Hospital del Mar Research Institute Barcelona

Liveration

Funded by the European Union

Explanatory note: In case of doubt or contradiction between the Spanish original and the English version of these technical specifications, the Spanish version shall prevail.

TECHNICAL SPECIFICATIONS GOVERNING THE CONTRACTING OF THE RECRUITMENT AND FOLLOW-UP SERVICE OF PATIENTS IN NINETEEN FOREIGN CENTRES WITHIN THE FRAMEWORK OF THE "LIVERATION" RESEARCH PROJECT, FOR THE HOSPITAL DEL MAR RESEARCH INSTITUTE FOUNDATION.

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1. PURPOSE OF THE CONTRACT

The purpose of this Technical Specification (hereinafter, PPT) is to regulate the provision of the recruitment and follow-up service of patients in nineteen foreign centers within the framework of the "LIVERATION" research project, for the Hospital del Mar Research Institute Foundation. This project is funded by the European Commission, within the framework of the Horizon Europe programme. Project 101104360 – LIVERATION.

The service will be divided into 19 lots, which are detailed below:

- **Lot No. 1**: 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 Hôpital de Beaujon (Paris, France).

- **Lot No. 2:** 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 Hôpital Paul Brousse (Paris, France).

- **Lot No. 3:** 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 Hôpital de Strasbourg (Strasbourg, France).

- **Lot No. 4:** 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 Policlinico Tor Vergata (Rome, Italy).

- **Lot No. 5:** 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 Ospedale San Raffaele (Milan, Italy).

- **Lot No. 6:** 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 Ospedale Miulli (Acquaviva delle Fonti, Italy).

- **Lot No. 7:** 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 Tumori Napoli Institute (Naples, Italy).

- **Lot No. 8:** 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 Ospedale San Camilo Forlanini (Rome, Italy).

- **Lot No. 9:** 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 University Clinical Centre Ljubljana (Ljubljana, Slovenia).

- **Lot No. 10:** 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 Szpital Uniwersytecki im. Karola Marcinkowskiego w Zielonej Górze (Zielona Góra, Poland).

- **Lot No. 11:** 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 Uniwersytecki Szpital Kliniczny im. Norberta Barlickiego w Łodzi (Łodz, Poland).

- **Lot No. 12:** 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 l'Uniwersyteckie Centrum Kliniczne Warszawskiego Uniwersytetu Medycznego/Centralny Szpital Kliniczny (Warsaw, Poland).

- **Lot No. 13:** 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 SPSK im. Andrzeja mielęckiego Śląskiego Uniwersytetu Medycznego w Katowicach (Katowice, Poland).

- **Lot No. 14:** 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 Kantonspital Winterthur (Winterthur, Switzerland).

- **Lot No. 15:** 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 General Hospital of Athens "Laiko" (Athens, Greece).

- **Lot No. 16:** 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 Agios Savvas Hospital (Athens, Greece).

- **Lot No. 17:** 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 Metaxa Anticancer Hospital (Pireas, Greece).

- **Lot No. 18:** 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 General University Hospital of Larissa (Larissa, Greece).

- **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 General Hospital of Athens "Ippokrateio" Vas (Athens, Greece).

Each of the 19 centers referred to must recruit 30 patients, that is, 570 patients in total.

2. TECHNICAL PROPOSAL

The bidder must declare compliance with all the technical aspects and aspects related to the assignment of resources detailed in this document, with respect to the lot to which it is submitted.

The technical requirements and specificities are common to the 19 Lots – **although the bidder will only be invited to participate in a single lot, in order to guarantee the fulfilment of the planned objective, consisting of recruitment within a period of 9 months and subsequent monitoring of the number of patients indicated in each lot**.

a Hospital Organization.
b Technical skills of the group.
c Acceptance of the protocol.
d Ethics Committee.

a. Hospital Organization.

The tenderer shall comply with the following conditions:

i Have a team made up of at least 2 liver surgeons, as Principal Investigator (PI) and Assistant Research Physician, respectively.

ii At least one of the two affiliated professionals must be the author of at least 15 publications in medical journals cited in PUBMED: PubMed (nih.gov).

iii The assigned professionals must have performed, individually or jointly, in the last year, at least 30 liver tumor resection surgeries.

b. Technical skills of the group.

i The Principal Investigator (PI) must declare that he or she has read the protocol, understood it, and is able to perform the technique under study (called "additional coagulation of the liver tumor margin after surgical resection").

ii The PI should recruit patients according to inclusion and exclusion criteria, randomize them according to the study protocol, and perform the assigned surgical technique according to the arm to which the patient has been randomized. Subsequently, the patient will have to be followed for three years to observe local recurrences of the liver tumor.

iii The PI and the assistant research physician will be able to provide the updated GCP ("Good Clinical Practices") certificate, undertaking to provide it as soon as required by the contracting authority.

iv The PI and the attending physician should have experience in completing randomized and prospective studies, experience in completing CRFs (Case Record Forms), and experience in receiving follow-up visits. They must be able to accredit the aforementioned experience as soon as required by the contracting authority.

c. Acceptance of the protocol.

The head of the Digestive Surgery Service of each of the awarded centres must express their acceptance of the content of the clinical trial protocol.

d. Ethics Committee.

The trial must be approved by the Research Ethics Committee of the awarding centres. They will not be able to start the service until they have obtained the approval of the corresponding IEC.

3. ADDITIONAL REQUIREMENTS AND OBLIGATIONS

3.1 The successful bidder must provide the service correctly and in accordance with the provisions of the Protocol and Proposal of the Study.

In this regard, bidders interested in having a copy of the Protocol should send an e-mail to the following address: cfuste@researchmar.net.

3.2 The successful bidder is obliged to respect the confidentiality of the patients and to allow the trial to be monitored by the coordinator (Hospital del Mar).

The Awardee shall keep confidential any data, documents or other material (in any form) that is identified as sensitive or confidential in writing or orally during the provision of services and for at least 10 years after the completion of the Project.

3.3 The services must be carried out in accordance with the highest applicable EU ethical and quality standards, and have and transfer the corresponding operating health licenses and accreditations, at the time required by the research group.

3.4 The awardee must ensure equal treatment of all patients and their rights.

3.5 The successful bidder is obliged to provide the services covered by this contract in compliance at all times with the provisions in force on the prevention of occupational risks.

3.6 The successful bidder will carry out the test at its facilities and may not subcontract the contract partially or totally to third parties.

3.7 The successful bidder must collaborate with monitors and auditors acting at the request of the Promoter, or, where appropriate, collaborate with the granting Authority, OLAF, Court of Auditors (ECA), etc.

3.8 The successful bidder shall comply with Article 17.2 on visibility, Article 18 on specific rules for the provision of services, and Article 19 on information in the Grant Agreement.

3.9 The successful tenderer shall keep records and other supporting documents demonstrating the proper performance of the service of the action in accordance with the applicable legislation and Article 20 of the Grant Agreement. Data entry in the Data Collection Notebook (CRD) or Case Record Form (CRF) will be in English.

Barcelona, at the date of the electronic signature.

Dr. Patricia Sánchez-Velázquez.
IP Project 101104360 – LIVERATION
Research Group on Ablation Therapies in Oncological Surgery
IMIM Foundation