

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

REPORT JUSTIFYING THE ASPECTS ESTABLISHED IN ARTICLES 28, 100, 101 AND 116.4 OF LAW 9/2017 ON PUBLIC SECTOR CONTRACTS IN RELATION TO THE CONTRACT FOR THE RECRUITMENT AND MONITORING OF PATIENTS IN NINETEEN FOREIGN CENTRES WITHIN THE FRAMEWORK OF THE "LIVERATION" RESEARCH PROJECT FOR THE HOSPITAL DEL MAR RESEARCH INSTITUTE FOUNDATION.

In accordance with the provisions of articles 28, 100, 101 and 116.4, of Law 9/2017, of November 8, on Public Sector Contracts (hereinafter, LCSP), the procurement file must justify the aspects detailed in the aforementioned precepts of the aforementioned regulation. To this end, the purpose of this report is to comply with the provisions of the aforementioned articles and is issued, therefore, in order to justify the aspects established below in relation to the **contract for the recruitment and follow-up of patients in nineteen foreign centers within the framework of the research project "LIVERATION", for the Hospital del Mar Research Institute Foundation (hereinafter, also the IMIM Foundation).**

I) Object of the contract:

The purpose of the contract is the patient recruitment and follow-up service in nineteen foreign centers, 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.

The main objective of the LIVERATION project is to conduct a multicenter, ambitious and pragmatic clinical trial with patients with CRLM (colorectal liver metastasis) and HCC (hepatocellular carcinoma), in foreign centers, in order to determine whether the margin of additional ablation produced by radiofrequency can reduce the recurrence rate and improve patient survival. The patient-centered nature of the intervention and its comparability with other therapeutic alternatives will also be evaluated in terms of quality of life and patient experience in real-world settings.

Specifically, it is intended to carry out the aforementioned service in the following centers:

- Hôpital de Beaujon, Paris (France)
- Hôpital Paul Brousse, Paris (France)
- Hôpital de Strasbourg, Strasbourg (France)
- Policlinico Tor Vergata, Rome (Italy)
- Ospedale San Raffaele, Milan (Italy)
- Ospedale Miulli, Acquaviva delle Fonti (Italy)
- Istituto Tumori Napoli, Naples (Italy)
- Ospedale San Camilo Forlanini, Rome (Italy)
- University Clinical Centre Ljubljana (Department for Abdominal Surgery), Ljubljana (Slovenia)
- Szpital Uniwersytecki im. Karola Marcinkowskiego w Zielonej Górze, Zielona Góra (Poland)
- Uniwersytecki Szpital Kliniczny im. Norberta Barlickiego w Łodzi, Łodz (Poland)
- Uniwersyteckie Centrum Kliniczne Warszawskiego Uniwersytetu Medycznego/Centralny Szpital Kliniczny, Warsaw (Poland)
- SPSK im. Andrzeja Mielęckiego Śląskiego Uniwersytetu Medycznego w Katowicach,

- Katowice (Poland)
- Kantonspital Winterthur, Winterthur (Switzerland)
 - General Hospital of Athens "Laiko", Athens (Greece)
 - Agios Savvas Hospital, Athens (Greece)
 - Metaxa Anticancer Hospital, Pireas (Greece)
 - General University Hospital of Larissa, Larissa (Greece)
 - General Hospital of Athens "Ippokrateio" Vas, Athens (Greece)

This object corresponds to the code CPV 73210000-7 "Research consulting services" of the European Commission.

II) Needs to be satisfied, suitability of the object and content of the contract:

This contract will satisfy, directly, clearly and proportionally, the needs specified in the first point of this report.

The Hospital del Mar Research Institute Foundation requires the services mentioned in the object of the contract within the framework of the aforementioned research project.

III) Insufficiency of the entity's own means to carry out the service object of the contract:

Insufficiency of personal and material resources: The Hospital del Mar Research Institute Foundation requires other centres to reach minimum recruitment for the execution of the project. At the state level, only 160 patients can be recruited out of the 730 needed, so these remaining 570 patients are those who must be recruited by hiring the 19 foreign centers.

Therefore, given that the service object of the contract cannot be carried out with the entity's own means, it is absolutely necessary to contract the service object of the contract with external centers.

IV) Tender budget:

The base tender budget is understood as the maximum expense limit that, under the contract, may be committed by the contracting body, including Value Added Tax (VAT).

Each of these 19 centers that are expected to be hired must recruit 30 patients within 9 months of signing the contracts:

30 x 19 = 570 patients to recruit in total.

The tender budget corresponds to the budgetary forecasts determined by the European Union Grant Agreement, which have been calculated at € 500.00 per recruited patient 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 center:

$570 \times 500 = 285.000,00 \text{ €}$

This is a service contract at unit prices.

The € 500.00 per recruited patient will be paid as follows:

- A first payment of 60% of the amount indicated will be made after visit no. 4 (90 days).
- A second payment of 20% of the amount indicated will be made after visit no. 5 (1 year).

- Finally, a third and final payment of 20% of the indicated amount will be made at the end of the patient follow-up (3 years, approx.).

Considering that the tender budget must be adequate to the prices of certain in the Grant, Agreement received from the European Union, having to take into account direct and indirect costs, and other possible expenses calculated for its determination, the following tender budget is fixed:

Base Imposable:	285.000,00 €
VAT at 21%:	59.850,00 €

Total:.....	344.850,00 €

The amount listed is broken down as follows:

- **Lot no. 1: Patient recruitment in 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 Hôpital de Beaujon, Paris (France):**

30 patients will be recruited in 9 months at a price of € 500.00 per patient recruited and followed for 3 years.

$$30 \times 500 = 15.000,00 \text{ €}.$$

- **Lot no. 2: Patient recruitment in 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 Hôpital Paul Brousse, Paris (France):**

30 patients will be recruited in 9 months at a price of € 500.00 per patient recruited and followed for 3 years.

$$30 \times 500 = 15.000,00 \text{ €}.$$

- **Lot no. 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):**

30 patients will be recruited in 9 months at a price of € 500.00 per patient recruited and followed for 3 years.

$$30 \times 500 = 15.000,00 \text{ €}.$$

- **Lot no. 4: 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 settings at the Policlinico Tor Vergata (Rome, Italy):**

30 patients will be recruited in 9 months at a price of € 500.00 per patient recruited and followed for 3 years.

$$30 \times 500 = 15.000,00 \text{ €}.$$

- **Lot no. 5: Patient recruitment in 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 Raffaele (Milan, Italy):**

30 patients will be recruited in 9 months at a price of € 500.00 per patient recruited and followed for 3 years.

$$30 \times 500 = 15.000,00 \text{ €}.$$

- **Lot no. 6: Patient recruitment in 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 Miulli (Acquaviva delle Fonti, Italy):**

30 patients will be recruited in 9 months at a price of € 500.00 per patient recruited and followed for 3 years.

30 x 500 = 15.000,00 €.

- **Lot no. 7: 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 Istituto Tumori Napoli (Naples, Italy):**

30 patients will be recruited in 9 months at a price of € 500.00 per patient recruited and followed for 3 years.

30 x 500 = 15.000,00 €.

- **Lot no. 8: Patient recruitment in 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):**

30 patients will be recruited in 9 months at a price of € 500.00 per patient recruited and followed for 3 years.

30 x 500 = 15.000,00 €.

- **Lot no. 9: Patient recruitment in 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 University Clinical Centre Ljubljana (Ljubljana, Slovenia):**

30 patients will be recruited in 9 months at a price of € 500.00 per patient recruited and followed for 3 years.

30 x 500 = 15.000,00 €.

- **Lot no. 10: Patient recruitment in 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):**

30 patients will be recruited in 9 months at a price of € 500.00 per patient recruited and followed for 3 years.

30 x 500 = 15.000,00 €.

- **Lot no. 11: Patient recruitment in 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 Uniwersytecki Szpital Kliniczny im. Norberta Barlickiego w Łodzi (Łódź, Poland):**

30 patients will be recruited in 9 months at a price of € 500.00 per patient recruited and followed for 3 years.

30 x 500 = 15.000,00 €.

- **Lot no. 12: Patient recruitment in 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 Uniwersyteckie Centrum Kliniczne Warszawskiego Uniwersytetu Medycznego/Centralny Szpital Kliniczny (Warsaw, Poland):**

30 patients will be recruited in 9 months at a price of € 500.00 per patient recruited and followed for 3 years.

30 x 500 = 15.000,00 €.

- **Lot no. 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 to SPSK im. Andrzeja Mielęckiego Śląskiego Uniwersytetu Medycznego w Katowicach (Katowice, Poland):**

30 patients will be recruited in 9 months at a price of € 500.00 per patient recruited and followed for 3 years.

30 x 500 = 15.000,00 €.

- **Lot no. 14: Patient recruitment in 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):**

30 patients will be recruited in 9 months at a price of € 500.00 per patient recruited and followed for 3 years.

30 x 500 = 15.000,00 €.

- **Lot no. 15: 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 settings at the General Hospital of Athens "Laiko" (Athens, Greece):**

30 patients will be recruited in 9 months at a price of € 500.00 per patient recruited and followed for 3 years.

30 x 500 = 15.000,00 €.

- **Lot no. 16: 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 settings at the Agios Savvas Hospital (Athens, Greece):**

30 patients will be recruited in 9 months at a price of € 500.00 per patient recruited and followed for 3 years.

30 x 500 = 15.000,00 €.

- **Lot no. 17: 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 settings at Metaxa Anticancer Hospital (Pireas, Greece):**

30 patients will be recruited in 9 months at a price of € 500.00 per patient recruited and followed for 3 years.

30 x 500 = 15.000,00 €.

- **Lot no. 18: 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 settings at General University Hospital of Larissa (Larissa, Greece):**

30 patients will be recruited in 9 months at a price of € 500.00 per patient recruited and followed for 3 years.

30 x 500 = 15.000,00 €.

- **Lot no. 19: Recruitment of patients in 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 settings at the General Hospital of Athens "Ippokrateio" Vas (Athens, Greece):**

30 patients will be recruited in 9 months at a price of € 500.00 per patient recruited and followed for 3 years.

30 x 500 = 15.000,00 €.

V) Estimated contract value:

Breakdown of estimated contract value:

- Base tender budget (excluding VAT)	285.000,00 €
- Possible extension:	0,00 €
- Possible modifications:	0,00 €

ESTIMATED CONTRACT VALUE: 285.0000,00 €

In accordance with article 204 of the LCSP, it is foreseen that a modification of the contract can 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.

VI) Duration of the 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. The possibility of extending the contracts for a period of up to 9 months is foreseen 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.

This duration has been determined taking into account the nature of the benefit, in accordance with art. 29.1 of the LCSP, in order to enable compliance with the milestones and objectives described in this report.

VII) Justification of the procedure used to award the contract:

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 this justifying report have been validated in the Grant Agreement for its 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.

VIII) Justification for division into lots:

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.

IX) Solvency criteria:

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 Contracts, 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.

X) 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 value
- 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.

XI) Special conditions of execution:

In compliance with article 202 of the LCSP, as a special condition of execution with respect to social aspects, the following is proposed:

- The awarded centres assume, as a special condition of execution, the obligation to guarantee equal treatment of all patients and their rights.

This condition has the character of an essential obligation of the contract and its breach may be penalized as a very serious misconduct or cause of contractual termination.

Justification of the special execution condition established: The special execution condition that has been established is of a social nature and is aimed at guaranteeing that the contract is executed guaranteeing the best social conditions. This condition is appropriate and proportionate according to the nature of the contract, and has been established with the understanding that it will imply an improvement in the quality of the provision of the service

XII) Subcontracting:

Subcontracting will only be possible with the express authorisation of the person responsible for the contract of the Hospital del Mar Research Institute Foundation, in accordance with the provisions of art. 215 of the LCSP.

XIII) Assignment of the contract

The successful bidder may not transfer the service presentations of this contract without prior authorisation from the contracting body, in accordance with art. 214 of the LCSP.

XIV) Other aspects:

In this service there is a data processing order. The processing of data derived from the provision of the contracted service will be regulated by the standard contractual clauses on processing orders approved by the European Commission through Commission Implementing Decision (EU) 2021/915 of 4 June 2021 on standard contractual clauses between controllers and processors contemplated in Article 28, section 7 of Regulation (EU) 2016/679 of the European Parliament and of the Council and Article 29(7) of Regulation (EU) 2018/1725 of the European Parliament and of the Council (relevant text for the purposes of the EEA).



Barcelona, on the date of the electronic signature.

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