

# TENDER FOR SUBCONTRACTING A SPECIALIZED BUSINESS SCHOOL OR COMPANY THAT CAN ASSIST THE CONECT4CHILDREN (C4C) CONSORTIUM IN THE DEVELOPMENT OF A SUSTAINABLE BUSINESS MODEL FOR A PAN-EUROPEAN PAEDIATRIC CLINICAL TRIALS NETWORK

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### 1. INTRODUCTION TO THE PROJECT

The requested services are part of **connect4children (c4c)** project, that is funded by the “**Innovative Medicines Initiative 2**” Joint Undertaking under the grant agreement No 777389. The Joint Undertaking receives support from the European Union’s Horizon 2020 research and innovation programme and EFPIA.

**c4c** is a large collaborative pan-European network that aims to facilitate the development of new drugs and other therapies for the entire paediatric population. It is a pioneering opportunity to build capacity for the implementation of multinational paediatric clinical trials whilst ensuring the voices of children, young people and their families are heard.

The 72 month-long project was launched on May 1<sup>st</sup> 2018.

**c4c** is committed to meeting the needs of paediatric patients thanks to a novel collaboration between the academic and the private sector, which includes 33 academic and 10 industry partners from 20 European countries, and more than 50 third parties and around 500 affiliated partners.

**c4c** endeavours to provide a sustainable, integrated platform for the efficient and swift delivery of high-quality clinical trials in children and young people across all conditions and phases of the drug development process.

**c4c** strives to bring innovative processes to all stages of clinical development by generating a new model of organization and of the clinical development process.

By emphasizing inclusiveness and collaboration across geographical, specialty, sectoral, cultural and societal backgrounds, it will set up a new infrastructure to support all evaluations of medicines in children.

In this manner, it will become a benchmark in the currently fragmented European clinical research environment. Best practices and up-to-date expert advice will inform the **c4c** approaches and methods, which will subsequently be refined in the context of viability trials.

An important element of c4c is the working towards a well-functioning business model and long-term sustainability – making sure that the network will continue to assume its defined key function beyond the IMI 2 funding in a sustainable long-term way. An entire Work Package (WP3) has been designed to achieve this goal, with a set of well-defined sub activities assigned to be carried out by a set of Consortium partners. External support will be crucial, to complement the specific skills and expertise of the leading WP3 partners, in particular regarding more broadly the options for business concept development, more extensive understanding of the markets, sector specific legal and organization management competences related to the not for profit Public-Private sector across Europe.

## **2. SUBCONTRACTING SERVICE AND DELIVERABLES**

### **2.1. SUBCONTRACTING SERVICE**

**c4c includes specific activities to be supported by the External Provider:**

#### **Task 3.2. Targeted market, positioning and services portfolio definition**

Based on the Benchmarking exercise – defined Market, identification of Customer Needs, provide strategic and operational support to Market positioning, and Service Portfolio Definition, while challenging added value and possible hidden opportunities.

#### **Task 3.3. Legal requirements, Financial needs, fee scheme and alternative ways of funding**

Provide strategic input in view of different contracts / funding schemes and to identify appropriate form, aligned with the business plan, main service, ethical consideration etc., in collaboration with a working group to be created.

#### **Task 3.4. Development of business plan**

Joint outcomes, results and ideas from the previous tasks to join in order to form a comprehensive Business Plan for the Network: rationale, mission, vision, capacities, market positioning, revenue and expansion model, 5 years Net Present Value, to be submitted by the WP3 leads to the network governing bodies by M36, April 2021.

#### **Task 3.6. Business model stress tests**

Support the design and evaluation for the Pilot.

#### **Task 3.7. Methodology to assess financial viability of services to be provided after IMI support**

Provide methodological input.

To carry out the above-mentioned Tasks 3.2 to 3.7, it is necessary to involve an external organization with the right expertise in the field of business concept / management / economics / sustainable financing. Expertise doing similar activities in the field of management / health innovation / health systems / public private collaboration will be considered in the evaluation process. There is more than 15 years of expertise with this in Europe, while at the present moment, there is only a limited amount of literature, case studies or suitable metrics in the field of a sustainable business concept of public private partnership. However, this activity is essential to sustain the success of c4c.

## 2.2. DELIVERABLES

There are specific deliverables to report the execution of the Tasks previously described.

The external provider will give support to the Consortium partners achieving the Deliverables as defined in the c4c WP3 project description.

D3.2. Services portfolio report [M16], August 2019

D3.3. Roles and responsibilities per partner providing services [M18], October 2019

D3.5. Report on variable/fixed costs of the network, alternative funding, overview on fee scheme [M36], April 2021

D3.6. Business plan report [M36], April 2021

D3.7. Report on the feedback received from the main private and public stakeholders [M42], October 2021

D3.8. Report on the main conclusions drawn from the stress tests [M72], April 2024

## 3. REQUIREMENTS FOR THE APPLICANT AND FOR THE TECHNICAL PROPOSAL

### 3.1. REQUIREMENTS ABOUT THE APPLICANT

- Be an institution focused in the business excellence / management / entrepreneurship / innovation field.
- Have at least more than 15 years of expertise (see below). Every 5 years of additional expertise will be considered in the evaluation.
- Specific **expertise** in:
  - Leading big, complex European (FP / H2020/IMI2) and International Projects
  - European health, research and innovation policy, global health, access to policy and industry initiatives in the field of innovative coordination / open innovation / cross sector collaboration
  - Leading a broad, multidisciplinary team – bringing together expertise in entrepreneurship / marketing / operation management / accounting/financing and (health) economics (HTA)
  - Expertise in hospital management / health systems / health policy / regulatory and funding
  - Expertise in defining, implementing strategies & execution
  - Practical managerial implementation / organisational set up / structures and M&E to assure long term viability of the solution
  - Working with public private partnership / in particular IMI (Innovative Medicine Initiative) and others such as EIT Health
  - Writing well both managerial, hands-on recommendations but also scientific publications to disseminate the expertise in the field of business excellence and management.

### 3.2. REQUIREMENTS REGARDING THE PROPOSAL OF SERVICE

To design the technical proposal to perform every task detailed in this tender, including:

- Detailed planning of activities and objectives
- Methodology to:
  - Collect the information (quantitative and qualitative)

- Design the metrics
  - Analyse the data and report the outcomes
  - Study other relevant features regarding sustainable business models
- Calendar
- Team
- Budget: The maximum amount of money available to hire a subcontractor to perform all the activities detailed in this document is 400.000,00 Euros. The proposed budget, along with the quality of the technical proposal, will be considered and scored in the assessment phase to choose the subcontractor.

## 4. SUBMISSION OF PROPOSALS AND EVALUATION

### 4.1 Deadline for the submission of the proposals:

The deadline to submit proposals is April 5<sup>th</sup> 2019, at 12 pm CET.

### 4.2 Documentation to be submitted:

#### 4.2.1 Documentation about the applicant

- Curriculum with the expertise of the institution to demonstrate expertise in performing such work with the team. Detail the specific expertise in:
  - The creation of sustainable business concepts/public private partnerships business models
  - Definition of strategies and their implementation for a pan European Paediatric Clinical Trials network operating as a not for profit organization across different European member states
- Composition of the team:
  - Description of the staff involved in the activities, including distinctive skills
  - Publications / past works regarding the topic of this proposal

#### 4.2.2 Documentation about the technical proposal

- Technical proposal of tasks detailed in the section 3.2.
- Budget

The above documentation will need to be submitted to:

heidrun.hildebrand@bayer.com

jaana.kallio@hus.fi

Federico.Martinon.Torres@sergas.es

silvia.faggion@pentafoundation.org

### 4.3 Criteria of evaluation:

An interdisciplinary team of c4c WP3 partners:

Fondazione PENTA – Onlus (PENTA)  
Bayer Aktien Gesellschaft (BAYER)  
Servizo Galego de Saude (SERGAS)  
Helsingin Ja Uudenmaan Sairaanhoidopiirin Kuntayhtyma (HUS)

with the support of 2 External Experts will assess the different proposals submitted.

This will be formed by:

- c4c Coordinator (PENTA)
- KOL / Coordinator of the Clinical Trials Unit, Principal Investigator of c4c (SERGAS)
- KOL / WP3 partner (HUS)
- Industry Representative (BAYER)
- International Expert in clinical trials coordination
- International Entrepreneurship Expert

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

1. Science and Technical Expertise of the proposal: 15 points
2. Proposed methodology / partner and STH involvement: 15 points
3. Curriculum and expertise of the institution: 15 points
4. Composition and expertise of the team: 15 points
5. Publications / past works regarding the topic of this proposal: 10 points
6. Budget: 10 points

Only the proposals which achieve at least 50 points will be considered as candidate to perform the activities of this contract. The best technical quality proposal with the fairest budget will be selected.

## **5. CONTRACT DURATION**

From 1.5.2019 to 30.4.2024.

## **6. WORKING METHODOLOGY**

The subcontractor selected will work under the coordination of PENTA, who is leading the project management tasks in c4c, and in close collaboration with the responsible WP3 partners (SERGAS, BAYER, HUS). The subcontractor will take part in different working groups, formed by c4c partners and their third parties, to deliver the different activities.

Regular telephone conferences will be established across the project (on a monthly basis, and on additional request) as well as at least one face-to-face meeting once a year.

PENTA/WP3 coordinator will request regular updates by the subcontractor about the status of the activities in order to follow up on its development and to contribute to the regular interim reports to IMI.

## **7. ADDITIONAL INFORMATION**

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

- Heidrun Hildebrand: [heidrun.hildebrand@bayer.com](mailto:heidrun.hildebrand@bayer.com)
- Federico Martinon Torres: [Federico.Martinon.Torres@sergas.es](mailto:Federico.Martinon.Torres@sergas.es)
- Jaana Kallio: [jaana.kallio@hus.fi](mailto:jaana.kallio@hus.fi)