TinyBrains Tender for Contracting

an animal facility to conduct the pre-clinical studies with the Tinybrains research platform, an optical neuroimaging device to decipher the missing link between the cellular brain damage and the neurovascular unit during acute illness, in the activities of the Horizon 2020 EU Research and Innovation Programme (TINYBRAINS).







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1. INTRODUCTION TO THE PROJECT

The requested services are part of the TinyBrains project, funded by the European Union's Horizon 2020 research and innovation program under grant agreement no 101017113.

TinyBrains is an international and multidisciplinary consortium focused on developing an optical neuroimaging device to understand the mechanisms of brain damage in infants born with severe congenital heart defects.

TinyBrains is committed to meeting the needs of pediatric CHD patients thanks to a collaboration between the academic, clinic, and private sector, including six institutions in three different countries.

TinyBrains endeavors to understand the mechanisms underlying brain damage in CHD patients by developing a novel research tool focused on cutting-edge research for preventing brain injury in newborns and infants.

TinyBrains aims to encounter the cellular origin of these neurodevelopmental problems by helping to analyze the link between energy demand and oxygen supply in pre-clinical and clinical studies.

The pre-clinical studies will be conducted using a pediatric animal model (piglet) of severe brain injury associated with cardiothoracic surgery and circulatory arrest as a first approach to study the coupling between oxygen metabolism and electrophysiology.

This model will be used to have a controlled environment of brain injury to study the utility of the TinyBrains prototype to predict the timing and underlying mechanisms of brain injury.

Fundació Sant Joan de Déu is TinyBrains' project partner responsible for the pre-clinical and clinical studies.





2.1. CONTRACTING SERVICE

The TinyBrains project includes specific studies on a neonatal animal model (piglets) of brain damage (WP 4). Currently, at Sant Joan de Déu Hospital, the animal lab facility cannot accommodate the animal experiments of TinyBrains.

To conduct those specific activities, it is necessary to involve an external organization with the right expertise in the management of neonatal piglet animal models and the capacity to carry out cutting-edge pre-clinical studies.

Expertise in diagnostic imaging will also be required to conduct in-site MR to complete the scheduled bioimaging studies without transferring the animals to other facilities.

To have a controlled environment of brain injury to study the utility of the Tinybrains prototype, an animal model of severe brain damage associated with cardiac surgery and cardiac arrest will be built using one-week-old male and female Yorkshire piglets.

Animals have to be housed in the corresponding animal facility with daily care monitoring by a trained veterinary technician.

The study design foresaw different situations with various degrees of brain damage. The device will be placed on the piglet's head before surgery and remain in place during the procedure.

The activities to be performed by the supplier contracted by Fundació Sant Joan de Déu (FSJD) linked to this tender will be those listed below:

• Support to obtain the approval of the ethical committee for the animal experimentation and submission to the Generalitat of Catalonia.

• Capacity to manage Piglet animal model (5 days old), including animal purchasing and maintenance (1 day of quarantine and 1 day of experimental action).

• Animal care for 2 days. 1 weight control per animal, and veterinary examination, including blood extraction for baseline haematology and biochemistry analysis from all animals.

- Activities related to the experimental study including:
 - Sedation and parenteral and gas anesthesia.
 - Baseline magnetic resonance imaging (MRI) of the brain.
 - Cannulation of the arterial and venous femoral route in an echo-guided manner.
 - 4 blood gas determinations for each animal.
 - MRI of the brain post-surgery.
 - Euthanasia, necropsy, and corpses cremation.
 - Post-processing of MRIs performed by a specialist radiologist.





3.1 REQUIREMENTS ABOUT THE SUPPLIER

- Be a facility focused on advanced biomedical research, innovative surgeries, and bioimaging technology.
- Have previous experience with preclinical studies conducted with piglet animal models with high-expert/qualified staff.
- Accountable for purchasing animals (5 days old piglets) and being in charge of the animal care, including the quarantine period and during the experimental procedure.
- Be a center with operating theatres specific for large animals and with the capacity to be configured according to needs.
- Specific expertise in:
 - Procedures concerning piglet animal model, including sedation and parenteral and gas anesthesia; cannulation of the arterial and venous femoral route in an echoguided manner and any other support needed during the cardiac surgery.
 - Acquisition of magnetic resonance imaging (MRI) of the brain.
 - Post-processing and analysis of MRI images.
 - Additional expertise in cardiac surgery will be considered in the evaluation with an extra value.

3.2. REQUIREMENTS REGARDING THE PROPOSAL OF SERVICE

Design the technical proposal to perform every task and subtask detailed in this tender. Including:

- Detailed planning of activities and objectives
- Calendar
- Team
- Budget: The maximum amount of money available to hire a contractor to perform all the actions detailed in this document is 84.000 euros. This budget is associated with the total number of animals required for the study, 25, and can be modified according to later needs.

4. WORKING METHODOLOGY

The contractor selected will work under the coordination of FSJD, leading the preclinical studies conducted with the TinyBrains prototype. In addition, the contractor will take part in different specific activities.

5. BUDGET

The quality of the technical proposals submitted and the related budget will be considered in the assessment phase to choose the contractor.





6. SUBMISSION OF PROPOSALS AND EVALUATION

6.1. DEADLINE FOR THE SUBMISSION OF THE PROPOSALS:

The deadline to submit proposals is the 24th of January of 2022, at 12 pm CET.

6.2. DOCUMENTATION TO BE SUBMITTED:

6.2.1. Documentation about the supplier

- Curriculum with the expertise of the institution regarding the preclinical study proposed. Detail the specific expertise in:
 - Sedation and parenteral and gas anesthesia.
 - Baseline magnetic resonance imaging (MRI) of the brain.
 - Cannulation of the arterial and venous femoral route in an echo-guided manner.
 - 4 blood gas determinations for each animal.
 - MRI of the brain post-surgery.
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- Composition of the team: Resume of the staff involved in the activities.

6.3. CRITERIA OF EVALUATION:

An interdisciplinary team of FSJD will assess the different proposals submitted. This will be formed by:

- Head of the Cardiology service, Principal Investigator of TinyBrains Project.
- Senior physician of neonatal service, Co-PI of TinyBrains Project.
- International Project Manager.

The expertise and the proposal of activities will be evaluated together. The maximum score for every aspect will be:

- Curriculum of expertise of the institution: 5 points
- Composition and expertise of the team: 5 points
- Geographic proximity: 5 points
- Technical proposal: 10 points
- Budget: 5 points

Only the proposals which achieve at least 20 points will be considered as candidates to perform the activities of this contract. The best technical quality proposal with the fairest budget will be selected.





7. CONTRACT DURATION

Between 1-Feb-22 and 31-Dec-24.

8. ADDITIONAL INFORMATION

For any additional information related to this tender, the contact persons and email will be:

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