of 9 months from the formalization of the contracts and, subsequently, the corresponding follow-up will be carried out until the end of the project scheduled for 05/31/2028.

Extension: The possibility of extension is foreseen for a period of up to 9 months in the event that the financier extends the term of execution of the project. This extension will not imply an increase in the contracted amount.

Trial period: NO.

E.- VARIANTS

Admission of variants: NO.

Elements: Not applicable.

Conditions: Not applicable.

F.- PROCEDURE AND PROCESSING OF THE CONTRACT

Award Procedure: In accordance with Additional Provision 1, section 1, letter d) of the LCSP, and in view of the fact that the contracts to be awarded will be formalized and executed abroad, this contract will be awarded through a negotiated procedure without publicity in accordance with article 168 a) section 2 of the LCSP, given that there are technical reasons, given that only the centers detailed and listed in section IV) of the justifying report have been validated in the Grant Agreement for their capacity, resources and means necessary to carry out said service. The selection of these centers has been based on:

- The presence of highly qualified surgeons specializing in liver cancer and metastasis.
- The number of patients these sites have provided that could be added to the study.

Type of contract: Service contract in accordance with article 17 of the LCSP.

Subject to harmonized regulation: Yes.

Procedure: Ordinary

Electronic processing: Yes.

Online submission of offers: Yes. See "Guide to online submission of offers" attached.

Submission of offers via Digital Envelope tool: NO.

Allowable electronic document formats: PDF and zip formats authenticated by electronic signature are supported. If the documents are not available in this format because they were originally issued on paper, they will provide digitized copies, in accordance with the provisions of the legislation on common administrative procedure of Public Administrations.

Electronic auction: NO.

G.- SOLVENCY and BUSINESS CLASSIFICATION

G1. Economic, financial and technical solvency: In accordance with article 92 of the LCSP, developed by regulations in article 11.5 of Royal Decree 1098/2001, of 12 October, approving the General Regulations of the Law on Public Administration Dealings, bidders are exempt from accrediting economic, financial, technical or professional solvency, given that the estimated value of each lot does not exceed the amount indicated in said provision.

G2. Specific solvency: Not applicable.

G3. Business classification: Not applicable.

H.- MANDATORY DOCUMENTATION TO BE INCLUDED IN THE ENVELOPES: In accordance with the provisions of clause 5 of the Specifications of particular administrative clauses of the tender, and that indicated in Annex 9 of the PCAP.

I.- PROVISIONAL GUARANTEE: Not applicable.

J.- DEFINITIVE GUARANTEE: Not applicable, in accordance with the provisions of the First Additional Provision, first section, letters f) and g) of the LCSP.

K.- CONTRACTING BODY: Director of the Hospital del Mar Medical Research Institute Foundation.

K1. CONTRACTING COMMITTEE: In accordance with article 326 of the LCSP, a Contracting Committee is not constituted.

L.- SUBCONTRACTING AND ASSIGNMENT OF THE CONTRACT

L1. Subcontracting: Subcontracting will only be possible, with prior express authorization from the person responsible for the contract of the Fundació Institut Hospital del Mar d'Investigacions Mèdiques, as established in article 215 of the LCSP.

L2. Assignment of the contract: The successful bidder may not transfer the service provisions of this contract without prior authorisation from the contracting body, in accordance with article 214 of the LCSP.

M.- PRICE REVISION

Price revision proceeds: NO.

Applicable formula (if applicable): Not applicable.

N.- WARRANTY PERIOD

It is necessary to define the Guarantee Term: No.

If so, term and time of start of the computation: -

O.- PUBLICITY OF THE PROCEDURE: Publicity of the award and formalization of the contract in the Official Journal of the European Union (OJEU) and in the Contractor Profile of the Hospital del Mar Medical Research Institute Foundation within the Public Procurement Services Platform of the Generalitat de Catalunya (<https://contractaciopublica.gencat.cat/>).

P.- WORK PROGRAM: In accordance with the technical specifications of the tender.

Q.- DISPROPORTIONATE OFFERS: See Annex 4 of the PCAP.

R.- ECONOMIC AND TECHNICAL ASPECTS SUBJECT TO NEGOTIATION/AWARD CRITERIA: See Annex 4 of the PCAP.

S.- REGIME OF PENALTIES and CAUSES OF TERMINATION OF THE CONTRACT IN ADDITION TO THOSE ESTABLISHED IN GENERAL: See Annex 6 of the PCAP.

T.- SPECIAL CONDITIONS OF EXECUTION: In accordance with Annex 14 of the PCAP of the tender.

U.- RESPONSIBLE FOR THE CONTRACT: Ms. Patricia Sánchez Velázquez, PI of the "LIVERTION" Project, of the Research Group on Ablation Therapies in Oncological Surgery of the IMIM Foundation.

V.- QUERIES RELATED TO THE FILE

E-mail: contractacio@hmar.cat

Those interested in the tender procedure may request additional information from the contracting body on the Specifications and other complementary documentation, provided that they have requested this before the deadline for submitting proposals.

Mandatory visit to the facilities: NO.

W.- PRESENTATION OF PROPOSALS

Place: Telematic offer within the Public Procurement Services Platform of the Generalitat de Catalunya (<https://contractaciopublica.gencat.cat/>).

Date and time: The one established in the invitation to participate.

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- 6.7.- Determination of the most advantageous offer
- 6.8.- Submission of documentation prior to award
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7. FORMALIZATION OF THE CONTRACT

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8. EXECUTION OF THE CONTRACT

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9. MODIFICATIONS TO THE CONTRACT

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15. TERMINATION OF THE CONTRACT

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ANNEX 3.- MEANS OF ACCREDITATION OF ECONOMIC, FINANCIAL AND TECHNICAL SOLVENCY, AND MANDATORY SPECIFIC DOCUMENTATION

ANNEX 4.- ECONOMIC AND TECHNICAL ASPECTS SUBJECT TO NEGOTIATION/AWARD CRITERIA

ANNEX 5.- MODIFICATIONS OF THE CONTRACT

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ANNEX 14.- SPECIAL CONDITIONS OF EXECUTION

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I. GENERAL PROVISIONS

1. ELEMENTS OF THE CONTRACT

1.1.- Applicable legislation and legal nature of the contract

This contract is private and is typified as indicated in **section F of the characteristics table**.

The contract is governed by the clauses contained in this Specific Administrative Clauses Specifications (PCAP) and by the Technical Specifications Sheet (PPT).

It will also be governed by the following regime:

- Law 9/2017, of 8 November, on Public Sector Contracts, transposing into Spanish law the Directives of the European Parliament and of the Council 2014/23/EU and 2014/24/EU, of 26 February 2014 (LCSP).
- Royal Decree 817/2009, of 8 May, which partially develops the Public Sector Contracts Act and other regulations that develop it.
- General Regulation of the Law on Public Administration Contracts (RGLCAP), approved by Royal Decree 1098/2001, of 12 October, as long as it is not repealed by the aforementioned regulations.
- Decree-Law 3/2016, of 31 May, on urgent measures in the field of public procurement.
- Order PDA/21/2019, of 14 February, determining the electronic notification system of the Administration of the Generalitat de Catalunya and its public sector.
- Decree 96/2004, of January 20, which regulates the use of electronic, computer and telematic means in contracting the Administration of the Generalitat.
- Decree 107/2005, of 31 May, on the creation of the Electronic Register of Bidding Companies of the Generalitat de Catalunya.
- Law 29/2010, of 3 August, on the use of electronic media in the public sector of Catalonia.
- The current regulations on the protection of personal data and, particularly, Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights and Regulation (EU) 2016/679, of the Parliament and of the Council, of April 27, 2016, regarding the protection of natural persons with regard to the processing of personal data and the free circulation of these data and repealing Directive 95/46/ EC (hereinafter, General Data Protection Regulation).
- Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights.
- Royal Decree 1720/2007, of 21 December, approving the Regulations implementing Organic Law 15/1999, of 13 December, on the Protection of Personal Data.
- Royal Decree 203/2021, of 30 March, approving the Regulation of action and operation of the public sector by electronic means.
- Law 1/1998, of 7 January, on language policy and its implementing regulations.
- In addition, the remaining rules of administrative law or, where appropriate, the rules of private law are applicable.
- Additionally, it is also governed by the rules applicable to public sector contracts in Catalonia and by its applicable sectoral regulations.

Specific legislation, if applicable:

- Royal Decree-Law 8/2010, of 20 May, adopting extraordinary measures to reduce the public deficit (Official State Gazette no. 126, of 24 May).
- Royal Legislative Decree 1/2015, of 24 July, approving the revised text of the Law on Guarantees and Rational Use of Medicines and Health Products.
- Royal Decree 1591/2009, of 16 October, regulating medical devices.
- Law 31/1995, of 8 November, on the prevention of occupational hazards.
- Royal Decree 192/2023, of 21 March, regulating medical devices.
- Regulation (EU) No. 536/2014, of the European Parliament and of the Council, of 16 April 2014, on clinical trials with medicinal products for human use.
- Law 14/2007, of 3 July, on biomedical research.
- Royal Decree 1090/2015, of 4 December, regulating clinical trials with medicines, the Drug Research Ethics Committees and the Spanish Registry of Clinical Trials.
- Decree 406/2006, of 24 October, regulating the requirements and accreditation procedure for clinical research ethics committees.
- Royal Decree 957/2020, of 3 November, regulating observational studies with medicinal products for human use.
- Royal Decree 1275/2011, of 16 September, creating the Spanish Agency for Medicines and Medical Devices and approving its Statute.
- Royal Decree 1716/2011, of 18 November, which establishes the basic requirements for the authorization and operation of biobanks for biomedical research purposes and the treatment of biological samples of human origin, and regulates the operation and organization of the National Register of Biobanks for biomedical research.
- Law 21/2000, of 29 December, on the rights to information relating to health and patient autonomy, and clinical documentation.
- Law 41/2002, of 14 November, regulating patient autonomy and rights and obligations regarding clinical information and documentation.
- Law 26/2011, of 1 August, on regulatory adaptation to the International Convention on the Rights of Persons with Disabilities.
- Declaration of Helsinki, approved in June 1964 by the World Medical Association (updated in Fortaleza, Brazil).
- Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being in Relation to the Applications of Biology and Medicine (Oviedo Convention, April 1997).
- Instruction 1/2017 of the General Directorate of Professional Planning and Health Regulation of the Department of Health of the Generalitat de Catalunya, of October 26, 2017.
- Common specific criteria for the accreditation, inspection and renewal of the accreditation of clinical research ethics committees approved by the Technical Inspection Committee (CTI) of 15 December 2016, published on the AEMPS website on 3 March 2017.

1.1.1.- This Specification of Clauses and its Annexes will be contractual. The contract shall be in accordance with the content of this Specification, the clauses of which shall be considered an integral part of the respective contract.

1.1.2.- The interpretation of the contract and discrepancies regarding its application, where appropriate, will be made taking into account first the Specifications and the Technical Specifications, which will prevail over any other regulation. In aspects not regulated by them, the regulations listed in section 1.1 will apply in their order of priority.

1.1.3.- Ignorance of the contract in any of its terms and of the other contractual documents of any kind that may have application in the execution of the agreed thing, will not exempt the successful bidder from the obligation to comply with them.

1.2.- Contracting body

The contracting body, the Hospital del Mar Medical Research Institute Foundation (IMIM Foundation), is indicated in **section K of the characteristics table**.

1.3.- Processing and award procedure

The procurement file will be subject to the processing and procedure described in **section F of the characteristics table**.

1.4.- Regime of resources

Special resource on contracting:

In the case of a contract subject to special appeal in the field of contracting in accordance with the provisions of article 44 et seq. of the LCSP, the acts referred to in said article, which are adopted in the contracting procedure, may be subject to special appeal in matters of contracting, in accordance with the provisions of said article.

This appeal is optional, free of charge for appellants, it may be lodged in the places established in article 16.4 of Law 39/2015, of October 1, on the common administrative procedure of public administrations, in the registry of the contracting body or before the Catalan Court of Public Sector Contracts, previously or alternatively, in the filing of the contentious-administrative appeal, in accordance with Law 29/1998, of 13 June, regulating contentious-administrative jurisdiction, and will be governed by the provisions of articles 44 and following of the LCSP and Royal Decree 814/2015, of 11 September, approving the Regulation of special procedures for reviewing decisions in contractual matters and the organisation of the Central Administrative Tribunal for Contractual Appeals.

If the document filing the appeal is filed in a register other than that of the contracting body or the Catalan Court of Public Sector Contracts, it must be communicated to said Court immediately and as quickly as possible.

No ordinary administrative appeals shall be lodged against acts subject to special appeal.

Against the acts adopted by the contracting body in relation to the effects, modification and termination of this contract that are not susceptible to special appeal in matters of contracting, the corresponding ordinary administrative appeal will be lodged in accordance with the provisions of Law 26/2010, of August 3, on the Legal Regime and Procedure of the Public Administrations of Catalonia, and Law 39/2015, of 1 October, on the Common Administrative Procedure of Public Administrations; or contentious-administrative appeals, in accordance with the provisions of Law 29/1998, of 13 July, regulating contentious-administrative jurisdiction.

Appeal of improper height:

In the case of a contract not subject to special appeal in the field of contracting, the acts derived from this award procedure may be challenged administratively by virtue of the provisions of article 44.6 of the LCSP

before the head of the Department of Health of the Generalitat de Catalunya, within the period and requirements that are reported in the notification of the corresponding act or the contentious-administrative appeal, in accordance with the provisions of Law 29/1998, of 13 July, regulating contentious-administrative jurisdiction.

If it is intended to challenge the tender announcement or these specifications, the deadline for lodging the appeal is one month from the day following its publication in the Contractor Profile of the Hospital del Mar Medical Research Institute Foundation.

The maximum period for issuing and notifying the resolution of the appeal will be three months. After this period has elapsed without a decision having been issued, the appeal may be considered rejected.

Against the express rejection or silence of the appeal, a contentious-administrative appeal may be filed before the contentious-administrative courts of Barcelona, within two months from the day following receipt of the corresponding notification (if the resolution is express) or within a period of 6 months from the day following the day on which said appeal is considered rejected by silence.

1.5.- Disability regime

This contract is subject to the disability regime provided for in articles 38 to 43 of the LCSP.

1.6.- Competent jurisdiction

In the case of being a contract subject to harmonized regulation, the contentious-administrative jurisdictional order will be competent to hear about issues related to its preparation and award. Matters relating to the effects, fulfilment and termination of the contract shall be the competence of the courts and tribunals of the civil jurisdictional order.

In contracts that are not subject to harmonized regulation, civil jurisdiction will be competent to hear matters relating to the preparation, awarding, effects, compliance and termination of private contracts concluded by the Hospital del Mar Medical Research Institute Foundation.

In any case, the competent courts and tribunals will be those of the city of Barcelona, expressly waiving any other jurisdiction of competence that may correspond.

1.7.- Responsible for the contract

The person responsible for the contract is described in **section One of the characteristics table**.

The person responsible for the contract is responsible for supervising its execution and adopting decisions and issuing the necessary instructions in order to ensure that the agreed benefit or benefits will be carried out correctly, within the scope of powers attributed to it.

The instructions given by the person responsible for the contract configure the obligations of execution of the contract together with its clauses and specifications.

2. PURPOSE AND SCOPE OF THE CONTRACT

2.1.- The purpose of the contract

The purpose of the contract is the performance of the service described in **section A of the characteristics table**.

The lots into which the contract is divided, if applicable, are identified in **section A of the characteristics table**.

The expression of the codification corresponding to the nomenclature of the Common Vocabulary of Contracts (CPV) is as shown in **section A of the characteristics table**.

2.2.- Needs to be met and suitability of contracts

As provided in article 28 of the LCSP, this tender is held as it is necessary for the fulfillment and realization of the institutional purposes of the Fundació Institut Hospital del Mar d'Investigacions Mèdiques, as described in the PPT and in the justifying report.

2.3.- Admissibility of variants

Variants will be accepted when this is stated in **section E of the characteristics table** and with respect to the aspects and under the conditions expressly established.

2.4.- Duration and extension of the contract

The term of the contract is established in **section D of the characteristics table**.

The contract may be extended if this is provided for in **section D of the characteristics table**. In this case, the extension will be agreed by the contracting body and will be mandatory for the contractor, provided that it is given at least two months' notice before the end of the term of the contract. The extension will not occur, in any case, by tacit agreement of the parties.

However, if at the expiration of the contract the new contract that guarantees the continuity of the service to be carried out has not been formalized, the original contract may be extended until the new contract begins, provided that the conditions and requirements required in article 29.4 of the LCSP are met.

3. BUDGET AND ESTIMATED VALUE OF THE CONTRACT

3.1.- Amount and estimated value of the contract

The base tender budget is established in **section B3 of the characteristics table**.

The estimated value of the contract is as established in **section B2 of the characteristics table**.

For the calculation of this estimated value of the contract, in accordance with the provisions of article 101 of the LCSP, the initial value of the contract plus possible extensions and modifications, if applicable, have been taken into account.

The price of the contract is that of award and must include, as an independent item, the Impost on the Value Added. The price will be considered to include taxes, fees, fees of any kind that are applicable, as well as all expenses arising as a result of the obligations established in the tender specifications that must be fulfilled during the execution of the contract.

Compliance with all regulatory procedures is guaranteed to ensure the existence of credit to meet the economic obligations arising from the contracts concluded.

In the event that the contract is formalized in the budget year prior to the start of its execution, advance expenditure file, the award will be subject to the suspensive condition of existence of adequate and sufficient credit to finance the obligations arising from the contract in the corresponding budget year.

3.2.- Price review

The formula or price revision system applicable to this contract is detailed in **section M of the characteristics table**. The price revision, if applicable, will only apply when the contract has been executed at 20% of its amount and two years have elapsed since its formalization.

II. PARTICIPATION, AWARD AND FORMALIZATION OF THE CONTRACT

4. INVITATION TO PARTICIPATE IN THE NEGOTIATED PROCEDURE

The contracting body, through the Procurement Service, will make a request for an offer to the companies qualified to carry out the object of the contract, with which it will negotiate the technical and economic aspects indicated in **Annex 4**.

5. PRESENTATION OF PROPOSITIONS

5.1.- Documentation and Digital Envelope

To participate in the tender, the invited bidder(s) must submit the required documentation and their proposal(s) in accordance with what is indicated in the annexes to this PCAP.

Proposals submitted by a temporary joint venture must be signed by representatives of all its member companies.

The proposals are secret and their presentation implies unconditional acceptance of the content of this Specifications, as well as the Technical Specifications and the declaration that it meets each and every one of the requirements for contracting, as well as authorisation for the Procurement Service and the contracting body to consult the data contained in the Electronic Register of Bidding Companies of the Government of Catalonia or the Official Register of Bidders and Classified Companies of the public sector, or the official lists of economic operators of a Member State of the European Union.

In accordance with article 23 of the RGLCAP, foreign companies must submit their documentation officially translated into Catalan and/or Spanish.

Digital Envelope

Bidders, when stated in **section F of the characteristics table**, must submit the documentation according their bids in the envelope(s) and within the maximum period indicated in the tender announcement, using the Digital Envelope tool accessible at the following web address:

<http://contractaciopublica.gencat.cat>

Once they access the web tool on Digital through this link, bidding companies must fill out a form to register with the tool and then receive a message, at the email (s) indicated in this registration form, to activate the offer. The email addresses indicated by bidders on the registration form for the Digital Envelope tool, which will be those used to send emails related to the use of the Digital Envelope tool, must be the same as those designated in their ESPD to receive notifications and communications via the e-NOTUM.

Bidders must keep the bid activation email, as the link contained in the activation message is the exclusive access they will have to submit their bids through the Digital Envelope tool. By accessing the bid submission website via this link, bidding companies must prepare all the required documentation and attach it in electronic format to the corresponding envelopes. Bidders can prepare and send this documentation in a phased manner, before submitting the bid.

In order to start sending the documentation, the tool will require bidding companies to enter a keyword for each envelope with encrypted documentation that forms part of the tender (for Envelope No. 1 no keyword is required, since the documentation is not encrypted). This keyword will encrypt the documentation at the time of sending the offers. Likewise, bid documents are decrypted using the same keyword, which must be safeguarded by bidders. It is important to properly guard this or these keys (they can be the same for all envelopes or different for each of them), since only bidders have them (the Digital Envelope tool does not save or remember the passwords entered) and they are essential for the decryption of offers and, therefore, for access to its content.

The Fundació Institut Hospital del Mar d'Investigacions Mèdiques will ask bidders, through the email indicated on the registration form for the offer of the Digital Envelope tool, to access the Digital Envelope

web tool to enter their keywords at the appropriate time. When bidders enter their keywords, the process of deciphering the documentation will begin, which will be stored in a secured virtual space that guarantees inaccessibility to the documentation before the opening of the envelopes, on the date and time established.

Bidding companies must always enter the keyword before the end of the opening act of the first envelope.

In the event that a bidder does not enter the keyword, the contents of the encrypted envelope will not be accessible. Thus, given that the submission of bids through the Digital Envelope tool is based on the encryption of documentation and necessarily requires the introduction by bidders of the key word(s), which only they keep throughout the process, in order to access the encrypted content of the envelopes, it will not be possible to evaluate the documentation of their offer that cannot be deciphered because they have not entered the bidder the keyword.

Once all the documentation of the offer has been completed and the documents that comprise it attached, the presentation of the offer itself will be made, which is not considered presented until it has been registered, with the corresponding entry note, through the tool. Once the offer has been submitted, the documentation sent can no longer be modified.

You can find support material on how to prepare an offer using the digital envelope tool in the "Electronic tendering" section of the Public Procurement Services Platform, at the following web address:
https://contractaciopublica.gencat.cat/ecofin_sobre/AppJava/views/ajuda/empreses/index.xhtml

In accordance with the provisions of section 1.h of the sixteenth additional provision of the LCSP, the sending of offers through the Digital envelope tool may be done in two phases, first transmitting the electronic fingerprint of the offer documentation, within the period of submission of offers, with the receipt of which will be considered made for all purposes, and then sending the documentation of the offer itself, within a maximum period of 24 hours. In case of or making this second referral within 24 hours, the offer will be considered to have been withdrawn. If this possibility is used, you must bear in mind that the documentation sent in this second phase must fully coincide with that with respect to which the fingerprint was previously sent, so there can be no modification of the electronic files that make up the offer documentation. In this regard, it is important not to manipulate these files (or, for example, to make copies of them, even if they are of identical content) so as not to vary their electronic fingerprint, which is what will be checked to ensure the coincidence of documents in offers sent in two phases.

Proposals submitted after the deadline will not be accepted for any reason.

The offers presented must be free of computer viruses and any type of program or harmful code, since in no case can documents affected by a virus be opened with the corporate tools of the Generalitat de Catalunya. Thus, it is the obligation of contractors to pass the documents through an antivirus and, in case of arriving documents of their offers with viruses, it will be their responsibility that the Administration can not access their content.

In the event that any document submitted by bidders is damaged, blank, illegible or affected by a computer virus, the contracting authority will assess, depending on the documentation affected, the legal consequences regarding the participation of said bidder in the procedure, which must arise from the impossibility of accessing the content of any of the documents of the offer. In the case of essential documents to know or assess the offer, the contracting authority may agree to exclude the bidder.

Bidders may submit a backup copy of the electronic documents presented in electronic physical format, which will be requested from the bidding companies if necessary, in order to be able to access the content of the documents in case they are damaged. In this sense, it is important not to manipulate these files so as not to vary their electronic fingerprint, which is the one that will be checked to ensure the coincidence of the backup documents, sent in electronic physical support, and those sent in the offer, through the Digital Envelope tool. Likewise, it should be borne in mind that this copy cannot be used in the case of having sent documents with viruses through the Digital Envelope tool, given the technical impossibility in these cases of being able to compare electronic fingerprints and, therefore, to be able to guarantee the non-modification of the offers once the submission period has ended.

The Digital Envelope tool does not allow the presentation of files larger than 25 Mb. For this reason, the files of offers of this size must be compressed or fragmented into several parts. The partitioning must be done manually (without using winzip or winrar automatic partitioning tools) and without incorporating any passwords. The files resulting from the partition are incorporated in the section of other numbered documentation (part 1 of 2, part 2 of 2).

The technical specifications necessary for the electronic submission of bids are available in the "Electronic tendering" section of the Public Procurement Services Platform, at the following web address:
https://contractaciopublica.gencat.cat/ecofin_sobre/AppJava/views/ajuda/empreses/index.xhtml

On the other hand, the admissible electronic document formats are those indicated in **section F of the characteristics table**.

Through the Digital Envelope tool, companies must sign the "summary" document of their offers, with an advanced electronic signature based on a qualified or recognized certificate, with the signature of which the entire offer is understood to have been signed, given that this document contains the electronic fingerprints of all the documents that make it up.

Documentation declared confidential:

The documents and data presented by bidders may be considered confidential if they include industrial, technical or commercial secrets and/or intellectual property rights, and when their dissemination to third parties may be contrary to their legitimate commercial interests and/or prejudice fair competition between companies in the sector; or when its treatment may be contrary to the provisions of the regulations on the protection of personal data.

Along with the documentation, bidders must include a declaration, which must be necessary and proportional to the purpose or interest to be protected and must expressly and justifiably determine which documents and/or technical data incorporated in the envelopes they consider confidential (**Annex 13**). Generic or unsubstantiated statements are not accepted. Under no circumstances will documents that are public access documents be confidential, nor the ESPD data contained in public registers or the economic offer of the bidder, which is read in a public act.

Without prejudice to the declaration of confidentiality of bidders, in the event of a request for information, it is up to the contracting authority to assess whether this qualification is correct, in accordance with the principles of publicity and transparency governing administrative action, and to correct it where appropriate, after hearing the bidders.

5.2.- Place of presentation

The envelopes must be presented according to the conditions indicated in **section W of the characteristics table**.

Proposals submitted after the deadline will not be accepted for any reason.

Bidders, when electronic processing is accepted and as stated in **section F of the characteristics table**, will submit their bids electronically through the "Digital Envelope" application available on the Public Procurement Services Platform (<https://contractaciopublica.gencat.cat>). In this case, the contracting authority may require bidders who have previously registered in the Electronic Register of Bidders the data corresponding to their personality and capacity to act, in the case of natural persons and, in the case of legal persons, those relating to the extension of the powers of representatives or proxies with the capacity to act on behalf of the company and bind it contractually; those referring to professional authorisations or qualifications and other requirements that may be necessary to act in the sector of its activity; and data relating to economic and financial solvency.

The sending of offers electronically may be carried out in two phases, first sending the electronic signature of the offer, with receipt of which it will be considered made for all purposes, and then the offer itself within 24 hours. If this second referral is not made within the indicated period, the offer will be considered to have been withdrawn.

5.3.- Envelope content

The Envelope must contain:

1. Index of documents.

2. Declaration of compliance with the requirements of aptitude to contract with the administration that will conform to the **form of the Single European Procurement Document**, in the terms established in **Annex 12, signed electronically by the legal representative of the bidder**.

This declaration replaces documentation accrediting capacity to act, non-existence of grounds for prohibition of contracting and solvency of bidders. Likewise, the declaration issued in accordance with the form of the Single European Procurement Document will identify an email address where all notifications concerning this file must be made, without prejudice to the provisions of **section F of the Characteristics Table**.

Bidders will indicate to the ESPD, where appropriate, information relating to the person or persons authorised to represent them in this tender process

In the case of companies that participate in the tender with the commitment to be grouped into a temporary union if they are awarded the contract, each must prove their personality, capacity and solvency, and present a separate ESPD. In addition to the ESPD, they must provide a document stating their commitment to formally constitute a temporary union in the event of being awarded the contract.

In the event that the bidder resorts to the solvency and means of other companies in accordance with the provisions of article 75 of the LCSP, or intends to sign subcontracts, he must indicate this circumstance in the ESPD and another ESPD must be submitted separately for each of the companies to whose solvency he resorts or intends to subcontract.

Bidders appearing in a national database of a Member State of the European Union, such as a company virtual file, an electronic document storage system or a prequalification system, which can be accessed free of charge, only have to provide in each part of the ESPD the information that does not appear in these rules. Thus, companies registered in the Electronic Register of Bidding Companies (RELI) of the Government of Catalonia, regulated by Decree 107/2005, of 31 May, and managed by the Technical Secretariat of the Consultative Board on Administrative Procurement, or in the Official Register of Bidders and Classified Companies of the Public Sector, are only obliged to indicate to the ESPD the information that is not registered in these registers, or that it is not in force or updated. In any case, these companies must indicate to the ESPD the necessary information that allows the contracting body, where appropriate, to access the corresponding supporting documents or certificates.

The documentation proving compliance with the requirements of this specification, the fulfilment of which has been indicated in the ESPD, must be provided by the bidder on whom the award proposal falls because they have presented the best offer, prior to the award.

Likewise, the contracting authority may ask bidders to submit all or part of the documentation proving compliance with the prerequisites, when they consider that there are reasonable doubts about the validity or reliability of the ESPD or when it is necessary for the proper development of the procedure. However, bidders who are registered in the RELI or in the Official Register of Bidders and Classified Companies of the Public Sector or who appear in a national database of a Member State of the European Union of free access, is not obliged to submit supporting documents or other documentary proof of the data registered in these registers.

3. Other required documentation:

- a Responsible declaration in accordance with the model established in **Annex 1**.

- b Declaration of the entrepreneurs who intend to tender in a **joint venture**, indicating the commitment to constitute it in accordance with section 3 of article 69 of the LCSP.
- c When the establishment of a provisional guarantee is required in accordance with **section I of the table of characteristics of the contract**, documentation proving that it has been constituted must be provided.
- d **Declaration of confidentiality**, signed by the bidder according to the model of **Annex 13**, indicating, where appropriate, the concurrence of confidentiality in the documents presented in the proposal.
- e Where appropriate, **an indication of the part of the contract that they intend to subcontract**, indicating their amount and the name or business profile, defined by reference to the conditions of technical or professional solvency, of the subcontractors to whom they decide to entrust its execution (article 215.2 a) LCSP.
- f In the event that **companies belonging to the same group**, understood as those that are in any of the cases of article 42.1 of the Commercial Code or companies in which any of the alternative cases established in the same article concur, submit different proposals to participate individually or in a temporary joint venture, they must submit an express declaration stating this circumstance, indicating the companies that comprise it and the name of the group, for the purposes of the provisions of article 149.3 of the LCSP. Likewise, those companies that present different proposals and concur in any of the alternative cases established in article 42.1 of the Commercial Code, an explicit declaration with respect to the partners that comprise it.

Failure to file this declaration will be understood as a declaration by the bidder that this circumstance does not occur.
- g Declaration of commitment to **affiliation during the execution of the contract of material and/or personal means**, when required. This commitment has the character of an essential obligation for the purposes provided for in article 211 of the LCSP.
- h **When electronic processing is accepted** and as stated in **section F of the characteristics table**, authorisation for notifications to be carried out electronically, through the e-NOTUM service, in which the persons authorised to receive notifications must be designated and the email address where to receive them must be indicated.
- i **Foreign companies** must provide a **declaration of submission to the Spanish courts and tribunals** of any order for all incidents that may arise from the contract, expressly waiving their own jurisdiction.
- j Any **other documentation** required in **section H of the characteristics table**.

DOCUMENTATION PROVING COMPLIANCE WITH THE REQUIREMENTS OF APTITUDE TO CONTRACT

The documentation listed below, if required, must be presented in original, in notarial testimony or in an authentic or legitimated copy, unless otherwise stated in this Specification.

Legal personality and capacity to act

A) Spanish bidders:

Individual entrepreneurs: They must provide the National Identity Document and documentation accrediting the degree or certificate of membership, as well as accreditation, where appropriate, of the trade name with which it operates in commercial traffic. In addition, natural persons must have the business or professional qualification that, where appropriate, is required to carry out the activity according to current regulations.

Legal persons: They must provide the deed or document of incorporation, the statutes or the founding act, and their modifications, stating the rules by which their activity is regulated, duly registered, where appropriate, in the corresponding public registry, according to the type of legal entity in question and the NIF of the company.

B) Bidders from EU member states:

The capacity to act of non-Spanish companies from Member States of the European Union or signatories to the Agreement on the European Economic Area must be accredited by registering in the appropriate professional or commercial registers of their Member State of establishment or submitting a sworn declaration or one of the certifications indicated in Annex XI of Directive 2014/24/EU.

C) Bidders from non-EU states:

The capacity of foreign companies not included in the previous section to act shall be accredited by means of a report issued by the Permanent Diplomatic Mission or by the Spanish Consular Office of the place of domicile of the company in which it appears, after accreditation by the company, that they are registered in the local professional, commercial or similar register, or, in their absence, who habitually act in local traffic within the scope of the activities covered by the object of the contract.

It must also be accompanied by a report from the respective Permanent Diplomatic Mission of Spain, or from the General Secretariat for Foreign Trade of the Ministry of Economy, on the status of signatory State to the agreement on public procurement of the World Trade Organization, provided that the contract is subject to harmonized regulation, or otherwise, the reciprocity report referred to in article 68 of the LCSP.

D) The representation of bidders:

Copy of the power of attorney granted by the person with sufficient powers of attorney when acting on behalf of another legal person, registered in the Commercial Register or in the corresponding registry and DNI of the proxy. In any case, a responsible declaration must be provided by the representative of the legal entity stating that the representation he/she holds is still valid.

E) Temporary joint ventures (UTE):

Business unions that are temporarily constituted for this purpose can also contract with the public sector, and it is not necessary to formalize them in a public deed until the contract has been awarded in their favour.

Each company will accredit its capacity to act in the manner indicated in the previous points as appropriate, indicating the name and circumstances of the entrepreneurs who subscribe to it and the participation of each of them. All member companies must prove their solvency, under the terms indicated in this specification. In order to determine the solvency of the temporary union, the one accredited by each of its members is accumulated.

Employers who are grouped together in temporary unions are jointly and severally obliged and must appoint a single representative or proxy of the union with sufficient powers to exercise the rights and fulfil the obligations arising from the contract until it is terminated.

The duration of temporary business unions must coincide with that of the contract until its termination.

Companies wishing to set up temporary joint ventures to participate in public tenders can find themselves using the meeting point functionality of the Generalitat's Public Procurement Services Platform, which can be found in the "Bidder profile" section.

Lack of concurrence of cases of prohibition of contracting

The absence of grounds for prohibition of contracting may be accredited in the terms established in art. 85 of the LCSP and with the following documentation:

- a Judicial testimony or administrative certification in accordance with art. 85 of the LCSP.
- b Compliance with tax and Social Security obligations:
 - Document accrediting registration in the Economic Activities Tax relating to the activities covered by the contract and, the last receipt of the tax, accompanied by a responsible declaration of not having cancelled the registration of the tax.
 - Positive certificate from the State Tax Administration Agency, certifying that the company is up to date with its tax obligations and the non-existence of tax debts with the State.
 - Positive certificate issued by the Social Security Treasury stating that it is up to date with compliance with the company's obligations to Social Security.
 - Positive certificate issued by the Delegated and Territorial Comptrollers, certifying that the company is up to date with its tax obligations with the Administration of the Generalitat de Catalunya.

Economic, financial, or technical and professional solvency:

Accreditation of economic and financial solvency in accordance with the means specified in **Annex 3** of this PCAP.

Accreditation of technical or professional solvency in accordance with the means established in **Annex 3** of this PCAP.

ACCREDITATION OF THE ABILITY TO CONTRACT THROUGH OFFICIAL CONTRACTOR REGISTERS OR LISTS

Bidders who are registered in the **Electronic Register of Bidders of the Generalitat (RELI)** or in the **Official Register of Bidders and Classified Companies of the State (ROLECE)** must provide a **responsible declaration** stating their registration and the validity of the registered data, attaching the **summary** file. In this case, it will not be necessary to provide the documentation listed in the previous points, provided that these data are registered.

If the registration data has changed, this must be expressly stated in the tax return, adding the corresponding documentation.

Proof of the content of bidder records shall be carried out by certification from the body in charge thereof.

The certificates of registration issued by the competent bodies to keep the official lists of employers authorised to contract established by the Member States of the European Union, referring to employers established in the Member State issuing the certificate, shall constitute a presumption of aptitude in relation to the qualitative selection requirements that appear in them. Certificates issued by competent certification bodies that comply with European certification standards issued in accordance with the legislation of the Member State in which the employer is established will have the same presumption value. The aforementioned documents must meet the requirements established in art. 97 of the LCSP.

ACCREDITATION OF THE APTITUDE TO CONTRACT THROUGH DOCUMENTATION PREVIOUSLY AVAILABLE BY THE HOSPITAL DEL MAR MEDICAL RESEARCH INSTITUTE FOUNDATION

Companies not registered in the Electronic Register of Bidding Companies of the Government of Catalonia (RELI) and/or in the Official Register of Bidders and State Classified Companies (ROLECE): bidders who, in contracting files processed in the year prior to the file subject to the contract, of which they had been awarded, had provided this contracting body with administrative documentation referring to personality legal, capacity to act and/or representation, required, it will not be necessary to provide it again in this tender, provided that said documentation is fully valid. To this end, bidders will

attach a responsible declaration with a list of the documents already provided, identifying the file and responsibly stating its full validity.

4. Technical and economic documentation

The **envelope** must contain all the documentation relating to the evaluable criteria indicated in **Annex 4**, and must conform to the model contained in **Annex 2** of this PCAP.

Any other documentation required of the PPT must be submitted to verify that the offer meets the required specifications.

5.4.- Criteria for presentation and custody of envelopes

The documentation must be presented in accordance with the provisions of **Annex 9** of this PCAP.

Offers will not be accepted in the following cases:

- Presentation simultaneously by the same company or an individual entrepreneur, except in cases in which variants are admitted and / or so mandated by the operation of the tool About 2.0.
- Submission in a temporary union with other companies when one or more of the companies that comprise it, have presented a joint proposal that forms part of another temporary union.
- Submission of the proposal after the deadline for unjustified reasons. Extemporaneous submission will be considered justified when it is due to operational reasons specific to the offer submission interface.
- When the proposal presents computer viruses or any type of harmful program or code. In the case of essential documents to know or assess the offer, the company will be excluded. In all other cases, the Bureau or technical service will assess, depending on the documentation affected, whether the impossibility of accessing the content is grounds for exclusion.
- Do not evacuate the procedure for amending or clarifying documentation within the period agreed by the competent body.
- Failure to prove the economic, financial, professional or technical capacity, classification or solvency required in this tender.
- When the object of the evaluation does not meet the minimum requirements established in the PPT.
- Failure to exceed the minimum score established, where appropriate, in the assessment criteria.
- Submission of documents that vary substantially from the established model or that have omissions, amendments or errors that prevent clear knowledge of what is considered essential to assess the offer.
- Exceeding the tender budget and/or the maximum unit prices, if applicable.
- Non-presentation of samples within the period granted for this purpose or in the specified place, if applicable.
- Any other that results from the application of the documentation governing the tender and the applicable legal and regulatory regulations.

The documentation justifying the proposal to be included in the envelope must be kept secret until it is opened.

5.5.- Withdrawal of proposals once presented

If the award decision has not been issued within four months from the opening of the proposals, the bidders admitted to the tender will have the right to withdraw their proposal.

5.6.- Advertising, use of electronic means and digital certificates

5.6.1.- The procedure will be publicized as established in **section O of the table of characteristics**, in accordance with articles 134 and 135 of the LCSP.

5.6.2.- In accordance with the fifteenth additional provision of the LCSP, the processing of this tender entails the practice of notifications and communications derived from it by exclusively electronic means.

However, oral communication may be used for communications other than those relating to the essential elements, i.e. specifications and offers, leaving the content of the oral communication duly documented, for example, through written or sound files or summaries of the main elements of communication.

The communications and notifications made during the contracting procedure and during the term of the contract will be made by electronic means through the e-NOTUM notification system, in accordance with the LCSP, Law 39/2015, of October 1, on the common administrative procedure of public administrations and Order PDA/21/2019, of February 14, which determines the electronic notification system of the Administration of the Generalitat de Catalunya and of its public sector. For these purposes, notifications and communications will be sent to the email addresses and mobile phones provided by companies for this purpose in the ESPD, in accordance with the provisions of this specification. Once the e-mail (s) have been received and, in the event that mobile phones have also been provided, the SMS, indicating that the corresponding notification has been made available in the e-NOTUM, must be accessed by the designated person(s), through the link that will be sent for this purpose. In the virtual space where the notification is deposited, it is possible to access said notification with a digital certificate or password.

The periods to be counted from the date of sending the notification notice, if the act subject to notification has been published on the same day in the contractor profile of the contracting body. Otherwise, the deadlines will be computed from the receipt of the notification by the company to which it is addressed.

However, the deadlines for notifications made on the occasion of the special appeal procedure by the Catalan Court of Contracts count in any case from the date of sending the notification notice.

On the other hand, in order to receive all the information related to this tender, companies that wish to do so and, in any case, bidders must subscribe as interested in this tender, through the subscription service to the news of the virtual tender space that for this purpose is made available at the web address of the contractor profile of the contracting body, accessible on the Generalitat's Public Procurement Services Platform: <https://contractaciopublica.gencat.cat>. This subscription will allow you to receive immediate notification at the email addresses of subscribers of any news, publication or notice related to this tender.

Likewise, certain communications that must be made on the occasion of or as a result of the tender and award procedure of this contract will be made through the bulletin board associated with the virtual tender space of said tender of the Public Procurement Services Platform. This electronic bulletin board, which provides reliable proof of the authenticity, integrity and date and time of publication of the information published, will also publish information relating to both the tender and the contract.

In addition, bidders can also register in the Bidder Profile, after the required authentication. The Bidder Profile consists of a set of services aimed at bidders with the aim of providing each bidder with their own space, with a series of tools that facilitate access to and management of contracting files of interest to them. To register, you must click on the "Bidder profile" section of the Public Procurement Services Platform and have the required digital certificate.

5.6.3.- Digital certificates:

In accordance with the first additional provision of DL 3/2016, the use of an advanced electronic signature based on a qualified or recognised electronic signature certificate will be sufficient in the terms provided for in Regulation (EU) 910/2014/EU, of the European Parliament and of the Council, of 23 July 2014, on electronic identification and trust services for electronic transactions in the internal market and repealing the Directive 1999/93/EC. Therefore, this is the minimum security level required for the electronic signature certificate accepted for signing the ESPD and the offer.

With regard to EU foreign certificates, qualified certificates will be accepted in any country of the European Union in accordance with article 25.3 of the aforementioned Regulation (EU) 910/2014/EU on electronic identification and trust services, which provides that "a qualified electronic signature based on a qualified certificate issued in a Member State will be recognised as a qualified electronic signature in the rest of the Member States".

6. ADJUDICATION

6.1.- Qualification of administrative documentation

After the deadline for submitting proposals, the Contracting Service will proceed to classify the administrative documentation presented by the candidate or candidates. If defects or smearable omissions are observed in the affidavit or in the rest of the documentation submitted, the corresponding candidate will be notified, recording the requirement in the file, granting a period not exceeding three working days.

6.2.- Negotiation of the terms of the contract

Once the administrative documentation has been qualified and the defects or omissions observed have been corrected, the contracting authority will negotiate with all the admitted candidates based on the offers submitted, in accordance with the provisions of article 169 of the LCSP.

The economic and technical aspects to be negotiated and the negotiation formation will be those indicated in **Annex 4**.

The procedure will ensure that all candidates receive equal treatment and, in particular, the particularities or advantages of each offer will not be communicated to the rest, but simply the order of each bidder according to the valuation phases foreseen.

The negotiation must be recorded in the file.

6.3.- Presentation of final bids

Once the negotiation phase is over, participating bidders will be asked to submit a final offer in writing that must respond to the outcome of the negotiation. The referral period will be established in the corresponding notification.

6.4.- Evaluation of offers and classification

When more than one candidate participates in the procedure, and for the purpose of determining the most advantageous offer, the service proposing the procurement will prepare a report in which the final bids of the bidders will be classified according to the results of the assessment, which will be submitted to the contracting body.

It will not be necessary to assess and classify when there is only one candidate who has submitted an offer in accordance with the technical requirements of the Specifications.

The award criteria, if applicable, are those set out in **Annex 4**.

6.5.- Electronic auction

When this is provided for in **section F of the characteristics table**, the electronic auction may be used to present price improvements or new securities related to certain elements of the bids that are likely to be expressed in figures or percentages, which improve it as a whole.

6.6.- Offers with abnormal or disproportionate values

Section Q of the characteristics table establishes the objective parameters according to which it will be appreciated, where appropriate, that a proposition cannot be fulfilled due to the inclusion of abnormal or disproportionate values.

In the event that one or more of the bids submitted incur a presumption of abnormality, the contracting authority will require the bidder(s) who have submitted the bidder to justify and break down reasonably and in detail the low level of prices, or costs, or any other parameter on the basis of which the abnormality of the offer has been defined. For this reason, the contracting authority will require the bidder(s) to specify

the specifications it deems appropriate regarding the viability of the offer and the relevant justifications. Bidders will have a period of 10 working days to submit the relevant information and documents.

After this period, if the contracting body does not receive the information and supporting documentation requested, it will be considered that the proposal cannot be fulfilled, leaving the bidder excluded from the procedure. If the contracting authority receives the information and supporting documentation requested within the deadline, it will evaluate it and decide, after providing technical advice to the corresponding service, or accepting the offer, because it considers its viability accredited or, otherwise, its rejection.

The contracting authority will reject offers incurred on presumption of abnormality if they are based on inappropriate hypotheses or practices from a technical, economic or legal perspective. Likewise, it will reject offers if it finds that they are abnormally low because they violate the regulations on subcontracting or do not comply with the applicable obligations in environmental, social or labor matters, national or international, including non-compliance with current sectoral collective agreements, in application of the provisions of article 201 of the LCSP.

6.7.- Determination of the most advantageous offer

Within four months of the opening of the proposals, the contracting body will agree which is/are the best offer(s).

When, once the award criteria have been applied, a tie is established between several bidders, the LCSP tie-breaking criteria will be applied.

6.8.- Submission of documentation prior to award

Once the bids have been assessed, the corresponding award proposal will be sent to the contracting body.

The proposed award does not create any right in favour of the bidder proposed as a successful bidder, as the contracting authority may depart from it provided that it justifies its decision.

Once the proposal has been accepted by the contracting body, the corresponding services will require the bidder who has submitted the best bid taking into account the award criteria, so that, within 10 working days from the next one who received the request, submit the documentation corresponding to compliance with the requirements of aptitude to contract, According to art. 140 of the LCSP and the provisions of section 5.3 of this Specification.

Likewise, proof of having constituted the definitive guarantee will be provided within the same period, in case it is requested in accordance with **section J of the characteristics table**, or any other documentation that, specifically and due to the nature of the contract, has been determined.

If the requirements are not complied with within the period indicated, it will be understood that the bidder has withdrawn their offer, proceeding to request the same documentation from the next bidder, in the order in which the bids have been classified. This entails the requirement of the amount of 3% of the base tender budget, excluding VAT, by way of penalty, which will be effective first against the provisional guarantee that, where appropriate, would have been constituted and, in addition, may give rise to declaring the bidder prohibited from contracting for the cause provided for in article 71.2 a) of the LCSP.

Likewise, the possible falsity in the responsible declarations of bidders may give rise to the cause of prohibition of contracting with the public sector provided for in article 71.1 e) of the LCSP.

6.9.- Definitive guarantee

In the event that it is requested in accordance with **section J of the characteristics table**, it will be an essential condition for the award of the contract that the first classified person has constituted within 10 working days, counting from the day after receiving the request to provide the supporting documentation indicated in section 6.8, the guarantee consisting of the amount indicated in **section J of the**

characteristics table, as a guarantee of the exact fulfillment of the obligations assumed, in accordance with articles 107 and following of the LCSP.

This guarantee may be constituted by the successful bidder in any of the ways provided for in article 108 of the LCSP, including withholding on the price. In the latter case, the bidder must submit a responsible declaration stating their request to constitute the definitive guarantee by withholding the percentage indicated in **section J of the table of characteristics** of the total invoice for the contract. Failure to comply with this requirement for reasons attributable to the successful bidder will prevent the contract from being formalised.

In the case of a temporary joint venture, the definitive guarantee may be established by one or more of the participating companies, provided that together it reaches the required amount and jointly and severally guarantees all the companies that make up the temporary union.

The definitive guarantee responds to the concepts defined in article 110 of the LCSP.

Once the execution period has elapsed and the guarantee of the contract to the full satisfaction of the Fundació Institut Hospital del Mar d'Investigacions Mèdiques has elapsed, a refund may be requested, in accordance with the provisions of article 111 of the LCSP.

6.10.- Awarding

The contracting body will award the contract within 5 working days of receiving the required documentation. In the case of a file with a diversity of successful bidders, this calculation will be made from the receipt, within the deadline, of the last documentation received.

Bidders will be notified of the award and published on the contractor profile of the contracting body.

The notification must be made by any of the means that allow proof of receipt by the recipient. This will preferably be carried out at the email address designated by bidders when submitting their proposals, in accordance with article 43 of Law 39/2015.

7. FORMALIZATION OF THE CONTRACT

7.1.- Formalization and perfection of the contract

The contract will be formalized in an administrative document. However, the successful bidder may request that the contract be elevated to a public deed, being at their own expense the corresponding expenses.

In accordance with the provisions of article 99.7 of the LCSP, it is expressly provided that, in the contacts awarded by lots, all lots/sublots awarded to the same bidder will constitute a single contract.

In the case of contracts not included in the scope of application of the special appeal on contracting:

The contract will be formalised within a maximum period of fifteen working days following that in which notification of the award to bidders is received.

In the case of contracts in which they are subject to special appeal in contracting matters:

The services dependent on the contracting body will require the successful bidder to formalise the contract within a period not exceeding five days from the period following that in which the request has been received, once the period provided for in the previous paragraph has elapsed without a special appeal having been lodged in the matter of contracting that entails the suspension of the formalisation or that the competent body for the resolution of the appeal has lifted the suspension.

The same procedure will be taken when the competent body for the resolution of the appeal lifts the suspension of the contract.

If the contract is not formalised within the period indicated in the previous section for reasons attributable to the successful bidder, the amount of 3% of the base tender budget, excluding VAT, will be required by way of penalty, which will be effective first against the definitive guarantee, if it has been established. In addition, this fact may lead to declaring the bidder prohibited from contracting, in accordance with article 71.2 b) of the LCSP.

In the event that the contract cannot be formalised with the successful bidder, it will be awarded to the next bidder who has submitted the best bid in accordance with the order in which the bids have been classified, upon submission of supporting documentation, the deadlines set out in the previous sections being applicable.

Temporary Unions of Companies that have concurred with a joint tender offer must, once the contract has been awarded in their favour, submit the public deed of incorporation of the temporary union stating the appointment of the representative or sole proxy of the union with sufficient powers to exercise the rights and fulfil the obligations arising from the contract until its termination.

The content of the contract will be as established in articles 35 of the LCSP and 71 of the RGLCAP and will not include any clause that implies alteration of the terms of the award.

The contract will be perfected with its formalization and this will be an essential requirement to be able to start its execution.

The formalization of this contract will be published within a period not exceeding fifteen days after its perfection in the contractor profile, together with the corresponding contract.

Once the contract has been formalized, the basic details of the contract awarded will be communicated to the Register of Contracts of the Generalitat de Catalunya.

Contracts of an amount not exceeding 15,000.00 euros per year (excluding VAT), due to their nature as minor contracts, in application of the provisions of article 153.6 of the LCSP, are excluded from this formalization.

7.2.- Publicity of the formalization of contracts

The formalization of this contract will be published in the contractor profile of the contracting body and in the corresponding official gazettes, in accordance with what is indicated in **section O of the table of characteristics**.

III. EXECUTION OF THE CONTRACT

8. EXECUTION OF THE CONTRACT

8.1.- Form of execution

The successful bidder must execute the contract in accordance with the principles of responsibility and effectiveness, meeting the agreed deadlines, and in accordance with the requirements of the specifications of particular administrative clauses and the corresponding technical prescriptions.

The Hospital del Mar Medical Research Institute Foundation has the power to verify, coordinate and monitor the correct performance of the contracted services and will exercise its management and inspection powers through the corresponding verifications.

The contracting body will also have the power to supervise, throughout the execution of the contract, that the service is executed with the utmost respect for the environment affected, in accordance with the obligations and requirements contained in this Specification.

8.2.- Work program

The Hospital del Mar Medical Research Institute Foundation may request the preparation of a work programme that must be approved by the contracting body when so determined in **section P of the characteristics table** and, in any case, in the work of successive treatment.

8.3.- Compliance with deadlines and correct execution of the contract

The contractor is obliged to comply with the total term of execution of the contract and the partial deadlines set, if any, in the work program.

If the contractor is late in complying with the total or partial delivery deadlines, for reasons attributable to it, the Fundació Institut Hospital del Mar d'Investigacions Mèdiques may choose, indistinctly, to terminate the contract with loss of guarantee or to impose penalties, in the manner and conditions established in clause 13 of this Specification, If applicable.

The Fundació Institut Hospital del Mar d'Investigacions Mèdiques shall have the same authority with respect to non-compliance or defective compliance, for reasons attributable to the contractor, of the service that is the object of the contract or in the event of non-compliance with the commitments or special conditions of execution, by virtue of which the contractor undertakes to dedicate or assign certain personal or material means. or when environmental or social conditions defined in the contract are established.

If the delay with respect to the fulfillment of the deadlines is caused by reasons not attributable to the contractor and the contractor offers to comply if the initial execution period is extended, a period will be granted, at least, equal to the lost time, unless the contractor requests a shorter one.

The amount of the penalty does not exclude compensation for damages to which the Hospital del Mar Medical Research Institute Foundation may be entitled due to the delay of the contractor.

In any case, the delayed constitution of the contractor will not require interpellation or prior intimation by the Fundació Institut Hospital del Mar d'Investigacions Mèdiques.

8.4.- Responsibility of the contractor

The contractor is responsible for the technical quality of the services and services performed, as well as for the consequences that may arise for the Hospital del Mar Medical Research Institute Foundation or for third parties from omissions, errors or inappropriate methods in the execution of the contract.

The contractor executes the contract at its own risk and is obliged to compensate for damages caused to third parties as a result of the operations required by the execution of the contract, except in the event that the damages are caused immediately and directly by an order of the Hospital del Mar Medical Research Institute Foundation.

8.5.- Confidentiality

The contractor must keep stealth with respect to the data or background that, not being public or notorious, are related to the object of the contract and of which he has knowledge on the occasion of it, unless the contracting body expresses otherwise, by reason of the nature and circumstances of the contract, in the technical specifications.

The successful bidder must respect the confidentiality of all the information to which he may have access by reason of this contract, and must adopt the appropriate measures so that, under no circumstances, can this information be used outside the exercise of the functions provided for in the framework of this contract.

8.6.- Data protection

The personal data of the legal representatives who subscribe to the application to participate in the tender, as well as the offer submitted, will be processed by the Fundació Institut Hospital del Mar d'Investigacions

Mèdiques in accordance with the provisions of current regulations on the protection of personal data and, particularly, in accordance with Organic Law 3/2018, of 5 December, on the protection of personal data and guarantee of digital rights and Regulation (EU) 2016/679, of the Parliament and of the Council, of 27 April 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (hereinafter, General Data Protection Regulation).

The personal data of the legal representatives of bidders will be processed for purposes specific to the administrative tender procedure, where appropriate, for monitoring the execution of contracts, as well as for accountability with the internal and external control bodies and/or bodies of the Public Sector of the Generalitat de Catalunya (General Comptroller of the Generalitat de Catalunya, Audit Office, Court of Accounts, among others).

When the documentation submitted by bidders incorporates personal data of their employees, bidders will ensure that the inclusion of such data does not infringe any rights of the persons affected by this inclusion, and must hold harmless the Fundació Institut Hospital del Mar d'Investigacions Mèdiques from any claim that may be filed as a result of the inclusion of such personal data in the offer. and its treatment by the Fundació Institut Hospital del Mar d'Investigacions Mèdiques, for the purposes of the tender procedure, monitoring the execution of the contract or accountability, among others related.

The legal representative of the bidder is responsible for the veracity and correctness of the data provided to the Fundació Institut Hospital del Mar d'Investigacions Mèdiques and has the power to exercise the rights of access, rectification, deletion, limitation of processing, portability and opposition to the processing of their data in accordance with the provisions of data protection regulations. To exercise them, you must write to the Data Protection Delegate of the Hospital del Mar Medical Research Institute Foundation.

The documentation provided to the Hospital del Mar Medical Research Institute Foundation may be considered public information in accordance with the provisions of Law 19/2014, of 29 December, on Transparency, Access to Public Information and Good Governance. As established in art. 24 of this regulation, access to public information by any interested party may include access to merely identifying personal data unless, in the specific case, the protection of such data must prevail.

When, as a result of this contract, it is necessary to process personal data transferred by the Fundació Institut Hospital del Mar d'Investigacions Mèdiques to the successful bidder, said access will be considered access to the data on behalf of third parties as data processor, in accordance with the provisions of the General Data Protection Regulations, or other applicable regulations. For this purpose, the successful bidder will only process the data in accordance with the instructions of the Fundació Institut Hospital del Mar d'Investigacions Mèdiques and will not apply or use them for a purpose other than that which constitutes the object of the contract. In addition, the successful bidder must sign the model contract regulating the personal data processing order that is attached as **Annex 15** to the PCAP.

When the execution of the contract does not require the processing of personal data, access by the parties to data of this nature will be prohibited, except for those strictly identifying that appear in the documentation concerning the tender, or in the corresponding contracts.

8.7.- Other obligations of the successful bidder

The contractor's obligations are also the following:

- 1 The contractor is obliged in the execution of the contract to comply with the applicable obligations in environmental, social or labour matters established by European Union law, national law, collective agreements or the provisions of international environmental, social and labour law that bind the State, and in particular those established in Annex V of the LCSP. For this purpose, the contractor company must send the justification of the effective realization of these payments to the contracting body when requested.

It is also obliged to comply with current provisions on the social integration of people with disabilities and tax purposes.

Failure to comply with the aforementioned environmental, social or labour obligations and, in particular, repeated breaches or delays in the payment of wages or the application of salary conditions lower than those derived from collective agreements that are serious and malicious, will give rise to the imposition of penalties referred to in this specification.

- 2 The contractor undertakes to comply with the salary conditions of workers in accordance with the applicable sectoral collective agreement.
- 3 The contractor undertakes to apply, when executing the services of the service, measures aimed at promoting equality between men and women.
- 4 The successful bidder must use Catalan in their relations with the Hospital del Mar Medical Research Institute Foundation derived from the execution of the object of the contract. In any case, the contractor and, where appropriate, the subcontractors, are subject in the execution of the contract to the obligations derived from Law 1/1998, of 7 January, on language policy and the provisions that develop it.
- 5 The contractor, in relation to the personal data to which he has access on the occasion of the contract, undertakes to comply with all the provisions of current regulations on the protection of personal data and, in particular, Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights and Regulation (EU) 2016/679, of the Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC.
- 6 In accordance with the provisions of articles 3.5 and 55.2 of Law 19/2014, of December 29, on transparency, access to public information and good governance, the contractor undertakes to provide the information established in said law.

9. MODIFICATIONS TO THE CONTRACT

Once the contract has been completed, it may only be modified for reasons of public interest, in the cases and in the manner specified in this clause, in **Annex 5** and in accordance with the provisions of articles 203 to 207 of the LCSP.

The modification of the contract not provided for in this clause may only be made when the requirements are met and the assumptions provided for in article 205 of the LCSP concur, in accordance with the procedure regulated in article 191 of the LCSP and with the particularities provided for in article 207 of the LCSP.

These modifications are mandatory for the contractor, unless they imply, alone or jointly, an alteration in their amount that exceeds 20% of the initial contract price, excluding VAT. In this case, the modification will be agreed by the contracting body with the prior written consent of the contractor; otherwise, the contract will be terminated in accordance with the cause provided for in article 211.1 g) of the LCSP.

The modifications of the contract will be formalized in accordance with the provisions of article 153 of the LCSP.

The announcement of modification of the contract, together with the allegations of the contractor and all the reports that, where appropriate, are requested prior to the approval of the modification, both those provided by the successful bidder and those issued by the contracting body, will be published in the contractor profile.

10. SUCCESSION, ASSIGNMENT OF THE CONTRACT and SUBCONTRACTING

10.1.- Succession and Assignment of the contract

- Succession in the person of the contractor:

In the event of a merger of companies in which the contractor company participates, the contract will remain in force with the absorbing entity or with the one resulting from the merger, which will be subrogated in all rights and obligations arising from it.

In cases of split, contribution or transfer of companies or branches of activity, the contract will continue with the entity to which the contract is attributed, which will be subrogated in the rights and obligations arising from it, provided that it meets the conditions of capacity, absence of prohibition to contract and the solvency required when agreeing to award the contract or that the beneficiary companies of these operations and, in the event of subsistence, the company from which the assets originate, companies or branches segregated, are jointly and severally responsible for the execution of the contract.

The contractor must notify the contracting body of the circumstance that occurred.

In the event that the contractor is a joint venture, when merger, spin-off or transfer of branch of activity operations take place with respect to one or more companies in the temporary union, the execution of the contract with the successful temporary union will continue. In the event that the absorbing company, the company resulting from the merger, the beneficiary of the spin-off or the acquirer of the branch of activity, are not companies forming part of the temporary union, they must have full capacity to act, are not subject to prohibition on contracting and maintain the required solvency, capacity or classification.

If the contract is attributed to a different entity, the definitive guarantee may be renewed or replaced, at the discretion of the granting entity, by a new guarantee subscribed by the new entity, taking into account the risk posed by the latter entity. In any case, the old definitive guarantee remains in force until the new guarantee is established. If the subrogation cannot occur because the entity to which the contract should be attributed does not meet the necessary solvency conditions, the contract will be terminated, being considered for all purposes as a case of termination due to the fault of the contractor.

- Assignment of the contract:

The rights and obligations arising from the contract may be transferred by the successful bidder to a third party when established in **section L2 of the characteristics table**.

Under no circumstances may the rights and obligations arising from the contract be assigned when the technical or personal qualities of the transferor have been the determining reason for the award of the contract.

In order for successful bidders to assign their rights and obligations to third parties, the following requirements must be met:

- a) That the contracting body authorizes, in advance and expressly, the assignment.
- b) The transferor has executed at least 20 percent of the amount of the contract.
- c) That the transferee has the capacity to contract and the solvency that is required, and that he is duly classified if this requirement has been demanded of the transferor, and not be involved in a cause of prohibition to contract.
- d) That the assignment is formalized, between the successful bidder and the assignee, in a public deed.

With the fulfillment of the aforementioned requirements, the assignee is subrogated in all the rights and obligations that would correspond to the transferor.

When the establishment of a definitive guarantee is required, the guarantee provided by the transferor may not be returned or cancelled until that of the assignee is formally constituted.

10.2.- Subcontracting

The contractor may arrange with other companies the partial realization of the service object of this contract, in accordance with the provisions of **section L of the table of characteristics** and for the percentage(s) that are expressly determined.

The conclusion of subcontracts is subject to compliance with the requirements and other circumstances regulated in article 215 of the LCSP.

Violation of the conditions established in the aforementioned article 215 to proceed with the subcontracting, as well as the lack of accreditation of the aptitude of the subcontractor or of the circumstances determining the emergency situation or those that make subcontracting urgent, may result in the imposition on the contractor of a penalty of up to 50% of the amount of the subcontract.

Subcontractors shall be obliged only to the main contractor, who shall therefore assume full responsibility for the execution of the contract with the Fundació Institut Hospital del Mar d'Investigacions Mèdiques, in accordance with this Specification and under the terms of the contract, including compliance with the environmental, social or labour obligations referred to in this Specification. as well as the obligation to submit to national and European Union regulations on data protection. The knowledge that the Fundació Institut Hospital del Mar d'Investigacions Mèdiques has of the contracts concluded or the authorisation granted does not alter the sole responsibility of the main contractor.

Under no circumstances do subcontractors have direct action against the Fundació Institut Hospital del Mar d'Investigacions Mèdiques (Hospital del Mar Medical Research Institute Foundation) for the obligations contracted with them as a result of the execution of the main contract and subcontractors.

Under no circumstances may the contractor partially execute the contract with persons disqualified from contracting in accordance with the legal system or included in any of the cases of article 71 of the LCSP.

The contractor must inform the person representing workers of subcontracting, in accordance with labor law.

Subcontracts are, in any case, private in nature.

Payment to subcontractors and supply companies is governed by the provisions of articles 216 and 217 of the LCSP.

In cases where the subcontracting amount is equal to or greater than 30% of the contract price, the Fundació Institut Hospital del Mar d'Investigacions Mèdiques will check strict compliance with payment to subcontractors and supply companies by the contractor. For these purposes, the contractor must provide, when requested, a detailed list of the subcontractors or supply companies specifying the conditions related to the payment period and must present proof of compliance with the payment within the deadline. These obligations are considered a special condition of execution, so their non-compliance may lead to the imposition of the penalties provided for in this specification, responding to the definitive guarantee of these penalties.

11. PAYMENT REGIME

The Hospital del Mar Medical Research Institute Foundation will pay the price from the date of issuance of the corresponding documents accrediting the total or partial completion of the contract, within the period established by the LCSP.

12. RESPONSIBILITIES

12.1.- Compensation for damages

The contractor must indemnify the Fundació Institut Hospital del Mar d'Investigacions Mèdiques and third parties for all damages caused as a result of the performance of the contract, in accordance with article 196 of the LCSP. In these cases, the compensation will be determined for the Fundació Institut Hospital

del Mar d'Investigacions Mèdiques, depending on the damages caused, after hearing the contractor and without prejudice to the criminal action that may apply.

13. REGIME OF BREACHES AND CONTRACTUAL PENALTIES

13.1.- Imposition of penalties

In accordance with the provisions of article 192 of the LCSP, a penalty regime is established for defective compliance with the provision or non-compliance with the commitments or special conditions for the execution of the contract, which appears in **Annex 6**.

The penalties will be imposed by resolution/agreement of the contracting body, which will be immediately enforceable, and will be effective by deduction on the invoices to be paid to the contractor.

14. PREROGATIVES OF THE ADMINISTRATION

Within the limits and subject to the requirements and effects indicated in the LCSP, the contracting body has the prerogative to interpret the contract, resolve doubts about its compliance, modify it for reasons of public interest, agree on its resolution and determine the effects. The resolutions of the contracting body are immediately enforceable and exhaust administrative channels.

The exercise of the prerogatives of the Administration shall be carried out through the procedure established in article 191 of the LCSP.

IV TERMINATION OF CONTRACT

15. TERMINATION OF THE CONTRACT

The contract is terminated by compliance or termination.

16. FULFILMENT OF THE CONTRACT

16.1.- Receipt and liquidation

The receipt and settlement of the contract will be carried out in accordance with the provisions of articles 210 and 311 of the LCSP and article 204 of the RGLCAP.

The Hospital del Mar Medical Research Institute Foundation will determine whether the service provided by the contractor complies with the requirements established for its execution and compliance and, where appropriate, will require the performance of the contracted services and the correction of the defects observed upon receipt.

If the work carried out is not adapted to the contracted service, as a result of faults or defects attributable to the contractor, it may reject it so that it will be exempt from the obligation to pay or will be entitled, where appropriate, to the recovery of the price paid.

16.2.- Guarantee period and return or cancellation of the definitive guarantee

The guarantee period for the services subject to tender is established in **section N of the characteristics table**.

The contract is understood to have been fulfilled by the contractor when the contractor has performed, in accordance with the terms of the contract itself and to the satisfaction of the Fundació Institut Hospital del Mar d'Investigacions Mèdiques, the entire service.

In any case, its confirmation requires the Fundació Institut Hospital del Mar d'Investigacions Mèdiques to formally and positively receive or conform within thirty days of the delivery or performance of the object of the contract.

17. TERMINATION OF THE CONTRACT AND EFFECTS

17.1.- Causes

The following are causes for termination of the contract:

(a) the death or unexpected disability of the individual contractor; However, the contracting authority may agree to continue the contract with the heirs or successors of the contractor.

b) Declaration of bankruptcy or declaration of insolvency in any other proceedings.

c) The common agreement between the parties. In this case, the rights of the parties shall conform to what these parties have validly stipulated.

d) The delay in meeting the deadlines by the contractor, in the terms established in the regime of breaches and penalties established in this PCAP and the LCSP.

e) The impossibility of executing the service in the initially agreed terms or the certain possibility of producing a serious injury to the public interest if the execution continues, when it is not possible to modify the contract under the terms of the LCSP.

f) The suspension, for reasons attributable to the Fundació Institut Hospital del Mar d'Investigacions Mèdiques, of the start of the service and for a period exceeding 6 months from the date established in the contract for delivery.

g) The delay of the Administration exceeding six months in the payment of the contract price.

h) Failure to comply with those obligations that, in accordance with the nature of the contract, must be considered essential, breach of the main obligation of the contract as well as other essential obligations of the contract if established in **Annex 7** of this PCAP and of the special conditions of execution indicated in **Annex 14** of this PCAP.

i) Those indicated for each type of contract by the LCSP.

j) Non-payment during the execution of the contract of wages by the contractor to the workers who were attached to it, or the breach of the conditions established in the collective agreements in force for its workers also during the execution of the contract.

17.2.- Effects

Failure by the Hospital del Mar Medical Research Institute Foundation to comply with the obligations of the contract determines, in general, the payment of damages incurred by said breach to the successful bidder.

When the contract is terminated due to non-compliance by the contractor, the contractor must compensate the Fundació Institut Hospital del Mar d'Investigacions Mèdiques for the damages caused. The compensation shall be paid first of all on the guarantee which, if any, has been established, without prejudice to the subsistence of the contractor's liability with respect to the amount exceeding that of the guarantee.

When the contract is terminated for the reasons set out in paragraph (e) above, the contractor shall be entitled to compensation of 3 per cent of the amount of the service not performed, unless the cause is attributable to him.

This Specification has been examined by the Legal Counsel of the Barcelona Mar Health Park Consortium and meets the requirements established by the current legislation regulating public sector contracts.

*Narcís Pérez de Puig
Head of Legal Advice*

Barcelona, on the date of the electronic signature.

ANNEX 1

RESPONSIBLE DECLARATION FORM

Mr. / Ms., with ID no....., acting on behalf of and representation of (bidder)., in his capacity as and with sufficient powers to sign this affidavit, aware of the announcement of the contracting procedure for the award of the Contract with the reference number of the file,

DECLARES RESPONSIBLY:

1.- That the specific identification data of (bidder) are:

- Company name: [.....]
- NIF [.....]
- Postal address: [.....]
- Contact person: [.....]
- Telephone: [.....]
- Fax: [.....]
- Email: [.....]
- Internet address (website address) (if applicable): [.....]
- SME: YES/NO

2.- That the bidder is not participating in this contracting procedure together with others.

(in case of affirmative answer)

- (a) *Indicate the role of the bidder within the group (main responsible, responsible for specific tasks, etc.): [.....]*
- (b) *Identify yourself to the other economic operators participating in the procurement procedure jointly: [.....]*
- (c) *If applicable, name of participating group: [.....]*

3.- That, for the purposes of this contracting procedure, the authorised representatives of the bidder are:

- Name: [.....]
- Position/Representation in which he acts: [.....]
- Postal address: [.....]
- Notary of the power of attorney: [.....]
- Power of attorney deed date: [.....]
- Telephone: [.....]
- Email: [.....]
- Tax ID number of the representative: [.....]

4.- That the company it represents complies with the legally established conditions for contracting with the public sector and meets each and every one of the aptitude, capacity and solvency requirements (economic, financial, technical and professional) established in the Specifications governing this tender and is in a position to be able to accredit it at the time required.

Consequently, it undertakes when required by the Fundació Institut Hospital del Mar d'Investigacions Mèdiques to provide, within the required period, documentation accrediting the capacity, aptitude and solvency required for the procedure.

5.- That the company it represents and its directors and/or representatives are not involved in any of the cases of incapacity or prohibition to contract as determined in current legislation.

6.- That the company is up to date with its obligations related to the payment of taxes and Social Security contributions, both in the country in which it is established and in the Spanish State.

7.- That the company has not breached its obligations in the areas of labour, social or environmental legislation.

8.- That the company is not aware of any conflict of interest with the Hospital del Mar Medical Research Institute Foundation due to its participation in this contracting procedure.

9.- That you accept that the documentation attached to the Specifications is contractual.

10.- That the company they represent complies with and undertakes to comply with the ethical principles and rules of conduct indicated by the Hospital del Mar Medical Research Institute Foundation, assuming responsibility for non-compliance.

11.- That the company it represents has not unduly withdrawn its proposal or candidacy in an award procedure, nor has it made it impossible to award a contract in its favor because it does not comply with the provisions of article 150.2 of the LCSP, within the period indicated for this purpose intervening grief, fault or negligence, nor has it ceased to formalize a contract awarded in its favor for reasons attributable to it.

12.- That in relation to the tender for the reference contract indicated above and in accordance with the practice of the notifications derived from it, designates as the preferred means of receiving said notifications the email address:

13.- That the company intends to subcontract (if applicable).....

14.- That the signatories of this declaration formally declare that the information they have provided in this tender for It is accurate and truthful and that they are aware of the consequences of a false statement.

15.- That the bidding entity undertakes to respect the content of the standard contractual clauses in accordance with the Implementing Decision (EU) 2021/915, provided for in Annex 15 of this Specific Administrative Clauses Specifications.

16.- That the bidding entity accepts the content of the clinical trial protocol.

17.- That the bidding entity declares that it is in a position to provide, when required by the contracting body, the documentation indicated in the Technical Specifications of the tender.

And for appropriate purposes, this responsible declaration is signed, in from.....
from.....

Electronic signature of the person formulating the proposal.

ANNEX 2

MODEL FOR ASSESSING AWARD CRITERIA

Exp. No.

COMPANY/EMPLOYER DETAILS

Name/Company name

N.I.F.

Telephone

Fax

Email

Mr./Ms. Residing in
on Street number..... and with NIF declares that,
aware of the conditions and requirements required to be the company awarded the contract of
..... with file numberundertakes (on its own behalf / on behalf of the
aforementioned company) to execute it strictly subject to the requirements and conditions stipulated
below:

COMMON ANNEX FOR THE 19 LOTS.

The bidder expressly declares compliance with all technical aspects and those relating to the assignment of means detailed in the Technical Specifications of the tender, with respect to the lot to which it is submitted.

- Economic offer:

Description	Unit price per recruited patient (excluding VAT).
Patient recruitment and monitoring service within the framework of the "LIVRATION" research project. Lot no. xx (indicate)	

Electronic signature of the person formulating the proposal

ANNEX 3

MEANS OF ACCREDITING ECONOMIC, FINANCIAL AND TECHNICAL SOLVENCY, AND MANDATORY SPECIFIC DOCUMENTATION

In accordance with article 92 of the LCSP, developed by regulations in article 11.5 of Royal Decree 1098/2001, of 12 October, approving the General Regulations of the Law on Public Administration Dealings, bidders are exempt from accreditation of economic, financial, technical or professional solvency, given that the estimated value of each of the lots does not exceed the amount indicated in said provision.

ANNEX 4

ECONOMIC AND TECHNICAL ASPECTS SUBJECT TO NEGOTIATION/AWARD CRITERIA

In accordance with articles 145.1, 169 and 170 of the LCSP and taking into account the object of the reference contract, the following automatic award criteria is proposed:

1. Economic and technical aspects subject to negotiation: Price.
2. Award criteria: Price, according to art. 146.1 of the LCSP.

These award criteria will be common for the 19 lots.

Criteria evaluated automatically (100 points):

In accordance with article 146.2 of the LCSP, the following will be used for the evaluation of offers according to criteria quantifiable through the mere application of formulas:

- Economic offer: up to 100 points, according to the application of the following formula:

$$P_v = \left[1 - \left(\frac{O_v - O_m}{IL} \right) \times \left(\frac{1}{VP} \right) \right] \times P$$

Where:

- Pv: Offer score to Rate
- Ov: Offer to be assessed
- Om: Better Offer
- IL: Bidding Amount
- VP = Weighting Value
- Q: Economic criteria points

In the formula, the associated weighting value is equal to 1 (VP = 1).

Formula justification: Application of Directive 1/2020 on the application of formulas for the assessment and scoring of economic and technical proposals approved by the Directorate General of Public Procurement of the Generalitat de Catalunya.

In accordance with the provisions of article 170.2 of the LCSP and pursuant article 169.5 of the same law, the IMIM Foundation will negotiate with the bidder the initial offers and all subsequent offers submitted by it, except for the final offers referred to in the aforementioned article 169.8 of the LCSP.

ANNEX 5

MODIFICATIONS TO THE CONTRACT

Contractual modifications will be made in accordance with the provisions established in the LCSP and Directive 2014/24/EU, of 26 February 2014, on public procurement.

In accordance with article 204 of the LCSP, it is foreseen that a modification of the contract may be processed in the following cases:

- Increase or decrease in the number of patients to be recruited by one of the awarded centres, with prior authorisation from the IMIM Foundation. This assumption is considered in anticipation that one of the awarded centres will not be able to reach the marked figure of 30 patients and, therefore, it is necessary for one or more of the other awarded centres to increase the number of patients to be recruited in order to reach the figure of 570 patients required to carry out the study.

In the event of an increase, under no circumstances may the 36 patients recruited per centre be exceeded.

This possible modification will not affect the total number of patients to be recruited (570), nor will it mean an increase in the estimated value of the contract.

The formalization of the modification must be made by appearance, after hearing with the successful bidder, before the end of the contract.

In accordance with article 309.1 of the LCSP, in the service contract where the price is determined by execution units, the variation that occurs exclusively in the number of units actually executed over those provided for in the contract that may be included in the settlement up to 10% of the contract price will not be considered modifications.

The successful bidder shall be obliged to follow the services strictly subject to the rules established for him, without the right to claim compensation and for any reason may not reduce the pace of deliveries or suspend them.

ANNEX 6

PENALTY REGIME

Defaults

These are very serious breaches:

- The total and absolute stoppage of the execution of the services subject to this contract attributable to the contractor.
- Resistance to the requirements made by the Hospital del Mar Medical Research Institute Foundation or non-observance thereof, when it causes very serious damage to the execution of the contract.
- The use of work systems, elements, materials, machines or personnel other than those provided for in the contractor's specifications and offers, where applicable, when it causes very serious damage to the execution of the contract.
- Delays in response time and resolution of problems that affect the quality of the environment and safety in the workplace. A delay of 3 months will be considered a very serious breach.
- The falsification of the services entered by the contractor in the collection document.
- Failure to comply with the requirements relating to the subcontracting of benefits and the assignment of contracts.
- Failure to comply with the deadline for starting the execution of benefits.
- Failure to comply with the partial execution of the services defined in the contract that causes very serious damage.
- Recidivism in the commission of serious breaches.
- The application in offers or invoices of unit prices higher than the maximum applicable prices of said tender.

These are serious breaches:

- Resistance to the requirements made by the Fundació Institut Hospital del Mar d'Investigacions Mèdiques, or its non-observance, when it does not cause very serious damage.
- The use of work systems, elements, materials, machines or personnel other than those foreseen in the project, in the specifications and in the contractor's offers, where appropriate, when it does not cause very serious damage to the execution of the contract.
- Failure to comply with the requirements of a formal order established in this specification and in the applicable provisions for the execution of the contract.
- Delays in response time and resolution of problems that affect the quality of the environment and safety in the workplace.
- Failure to comply with environmental quality conditions and failure to communicate changes that may affect these quality conditions.
- Recidivism in the commission of minor breaches.

These are minor breaches:

- In accordance with current regulations, smoking is prohibited throughout the Fundació Institut Hospital del Mar d'Investigacions Mèdiques, both indoors and outdoors. Failure by the workers of the successful bidder to comply with the smoking ban inside the centres and venues will be considered a minor misdemeanor.
- Failure to comply with the requirements of a formal order established in this specification and in the applicable provisions for the execution of the contract, which does not constitute serious breach.

Hardships

Irrespective of the obligation to compensate for damages that may arise, if any, the Fundació Institut Hospital del Mar d'Investigacions Mèdiques may apply the following penalties, based on the degree of damage, dangerousness and/or repetition:

- a Very serious breaches: discounts on the contract price for each commission of this type of breach. The amount of each penalty will be established according to the damage and may represent up to 10% of the total amount of the contract.
- b Serious breaches: discounts on the contract price for each commission of this type of breach. The amount of each penalty will be established according to the damage and may represent up to 5 per 100 of the total amount of the contract.
- c Minor breaches: discounts on the contract price for each commission of this type of breach. The amount of each penalty will be established according to the damage and may represent up to 2 per 100 of the total amount of the contract.

In the processing of the case, the contractor will be given a hearing so that he can make allegations, and the contracting body will decide.

A minor breach can become serious, and a serious one can become very serious in case of lack of due diligence in complying with the requirements made by the IMIM Foundation to the contractor. Therefore, the same breach may lead to the application of penalties corresponding to minor, serious or very serious breaches, as appropriate.

In the event that the contractor becomes in default with respect to the fulfillment of the deadlines established in the contract, the penalties established in art. 193.3 of the LCSP, without prejudice to those that may correspond in accordance with the provisions of this PCAP.

In those contracts in which the contractor has the obligation to present a work program, failure to comply with the partial deadlines established therein will be considered very serious breaches and may lead to the application of the penalties provided for this type of breach, or the termination of the contract.

In accordance with article 192 of the LCSP, these penalties will be proportional to the seriousness of the breach and their total amount will not exceed 50% of the contract budget.

ANNEX 7

ESSENTIAL OBLIGATIONS OF THE CONTRACT

The successful bidder is obliged to carry out the service in the best possible conditions and to comply with all the obligations arising from the Technical Specifications of the tender.

You are also obliged to:

- a The contractor is obliged to comply with current provisions on labor, Social Security and occupational health and safety.

It is also obliged to comply with current provisions on the social integration of people with disabilities, fiscal and environmental.

- b The successful bidder must use Catalan in their relations with the IMIM Foundation, derived from the execution of the object of the contract. In any case, the contractor and, where appropriate, the subcontractors, are subject in the execution of the contract to the obligations derived from Law 1/1998, of 7 January, on language policy and the provisions that develop it.
- c Submit at all times to the instructions given by the person responsible for the contract of the Hospital del Mar Institute of Medical Research Foundation.
- d Designate a person responsible for the smooth running of services, who will act as liaison to the person responsible for the contract of the Hospital del Mar Medical Research Institute Foundation.
- e Keep reservation of data or background that are not public or notorious and that are related to the object of the contract, of which you have been aware on the occasion of it.
- f Provide all sufficient personnel to carry out the object of the contract, in accordance with the established technical conditions and with full responsibility, to offer execution to the full satisfaction of the IMIM Foundation. All personnel carrying out the service will depend solely on the contractor awarded, for all purposes without any link of civil service or employment dependence with the Hospital del Mar Medical Research Institute Foundation.
- g Be responsible for all damages caused to third parties and to Fundació Institut Hospital del Mar d'Investigacions Mèdiques Mar or to the personnel dependent on it.
- h The execution of the contract is at the risk and venture of the successful bidder.
- i The subcontracting or assignment of the contract may not be carried out without the express authorisation of the Fundació Institut Hospital del Mar d'Investigacions Mèdiques and in accordance with articles 215 and 214 of the LCSP.
- j Compliance with the special implementing conditions established in Annex 14 of the PCAP.
- k The successful bidder must inform the Fundació Institut Hospital del Mar d'Investigacions Mèdiques if they fail to comply, at any time, during the duration of the contract, with any of the requirements and whether it is a circumstantial and punctual breach or not. In the event that the established minimum mandatory requirements for available means or service levels are not met, the Fundació Institut Hospital del Mar d'Investigacions Mèdiques may terminate the contract unilaterally and without obligation to compensate the supplier.
- l In the event that an exclusive negotiated procedure has been processed without advertising in accordance with article 168 of the LCSP, the successful bidder will be obliged to notify the IMIM Foundation of the loss of exclusivity when this occurs.

ANNEX 8

DISTRIBUTION OF LOTS, ANNUITIES AND BILLING TYPES

DISTRIBUTION OF LOTS:

Lots	Description	Taxable base	21% VAT	Total
1	Patient recruitment in a pragmatic clinical trial and subsequent follow-up and its comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world settings at the Hôpital de Beaujon (Paris, France).	15.000,00 €	3.150,00 €	18.150,00 €
2	Patient recruitment in a pragmatic clinical trial and subsequent follow-up and its comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world settings at the Hôpital Paul Brousse (Paris, France).	15.000,00 €	3.150,00 €	18.150,00 €
3	Patient recruitment in a pragmatic clinical trial and subsequent follow-up and its comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world settings at the Hôpital de Strasbourg (Strasbourg, France).	15.000,00 €	3.150,00 €	18.150,00 €
4	Recruitment of patients in a pragmatic clinical trial and subsequent follow-up and comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world environments at the Hospital Policlinico Tor Vergata (Rome, Italy).	15.000,00 €	3.150,00 €	18.150,00 €
5	Patient recruitment in a pragmatic clinical trial and subsequent follow-up and its comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world settings at Ospedale San Raffaele (Milan, Italy).	15.000,00 €	3.150,00 €	18.150,00 €
6	Patient recruitment in a pragmatic clinical trial and subsequent follow-up and its comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world settings at Ospedale Miulli (Acquaviva delle Fonti, Italy).	15.000,00 €	3.150,00 €	18.150,00 €
7	Recruitment of patients in a pragmatic clinical trial and subsequent follow-up and comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world environments at the Istituto Tumori Napoli (Naples, Italy).	15.000,00 €	3.150,00 €	18.150,00 €
8	Recruitment of patients in a pragmatic clinical trial and subsequent follow-up and comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world settings at the Ospedale San Camilo Forlanini (Rome, Italy).	15.000,00 €	3.150,00 €	18.150,00 €

9	Patient recruitment in a pragmatic clinical trial and subsequent follow-up and its comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world environments at the University Clinical Centre Ljubljana (Ljubljana, Slovenia).	15.000,00 €	3.150,00 €	18.150,00 €
10	Patient recruitment in a pragmatic clinical trial and subsequent follow-up and comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world settings at Szpital Uniwersytecki im. Karola Marcinkowskiego w Zielonej Górze (Zielona Góra, Poland).	15.000,00 €	3.150,00 €	18.150,00 €
11	Patient recruitment in a pragmatic clinical trial and subsequent follow-up and its comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world settings at Uniwersytecki Szpital Kliniczny im. Norberta Barlickiego w Łodzi (Łódź, Poland).	15.000,00 €	3.150,00 €	18.150,00 €
12	Patient recruitment in a pragmatic clinical trial and subsequent follow-up and its comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world settings at Uniwersyteckie Centrum Kliniczne Warszawskiego Uniwersytetu Medycznego/ Centralny Szpital Kliniczny (Warsaw, Poland).	15.000,00 €	3.150,00 €	18.150,00 €
13	Recruitment of patients in a pragmatic clinical trial and subsequent follow-up and their comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world environments at SPSK im. Andrzeja Mielęckiego Śląskiego Uniwersytetu Medycznego w Katowicach (Katowice, Poland).	15.000,00 €	3.150,00 €	18.150,00 €
14	Patient recruitment in a pragmatic clinical trial and subsequent follow-up and comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world settings at Kantonspital Winterthur (Winterthur, Switzerland).	15.000,00 €	3.150,00 €	18.150,00 €
15	Recruitment of patients in a pragmatic clinical trial and subsequent follow-up and comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world environments at the General Hospital of Athens "Laiko" (Athens, Greece).	15.000,00 €	3.150,00 €	18.150,00 €
16	Recruitment of patients in a pragmatic clinical trial and subsequent follow-up and comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world environments at the Agios Savvas Hospital (Athens, Greece).	15.000,00 €	3.150,00 €	18.150,00 €
17	Patient recruitment in pragmatic clinical trial and subsequent follow-up and comparability with other therapeutic alternatives in terms of quality	15.000,00 €	3.150,00 €	18.150,00 €

	of life and patient experience in real-world settings at Metaxa Anticancer Hospital (Pireas, Greece).			
18	Recruitment of patients in a pragmatic clinical trial and subsequent follow-up and comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world environments at General University Hospital of Larissa (Larissa, Greece).	15.000,00 €	3.150,00 €	18.150,00 €
19	Patient recruitment in a pragmatic clinical trial and subsequent follow-up and comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world settings at the General Hospital of Athens "Ippokrateio" Vas (Athens, Greece).	15.000,00 €	3.150,00 €	18.150,00 €
TOTAL		285.000,00 €	59.850,00 €	344.850,00 €

DISTRIBUTION OF ANNUITIES: Expected start date on June 1st, 2024.

Sum of Lots No. 1 to 19 (recruitment of 30 patients/centre):

Year	Taxable base	21% VAT	Total
2024	171.000,00 €	35.910,00 €	206.910,00 €
2025	57.000,00 €	11.970,00 €	68.970,00 €
2026	0,00 €	0,00 €	0,00 €
2027	0,00 €	0,00 €	0,00 €
2028	57.000,00 €	11.970,00 €	68.970,00 €
Total	285.000,00 €	59.850,00 €	344.850,00 €

BILLING TYPES:

Payment to the contractor will be made upon presentation of an invoice issued in accordance with current regulations on electronic invoicing, within the deadlines and conditions established in article 198 of the LCSP.

In accordance with the provisions of Law 25/2013, of 27 December, on the promotion of electronic invoicing and the creation of the accounting register of invoices in the public sector, invoices must be signed with an advanced signature based on a recognised certificate, and must necessarily include the contracting file number.

The format of the electronic invoice and signature must comply with the provisions of Annex 1 of Order ECO/306/2015, of 23 September, which regulates the procedure for processing and annotating invoices in the Accounting Register of invoices within the scope of the administration of the Generalitat de Catalunya and the public sector that depends on it.

The e.FACT platform is the general entry point for electronic invoices of the Administration of the Generalitat de Catalunya and its Public Sector.

Thus, the successful bidder must submit their invoices to the e.FACT service of the Open Administration Consortium of Catalonia (AOC), in its capacity as General Point of Entry for Electronic Invoices of the Public Sector of Catalonia. For more information you can consult this link:

http://economia.gencat.cat/ca/70_ambits_actuacio/tresoreria_i_pagaments/factura-electronica/.

The generation of these invoices will correspond to the services carried out duly formed by the Technical Services of the contracting entity.

The invoice must identify the file number with which the contract has been tendered.

The payment(s) of the service will be made in accordance with the content of the LCSP and only by bank transfer and upon receipt of the invoice to the Accounting Department of the contracting entity, through the channels described above.

During the term of the contract there will be no price increase.

Any modification to VAT will be subject to review, and no other increase may be affected.

The invoicing must be issued with rounding to two digits, in accordance with the provisions of article 11 of Law 46/1998, of December 17, on the introduction of the euro.

The monitoring of the status of invoices can be consulted on the website of the Department of the Vice-Presidency and of the Economy and Finance in the Treasury and Payments section (consultation of the status of invoices and payments of documents), from the day after the invoice is registered.

In the event of a delay in payment, the contractor has the right to receive, under the legally established terms and conditions, late payment interest and the corresponding compensation for collection costs in the terms established in Law 3/2004, of 29 December, which establishes measures to combat late payment in commercial transactions.

The contractor may transfer the collection rights under the terms and conditions established in article 200 of the LCSP. For the effectiveness of this transfer of rights to the Fundació Institut Hospital del Mar d'Investigacions Mèdiques, it must have been notified reliably, that is, by means of documentation that allows proof of the conclusion of the contract and the capacity of the parties involved.

ANNEX 9

MANDATORY DOCUMENTATION TO BE INCLUDED IN THE ENVELOPE

The documentation listed below must be submitted by means of a telematic offer available through the Public Procurement Services Platform of the Generalitat de Catalunya.

- **General documentation** (in accordance with the provisions of Clause 5.3 of this PCAP). The following documentation must also be included electronically signed:
 - o Model of Annex 1 of the PCAP.

- **Documentation relating to the award criteria in Annex 4**, which must comply with the provisions of the Technical Specifications of the tender **and must comply with the indications contained in Annex 2 of this PCAP**, signed electronically by the bidder or person representing them. Thus, it will be necessary to include:
 - o Model of Annex 2 of the PCAP.

ANNEX 10

ETHICAL PRINCIPLES and RULES OF CONDUCT TO WHICH BIDDERS AND CONTRACTORS MUST ADAPT THEIR ACTIVITY

In accordance with article 55.2 of Law 19/2014, of 29 December, on transparency, access to public information and good governance, the administrations and bodies included in the scope of application of this law must include, in the specifications of contractual clauses and in the rules for calling for subsidies or grants, the ethical principles and rules of conduct to which contractors and beneficiaries must adapt their activity. and shall determine the effects of an eventual breach of these principles.

In compliance with this legal provision, the ethical principles and rules of conduct to which bidders and contractors must adapt their activity in their contractual relations in the field of public procurement in the public sector of Catalonia are published.

These principles and rules of conduct must be included in all specifications of clauses or documents regulating contracting.

Likewise, and in accordance with article 3.5 of Law 19/2014, public sector contracts must include the obligations of successful bidders to provide information established by this Law, without prejudice to compliance with transparency obligations.

1.- Bidders and contractors must adopt ethically exemplary conduct, refrain from performing, encouraging, proposing or promoting any type of corrupt practice and inform the competent bodies of any manifestation of such practices that, in their opinion, is present or may affect the procedure or contractual relationship. In particular, they will refrain from any action that may violate the principles of equal opportunities and free competition.

2.- In general, bidders and contractors, in the exercise of their activity, assume the following obligations:

- a Observe the principles, rules and ethical canons of the activities, trades and/or professions corresponding to the services covered by contracts.
- b Do not carry out actions that jeopardize the public interest in the scope of the contract or the benefits to be tendered.
- c Report irregular situations that may arise in public procurement processes or during the execution of contracts.

3.- In particular, bidders and contractors assume the following obligations:

- a Immediately notify the contracting body of possible conflict of interest situations. In any case, situations of conflict of interest constitute those contained in article 24 of Directive 2014/24/EU.
- b Not request, directly or indirectly, that a public official or employee influence the award of the contract.
- c Not to offer or provide public officials or employees with advantages for themselves or for third parties with the intention of influencing a contractual procedure.
- d Respect the principles of free markets and competitive competition and refrain from conduct aimed at or likely to have the effect of preventing, restricting or falsifying competition, such as collusion or fraudulent competition behaviour (offers of receipt, elimination of offers, allocation of markets, rotation of offers, etc.).
- e Not to use confidential information, known through the contract and/or during the tender, to obtain, directly or indirectly, an advantage or benefit.
- f Collaborate with the contracting body in the actions that it carries out for the monitoring and/or evaluation of compliance with the contract, particularly providing the information requested for these purposes.
- g Comply with the obligations to provide information that transparency legislation and public sector contracts impose on successful bidders in relation to the reference Administration or Administrations, without prejudice to compliance with the transparency obligations that correspond directly to them by legal provision.

- h Report acts of which it becomes aware and that may lead to an infringement of the obligations contained in this clause.

4.- Failure to comply with the obligations contained in the previous section by bidders or contractors shall be foreseen as a cause, in accordance with public procurement legislation, of termination of the contract, without prejudice to those other possible consequences provided for in current legislation.

ANNEX 11

ETHICS CLAUSE

1 Senior managers, managerial staff, command positions, administrative positions and personnel at the service of the Public Administration and its public sector, who intervene, directly or indirectly, in the public procurement procedure are subject to the Code of Principles and Conduct recommended in public procurement and their provisions will be applied transversally to any action that forms part of any phase of the procurement procedure in accordance with the degree of intervention and responsibility in contractual procedures.

The presentation of the offer by bidders will imply their adherence to the Code of Principles and Conduct recommended in public procurement in accordance with the ethical and integrity commitments that form part of the contractual relationship.

2.1. Bidders, contractors and subcontractors assume the following obligations:

- a Observe the ethical principles, norms and canons of the activities, trades and/or professions corresponding to the services covered by the contracts.
- b Do not carry out actions that jeopardize the public interest in the scope of the contract or the benefits to be tendered.
- c Report irregular situations that may arise in public procurement processes or during the execution of contracts.
- d Refrain from conduct aimed at or likely to have the effect of preventing, restricting or falsifying competition, such as collusion or fraudulent competition behaviour (offers of receipt, elimination of offers, allocation of markets, rotation of offers, etc.).
- e At the time of submitting the bid, the bidder must declare whether he has any situation of possible conflict of interest, for the purposes of the provisions of article 64 of the LCSP, or an equivalent relationship with respect with interested parties in the project. If during the execution of the contract a situation of this nature occurs, the contractor or subcontractor is obliged to inform the contracting body.
- f Respect confidentiality agreements and rules.
- g In addition, the contractor must collaborate with the contracting body in the actions carried out by it to monitor and/or evaluate compliance with the contract, particularly by providing the information requested for these purposes and that transparency legislation and public sector contract regulations impose on contractors in relation to the Administration or administrations of reference, without prejudice to compliance with the transparency obligations that correspond directly to them by legal provision.

2.2. Bidders, contractors and subcontractors, or their subsidiaries or related companies, undertake to strictly comply with tax, labour and social security legislation and, specifically, not to carry out financial operations contrary to tax regulations in countries that do not have rules on capital control and are considered tax havens by the European Union.

2.3. All these obligations and commitments are considered special conditions for the execution of the contract.

2.4. The consequences or penalties for non-compliance with this clause will be as follows:

- In case of non-compliance with sections a), b), c), f) and g) of section 2.1, a minimum penalty of 0.60 euros is established for every 1000 euros of the contract price, excluding VAT, which may be increased justifiably and proportionally depending on the seriousness of the facts. The seriousness of the facts will be determined by the damage caused to the public interest, the repetition of the

facts or the obtaining of a benefit derived from the breach. In any case, the amount of each of the penalties may not exceed 10% of the contract price, excluding VAT, nor may its total exceed in any case 50% of the contract price.

- In the event of non-compliance with the provisions of letter d) of section 2.1, the contracting authority shall report the facts to the competent authorities in matters of competition.
- In the event of non-compliance with the provisions of letter e) of section 2.1, the contracting body will inform the Commission of Ethics in Public Procurement of the Generalitat de Catalunya so that it can issue the relevant report, without prejudice to other penalties that may be established.
- In the event that the seriousness of the facts requires it, the contracting body will inform the Anti-Fraud Office of Catalonia or of the control and audit bodies that are competent due to the matter.

ANNEX 12

Single European Procurement Document (ESPD)

It doesn't apply.

ANNEX 13

DOCUMENT CONFIDENTIALITY STATEMENT

FILE NUMBER:

Mr./Ms....., with address at
..... Street No., provided with D.N.I. number
....., in the name and representation of the company
....., domiciled at Calle
....., provided with N.I.F. no.

For the purposes of completing the provisions of article 133 of the LCSP, I declare under my responsibility that the documents listed below are confidential:

-File:.... page:.....

-File:.... page:.....

None of the documents included in my offer are confidential.

NOTES:

1.- In the event that no field is complemented, it will be understood that the information provided by the bidder is not confidential.

2.- Information that has been published in the Public Registers (RELI) will not be considered confidential.

3.- In order not to interfere with the principles of publicity and transparency of procedures and freedom of access to tenders, all documents will NOT be considered confidential except for those specific documents that the bidder indicates that affect technical or commercial secrets and confidential aspects of the offers. In this sense, **bidders must specify and justify the reasons why the documents marked as confidential are confidential, as well as if there are commercial or technical secrets susceptible to protection**, being the Contracting Body the one that ultimately and in case of discrepancy, will issue a reasoned resolution on the confidentiality or not of the documents marked as such.

Electronic signature of the person formulating the proposal.

ANNEX 14

SPECIAL CONDITIONS OF EXECUTION

The special conditions of mandatory execution are the following:

- a) The successful bidder will maintain, during the term of the contract, the working and social conditions of the workers employed in the execution of the contract, set at the time of submitting the offer, according to the applicable agreement. This condition can be accredited by an affidavit submitted by the contractor, when required.
- b) In accordance with the provisions of articles 3.5 and 55.2 of Law 19/2014, of December 29, on transparency, access to public information and good governance, the contractor undertakes to provide the information established in said law.
- c) It will perform the service object of the contract, in accordance with Annex 10 and Annex 11 of this Specification, relating to the "Ethical principles and rules of conduct to which bidders and contractors must adapt their activity" and the "Ethics clause" respectively.
- d) The successful bidder assumes, as a special condition of execution, the obligation to guarantee equal treatment of all patients and their rights.

These conditions are an essential obligation of the contract and their breach may be penalized as a very serious misconduct or cause of contractual termination.

ANNEX 15

MODEL OF CONTRACT REGULATING THE ASSIGNMENT OF PERSONAL DATA PROCESSING STANDARD CONTRACTUAL CLAUSES

In accordance with the Commission Implementing Decision (EU) 2021/915 of 4 June 2021 on standard contractual clauses between controllers and processors referred to in Article 28(7) of Regulation (EU) 2016/679 of the European Parliament and of the Council and in Article 29(7) of Regulation (EU) 2018/1725 of the European Parliament and of the Council.

SECTION I

Clause 1

Purpose and scope of application

- a) The purpose of these standard contractual clauses (hereinafter, "specifications") is to ensure compliance with Article 28(3) and 4 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).
- b) The controllers listed in Annex I have given their consent to be bound by this specification of clauses in order to guarantee compliance with Article 28, sections 3 and 4, of Regulation (EU) 2016/679 and/or Article 29, sections 3 and 4, of Regulation (EU) 2018/1725.
- c) This specification of clauses applies to the processing of personal data specified in Annex II.
- d) Annexes I to IV form part of the specifications.
- e) This specification of clauses is understood without prejudice to the obligations to which the controller is subject under Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725.
- f) This specification of clauses does not in itself guarantee compliance with the obligations relating to international transfers contemplated in Chapter V of Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725.

Clause 2

Invariability of the specifications

- a) The parties undertake not to modify the specifications, except to add or update information in the annexes.
- b) This is not obvious because the parties include in a broader contract the standard contractual clauses contained in this specification, nor because they add other additional clauses or guarantees provided that they do not directly or indirectly contradict the specifications of clauses or prejudice the fundamental rights or freedoms of the interested parties.

Clause 3

Interpretation

- a) When this specification of clauses uses terms defined in Regulation (EU) 2016/679 or in Regulation (EU) 2018/1725, they shall be understood to have the same meaning as in the corresponding Regulation.
- b) This specification of clauses must be read and interpreted in accordance with the provisions of Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725.
- c) No interpretations may be made of this specification of clauses that conflict with the rights and obligations established in Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 and/or that prejudice the fundamental rights or freedoms of the interested parties.

Clause 4

Hierarchy

In case of contradiction between this specification of clauses and the provisions of related agreements between the parties that are in force at the time this specification of clauses is agreed or begins to apply, this specification of clauses will prevail.

Clause 5

Incorporation clause

Not applicable

**SECTION II
OBLIGATIONS OF THE PARTIES**

Clause 6

Description of treatment or treatments

Annex II specifies the details of the processing operations and, in particular, the categories of personal data and the purposes for which the personal data are processed on behalf of the controller.

Clause 7

Obligations of the parties

7.1. Instructions

- a) The person in charge will process the personal data only following documented instructions from the person in charge, unless obliged to do so by virtue of Union or Member State law that applies to the processor. In this case, the person in charge will inform the person responsible for this legal requirement prior to treatment, unless this right prohibits it for important reasons of public interest. The person in charge may also give subsequent instructions at any time during the period of processing of personal data. These instructions must always be documented.
- b) The processor will immediately inform the person in charge if the instructions given by the person in charge infringe, in the opinion of the person in charge, Regulation (EU) 2016/679, Regulation (EU) 2018/1725 or the applicable provisions of Union or Member State law regarding data protection.

7.2. Purpose limitation

The person in charge will process the personal data only for the specific purposes of the treatment indicated in Annex II, except when he follows additional instructions from the person in charge.

7.3. Duration of processing of personal data

The processing by the person in charge will only be carried out during the period specified in Annex II.

7.4. Security of the treatment

- a) The person in charge will apply, as a minimum, the technical and organizational measures specified in Annex III to guarantee the security of personal data. One of these measures may consist of protection against security breaches resulting in accidental or unlawful destruction, loss or alteration of personal data, or unauthorized communication or access to such data ("breach of personal data security"). In determining an adequate level of security, the parties will duly take into account the state of the art, the costs of application, the nature, scope, context and purposes of the treatment, and the risks involved in the treatment for the interested parties.
- b) The processor will only grant access to the personal data processed to the members of its staff to the extent strictly necessary for the execution, management and monitoring of the contract. The person in charge will ensure that the persons authorized to process the personal data received have undertaken to respect confidentiality or are subject to a confidentiality obligation of a statutory nature.

7.5. Sensitive data

If the processing affects personal data revealing ethnic or racial origin, political opinions, religious or philosophical convictions, or union membership, genetic data or biometric data aimed at unambiguously identifying a natural person, data related to health or data relating to the sexual life or sexual orientation of a natural person, or data relating to criminal convictions and offences ("sensitive data"), the person in charge will apply specific restrictions and / or additional guarantees.

7.6. Documentation and compliance

- a) The parties must be able to demonstrate compliance with this specification.
- b) The person in charge will promptly and adequately resolve the queries of the person in charge related to the treatment in accordance with this specification of clauses.
- c) The person in charge will make available to the person in charge all the information necessary to demonstrate compliance with the obligations contemplated in this specification of clauses and that derive directly from Regulation (EU) 2016/679 and Regulation (EU) 2018/1725. At the request of the person in charge, the person in charge will allow and contribute to the performance of audits of the treatment activities covered by this specification of clauses, at reasonable intervals or if there are indications of non-compliance. When deciding whether to carry out an examination or an audit, the

person in charge may take into account the relevant certifications that are in the possession of the person in charge.

- d) The person in charge may choose to carry out the audit by himself or authorize an independent auditor. Audits may also consist of inspections of the premises or physical facilities of the manager and, where appropriate, be carried out with reasonable notice.
- e) The parties shall make available to the competent supervisory authorities, at their request, the information referred to in this clause and, in particular, the results of audits.

7.7. Appeal to sub-processors

- a) The person in charge may only subcontract to a sub-processor the treatment operations carried out on behalf of the person in charge by virtue of this specification of clauses with the specific prior written authorization of the person in charge. The person in charge must submit the request for specific authorisation at least 15 working days before the hiring of the sub-processor in question, together with the information necessary for the person in charge to resolve the request. The list of sub-processors authorised by the person in charge can be found in Annex IV. The parties shall keep Annex IV updated.
- b) When the processor hires a sub-processor to carry out specific processing activities (on behalf of the controller), he will do so by means of a contract that essentially imposes on the sub-processor the same data protection obligations as those imposed on the processor under this specification. The processor will ensure that the subprocessor complies with the obligations to which he is subject under this specification of clauses and Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725.
- c) The person in charge will provide the person responsible, at the request of the latter, a copy of the contract with the sub-processor and any subsequent modification thereof. To the extent necessary to protect trade secrets or other confidential information, such as personal data, the processor may expurgate the text of the contract before sharing the copy.
- d) The person in charge will continue to be fully responsible to the person responsible for compliance with the obligations imposed on the sub-processor by his contract with the person in charge. The person in charge will notify the person in charge of the breaches by the sub-person in charge of the obligations attributed to him by said contract.
- e) The person in charge will agree with the sub-processor a third-party beneficiary clause under which, in the event that the person in charge disappears de facto, ceases to exist legally or is insolvent, the person in charge will have the right to terminate the subprocessor's contract and order him to delete or return the personal data.

7.8. International transfers

- a) Transfers of data to a third country or to an international organization by the processor may only be carried out following documented instructions from the person in charge or by virtue of an express requirement of Union law or of the Member State to which the processor is subject; shall be carried out in accordance with Chapter V of Regulation (EU) 2016/679 or Regulation (EU) 2018/1725.
- b) The controller agrees that, when the processor resorts to a sub-processor in accordance with clause 7.7 to carry out specific processing activities (on behalf of the controller) and these activities involve a transfer of personal data within the meaning of chapter V of Regulation (EU) 2016/679, the processor and the subprocessor can ensure compliance with Chapter V of Regulation (EU) 2016/679 using standard contractual clauses adopted by the Commission, in accordance with Article 46(2) of Regulation (EU) 2016/679, provided that the conditions for the use of these standard contractual clauses are met.

Clause 8

Help for data controllers

- a) The person in charge will promptly notify the person in charge of the requests received from the interested party. It will not respond to this request by itself, unless the person in charge has authorized it to do so.
- b) The person in charge will help the person in charge to fulfill their obligations when responding to requests for the exercise of rights of the interested parties, taking into account the nature of the

treatment. In compliance with the obligations attributed to him by letters a) and b), the person in charge will comply with the instructions of the person in charge.

- c) In addition to the obligation of the person in charge to assist the person in charge under clause 8, letter b), the person in charge will also help the person in charge to guarantee compliance with the following obligations taking into account the nature of the treatment and the information available to the person in charge:
1. the obligation to carry out an assessment of the impact of processing operations on the protection of personal data ("impact assessment") when it is likely that a type of processing poses a high risk to the rights and freedoms of natural persons;
 2. the obligation to consult the competent control authorities before proceeding with the processing when an impact assessment related to data protection shows that the treatment would entail a high risk if the controller does not take measures to mitigate it;
 3. the obligation to guarantee that personal data are accurate and up to date, informing the person in charge without delay if the person in charge discovers that the personal data being processed is inaccurate or has become obsolete;
 4. the obligations under Article 32 of Regulation (EU) 2016/679.
- d) The parties shall establish in Annex III appropriate technical and organizational measures that oblige the person in charge to assist the person in charge in applying this clause, as well as the object and scope of the aid required.

Clause 9

Notification of personal data security breaches

In the event of a breach of the security of personal data, the processor will collaborate with the person in charge and help him comply with the obligations attributed to him by articles 33 and 34 of Regulation (EU) 2016/679 or articles 34 and 35 of Regulation (EU) 2018/1725, where appropriate, taking into account the nature of the treatment and the information available to the processor.

9.1. Violation of the security of personal data processed by the controller

In case of breach of the security of personal data in relation to the data processed by the person in charge, the person in charge will help the person in charge in the following:

- a) Notify the competent supervisory authorities of the breach of personal data without undue delay once they become aware of them, where appropriate (unless it is unlikely that such a breach of security constitutes a risk to the rights and freedoms of natural persons).
- b) Collect the following information, which, in accordance with [OPTION 1] Article 33(3) of Regulation (EU) 2016/679 / [OPTION 2] Article 34(3) of Regulation (EU) 2018/1725, must appear in the notification of the controller, which must include at least:
 1. the nature of the personal data, including, where possible, the categories and the approximate number of data subjects affected, and the categories and approximate number of personal data records affected;
 2. the likely consequences of a breach of the security of personal data;
 3. The measures adopted or proposed by the controller to remedy the breach of the security of personal data, including, where appropriate, the measures adopted to mitigate possible negative effects.

When and to the extent that all the information cannot be provided at the same time, the initial notification will provide the information available at that time and, as it is collected, additional information will be provided without undue delay.

- c) Comply, in accordance with article 34 of Regulation (EU) 2016/679, with the obligation to notify the interested party without undue delay of the breach of the security of personal data when it is likely that the breach of security entails a high risk to the rights and freedoms of natural persons

9.2. Violation of the security of personal data processed by the processor

In case of a breach of the security of personal data processed by the person in charge, he will notify the person in charge without undue delay once the person in charge has proof of it. This notification must include at least:

- a) a description of the nature of the security breach (including, where possible, categories and the approximate number of data subjects and data records affected);
- b) the data of a contact point where more information can be obtained about the breach of the security of personal data;
- c) its likely consequences and the measures taken or proposed to remedy the security breach, including measures taken to mitigate possible negative effects.

When and to the extent that all the information cannot be provided at the same time, the initial notification will provide the information available at that time and, as it is collected, additional information will be provided without undue delay.

The parties shall establish in Annex III the other elements to be provided by the processor when assisting the controller in complying with the obligations attributed to him by articles 33 and 34 of Regulation (EU) 2016/679, articles 34 and 35 of Regulation (EU) 2018/1725.

SECTION III FINAL PROVISIONS

Clause 10

Breach of the clauses and termination of the contract

- a) Without prejudice to the provisions of Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725, in the event that the processor fails to comply with the obligations attributed to him in this specification of clauses, the person in charge may order the person in charge to suspend the processing of personal data until he returns to comply with this specification of clauses, or terminate the contract. The person in charge will promptly inform the person in charge in case he cannot comply with this specification of clauses for any reason.
- b) The person in charge will be entitled to terminate the contract with regard to the processing of personal data by virtue of this specification of clauses when:
 1. The processing of personal data by the person in charge has been suspended by the person in charge in accordance with letter a) and this specification of clauses is not complied with again within a reasonable period and, in any case, within a period of one month from the suspension;
 2. the processor substantially or persistently fails to comply with this specification of clauses or the obligations attributed to him by Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725;
 3. the processor fails to comply with a binding resolution of a competent jurisdictional body or of the competent control authorities in relation to the obligations attributed to them by this specification of clauses, Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725.
- c) The person in charge will be entitled to terminate the contract with regard to the processing of personal data by virtue of this specification of clauses when, after having informed the person in charge that his instructions violate the legal requirements demanded by clause 7.1, letter b), the person in charge insists that these instructions be followed.

After the termination of the contract, the person in charge will delete, at the request of the person in charge, all the personal data processed on behalf of the person in charge and will accredit the person in charge who has done so, or return all personal data to the person in charge and delete the existing copies, unless the law of the Union or of the Member States requires the storage of personal data. Until the data is destroyed or returned, the processor will continue to guarantee compliance with this specification.

ANNEX I
Parts list

Responsible(s): *[Identity and contact details of the controller or data controllers and, where appropriate, the data protection officer]*

1. Entity: Hospital del Mar Medical Research Institute Foundation
Address: Carrer Dr. Aiguader, 88, 08003 Barcelona (Spain).
Representative: Joaquín Arribas López
Position: Director
Contact details: jarribas@researchmar.net

2. Data Protection Officer: Roc Mas Vélez
Address: Passeig Marítim, 25-29, 08003 Barcelona (Spain).
E-mail: protecciodedades@researchmar.net

Processor(s): *[Identity and contact details of the processor or processors and, where appropriate, the data protection officer]*

1. Entity:.....
Address:.....
Representation:.....
Charge:.....
Contact details: (email)
2. Data Protection Officer:
Address:.....
Email:.....

ANNEX II Description of treatment

Categories of interested parties whose personal data are processed:

- Identification data (name, surnames, age, identification number, etc.).
- Data related to the provision of services (patient number, medical history number, etc.).
- Health data (diagnosis, data relating to medical tests, blood tests, anamnesis, etc.).

Categories of personal data processed

- Patients treated at the centre of the person in charge of treatment.

Sensitive data processed (where applicable) and restrictions or guarantees applied that take full account of the nature of the data and the risks involved, such as, for example, strict limitation of purpose, access restrictions (including exclusive access by personnel who have taken a specialised course), a record of access to data, restrictions on subsequent transfers or additional security measures.

Personal data, especially special categories of data, must be processed in accordance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation) and Compliance with national regulations applicable to data security. Personnel participating in data processing activities must be subject to a commitment to confidentiality, as well as having received adequate training and instructions to guarantee the security of the personal data processed.

The data collected will be used by the parties exclusively to achieve the purposes described, as well as those that are compatible according to the applicable regulations.

Nature of the processing

The data processing will be carried out in accordance with the provisions of the protocol of the research project "*Unraveling the impact of Radiofrequency in liver surgery: the key to decrease local recurrence?*" (Liveration)", as well as according to the life cycle of the data in the collection.

International data transfers to third states or international organizations are not foreseen.

Purpose(s) of the processing of personal data on behalf of the data controller

The data processing aims to achieve the objectives proposed in the framework of the project "*Unraveling the impact of Radiofrequency in liver surgery: the key to decrease local recurrence?*" (Liveration)", in the manner identified in the protocol of said project.

Duration of treatment

The duration of treatment is established in relation to the duration of the research project "*Unraveling the impact of Radiofrequency in liver surgery: the key to decrease local recurrence?*" (Liveration)", as well as for the legal time of conservation of data appropriate in accordance with the applicable regulations.

In case of processing by (sub)processors, please also specify the purpose, nature and duration of processing.

ANNEX III

Technical and organizational measures, especially technical and organizational measures to guarantee data security

1. Encryption:

- The confidentiality and integrity of the information processed must be guaranteed, both stored in information management systems and in transit through the network, for which encryption mechanisms must be used:
 - Information "**on the transmission line**" using encryption based on TLS certificates 1.2 or higher.

2. Management of "Logs" and audit:

The Parties shall have a log management and audit system:

- It must enable periodic user review, to ensure that they are configured at the appropriate level of privilege and activate the accounts that should be so (eliminating personnel who have unsubscribed and their account remains active). The frequency will depend on each Organization.
- User interactions with the patient data management system must be recorded and stored in a secure environment for at least 2 years.
- Annotation records should include, as far as possible, sufficient information to track the activity of an individual/user with a timestamp, including access, modifications, insertions and searches performed.
- The patient data management system must provide a complete audit trail of the navigation performed by the account of the user accessing.
- The Parties shall periodically audit data processing systems.

3. Vulnerability management:

- The patient data management system must be developed using secure coding standards and be protected against web application attacks.

4. Requirements:

- **Equipment:** the equipment used for data processing must, as far as possible, comply with the following security criteria:
 - The hard drive must be encrypted.
 - You must have installed, operational and properly configured an antivirus system that will update the signatures daily.
 - You must have a firewall correctly configured in accordance with the security policy defined by the promoter.
 - You must have the latest updates to your operating system installed.
 - Access must be password protected or robust unlock pattern.
 - It must be a dedicated team used exclusively for the rehearsal tasks carried out on behalf of the promoters.
 - All services and connection interfaces that are not necessary must be disabled.
 - The work profile configured in the teams for users will lack administration privileges, unless their functions make it indispensable.
- **Personal:** Users with access to data processing equipment must:
 - Avoid installing and using applications that have not been formally approved by the person responsible for the systems.
 - Review and periodically delete residual information that may have been stored on the device, such as temporary files or downloaded documents.
 - Once the work that requires access to the patient's data management systems has been completed, proceed to close the session.

- **Work Environment:**

- The workplace must meet minimum privacy conditions, such as in a limited access area (including remote work), preventing other people from having access.
- If it is necessary to work from public access spaces, additional protection measures will be adopted to preserve the confidentiality of the information processed, such as the use of privacy filters on device screens.
- Work with information on paper should be avoided and never disposed of without the use of secure mechanisms (paper shredder or specific containers for confidential documentation).
- You will have to work from encrypted networks, never from free and/or free Wi-Fi networks.
- In the event of any anomaly that may affect the security of the information and the protection of the data processed, this circumstance must be communicated to the head of systems and/or data protection of your organization.

ANNEX IV
List of subprocessors

CLARIFICATION NOTE:

This annex must be completed when the specific authorisation of one or more sub-processors is required [clause 7.7, letter a), option 1].

The person in charge has authorised the following sub-managers to be used: