

**TENDER FOR SUBCONTRACTING A SPECIALIZED INTERNATIONAL CONSULTANCY OR LAW FIRM OR LEGAL ADVISOR THAT CAN ASSIST THE CONECT4CHILDREN (C4C) CONSORTIUM IN THE EVALUATION OF LEGAL REQUIREMENTS ACROSS A NUMBER OF EUROPEAN COUNTRIES TO SET-UP AND IMPLEMENTATION OF A NON-FOR-PROFIT PUBLIC-PRIVATE FUNDED LEGAL ENTITY TO HOST A PAN-EUROPEAN PAEDIATRIC CLINICAL TRIALS NETWORK**

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**1. INTRODUCTION TO THE PROJECT**

The requested services are part of **conect4children (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 1<sup>st</sup> May 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.

Sustainability of c4c network is one of the major goals of the project. Therefore, specific tasks are devoted to the definition of the main features, statutes, structure and implementation plans for a successor organisation able to take over the activities immediately after the end of the IMI2 funding. In a first step Work Package 3 will provide the insights gathered during the business plan development, including legal/policy environment in the concerned EU member states. While the full consortium will decide on the proposal made on the successor form Project Leadership Team (Work Package 1) and the Sustainability Work Package (WP3) will coordinate the activities.

Information about market, customers' needs, fee structure and financial forecast will be considered when defining the new legal form. Several scenarios of the successor form will be proposed, including aspects of the network likely to change following the end of the IMI2 project: the nature of an appropriate form for the successor organization (e.g., public-private, non-for-profit); membership; leadership; functions; location (geographical and distributed) and relationships with industry and other stakeholders. c4c will most probably operate as a conglomerate of business units and/or independent subsidiaries, across different EU countries. Possible legal structures may include, but not limited to companies, associations, foundations and/or charitable limited co-operations, research institutions. Further establishment as part of European Research Infrastructure Consortium-ERIC maybe a viable option to be included in the evaluation.

Given the heterogeneity of the relevant laws and regulations (incl. corporate, taxation, employment regulations, rules for public/private funding of non-for-profit organizations) in the different European countries, it is not feasible to evaluate requirements to place the successor organization for each of the 19 countries currently contributing to c4c. **Therefore, a short list of 3 countries was agreed by the consortium. These countries are Belgium, The Netherlands and Ireland.**

Due to the complexity and heterogeneity of the legal questions to be evaluated, respective legal expertise, able to cover legal requirements and jurisdiction of the short-listed countries needs to be included. Legal expertise will also be needed to support generation of different successor form scenarios based on the information gathered during the in-depth evaluation of the legal requirements.

(To support the implementation of the successor organization in the selected host country, more specific expertise related to the needs of the host country will be needed. Therefore, this expertise will be selected in a later separate call for tender after a decision on the final country was taken.)

## 2. SUBCONTRACTING SERVICE AND DELIVERABLES

### 2.1. SUBCONTRACTING SERVICE

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

**Task 3.3. Legal requirements, Financial needs, fee scheme and alternative ways of funding. This task will be devoted to defining the cost and income structure of the network post-IMI.**

#### **“Sub-task 3.3.2. Legal requirements**

An analysis of the contracts and agreements applicable in the shortlisted countries, needed to develop the portfolio services, will be performed. Aim is to develop standardized contract models to simplify the network internal procedures and interaction with external clients. Legal differences across countries and jurisdictions will be considered in order to ensure compliance with national laws of unified models.

**Further, a comprehensive study will be performed to define the appropriate legal form for the network to adopt after IMI support. Such appropriate form would need to consider several aspects: alignment with business plan, flexibility to develop main services of the network, coordination with national hubs and sites, compliance with ethical considerations, etc. A working group will be set up to carry out this task.**

To carry out the above-mentioned comprehensive legal study it is necessary to involve an external organization with the right expertise in the field of corporate law, tax law, policies related to public funding and mixed public-private funding of non-for-profit organizations on a country and/or at European level in any of the following countries **Belgium, The Netherlands, and Ireland**. Expertise in supporting generation of public-private partnerships, joint-public-private funding and/or non-for-profit legal entities, as well as, experience in working with European funded projects and organisations (e.g. HORIZON 2020, IMI, European Research Infrastructures (ERIC)) will be considered in the evaluation process.

As a result, an overview of the different requirements in the shortlisted countries and a SWOT analysis reflecting situation in any of the four countries will be provided by the sub-contractor.

### 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 project description.

#### D3.4: Final version of the legal requirements

Final version of the legal requirements for a successor organization in any of the selected countries, including:

- Detailed report of legal requirements per short listed countries
- Detailed report on impact of different funding models, including public vs private vs mixed funding based on local or European public funding schemes or a mixture of all above.
- SWOT (Strength, Weakness, Opportunity, Thread) analysis for different legal forms (e.g. public vs private vs public-private funded, for profit vs non-for-profit, company, association, foundation, charitable limited co-operation or research institution or established as part of European Research Infrastructure Consortium-ERIC) per country to

- support scenario building
- Final report summarizing SWOT analysis per country and ranking different scenarios to support final decision making by the consortium

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

#### 3.1. REQUIREMENTS ABOUT THE APPLICANT

- Established international law firm or consultancy company, with proven expertise in advising on corporate and public business law across Europe.
- Established working relationship/ local offices within the three short listed countries
- Experience in evaluation and generation of cross European company, association, foundation, charitable limited co-operation or research institution.
- Experience in working with public-private partnership consortia, in particular IMI JU (Innovative Medicines Initiative-Joint Undertaking)
- Solid understanding of the political and economic environment related to European Research and Health Care sector public funding (HORIZON 2020; European Research Infrastructure Consortium-ERIC) and comparable schemes on national level across Europe
- Specific **expertise** in:
  - Taxation laws related to publicly or mixed (public/private) funded non-for-profit organizations (EU funding schemes and local funding schemes in the shortlisted countries and/or across different European countries), including impact on cross funding between different European countries
  - Employment laws in the respective countries, with special emphasis on free movement and/or remote work environments across Europe
  - Corporate law with focus on public/private non-for-profit organisations (company, associations, foundations, charitable limited)
  - Interdisciplinary teamwork, working with large public-private consortia; ability to management and to work within multi-cultural teams
  - Providing tailored solutions for complex cases and deliver seamless services across jurisdictions.

#### 3.2. REQUIREMENTS REGARDING THE PROPOSAL OF SERVICE

Describe in detail how your organization will support the different tasks as laid out, keeping in mind the importance of a very close collaboration and coordination with the responsible c4c partners: SERGAS, BAYER, HUS and other relevant partners.

The technical proposal will have to include the scope of work with all the relevant information included 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
  - Preparation of the SWOT analysis and scenario building

- Criteria *proposed* to generate SWOT analysis
- Study other relevant features regarding suitable legal form and funding models
- Calendar with key activities and milestones
- Team and key contact person/s to be directly involved in the project
- Budget: The maximum amount of money available to hire a subcontractor to perform all the activities detailed in this document is 180,000.00 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 March 13<sup>th</sup>, 2020 at 11 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 evaluation and creation of legal requirements and evaluation of appropriate legal and funding structure of public-private partnerships
  - Definition of strategies and their implementation for a non-for-profit organization working across different European member states
  - Experience in working with European funded projects (e.g. HORIZON 2020, ERIC) and/or public-private consortia, specifically IMI;
  - 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 2.
- Budget
- Timetable

##### 4.3 Criteria of evaluation:

An interdisciplinary team of c4c partners:

Fondazione PENTA – Onlus (PENTA)

Bayer Aktien Gesellschaft (BAYER)

Servizo Galego de Saude (SERGAS)

Helsingin Ja Uudenmaan Sairaanhoidopiirin Kuntayhtyma (HUS)

University of Liverpool (ULIV)

with the support of External Expert will assess the proposals submitted.

The evaluation team will be formed by:

- c4c Coordinator (PENTA)
- c4c Task Lead (HUS)
- WP3 partner (SERGAS)
- Industry Representative (BAYER)
- Academic representative (ULIV)
- A representative of c4c External Advisory Board

*The expertise and the proposal of activities will be evaluated together, the best value for money will be selected. CVs and other certificates must be provided after separate request.*

#### Criteria for selection

##### **Type of company:**

Law firm or consultancy company

##### **Established company:**

Company has earlier experience in evaluation of legal requirements and/or generation of cross European companies, associations, foundations, charitable limited co-operations and/or research organisations

##### **Localization of company:**

Localization of main office in EU

##### **Working co-operation in short-listed countries (Belgium, Ireland, The Netherlands):**

Minimum requirement: Belong to a network of independent law firms across EU countries

##### **Points given from one of the following filled criteria**

Established partner in each country (10 points)

Own office present in each listed country (15 points)

##### **Composition and expertise of the team:**

Minimum requirement: Central project manager with some legal expertise from the 3 listed countries

##### **Points given from one of the following filled criteria**

1 senior legal expert, supported by junior legal experts from the single listed countries (10 points)

Senior legal expert from each of the shortlisted countries supported by research team (15 points)

##### **Curriculum and expertise of team members:**

Minimum requirement: Degree in Law or Entrepreneurship of the responsible person for the task

##### **Points given from one of the following filled criteria**

Over 3 years' but under 5 years' experience of the responsible person in corporate, taxation and employment law of short-listed countries (20 points)

Over 5 years' experience of the responsible person in corporate, taxation and employment laws of short-listed countries (25 points)

##### **Other experience:**

Company's Experience in evaluation and generation of cross European companies, associations, foundations, charitable limited co-operations, research organisations

Minimum requirement of company's experience: Belong to a pan-European consortium of law or consultancy firms involved in the evaluation of legal requirements for public-private partnership and/or non-for-profit organizations with multinational operations in at least two of the shortlisted countries within the last 3 years

Points given from one of the following filled criteria:

Directly involved in the evaluation of legal requirements for public-private partnership and/or non-for-profit organizations with multinational operations in at least two of the shortlisted countries within the last 3 years – no direct experience in working with IM/EU funded projects (15 points)

Directly involved/ have created a public-private, non-for-profit legal entity with multinational operations within the last 3 years in at least one of the shortlisted countries or in the evaluation of legal requirements for public-private partnership and/or non-for-profit organizations in all of the shortlisted countries, and direct experience with IMI and/or other EU funding schemes of Research and Health Care sector (35 points)

**Budget:**

Minimum requirement: Total budget under or same as 180 000 euros including planned meeting arrangements and travels

**Working methodology**

Minimum requirement: Description of working hours needed, types of communication with WP3 team and HUS and timetable for the work

Other methodological aspects (see 3.2) described (substance evaluated) (10, 20, or 30 points)

The selection will be done among those fulfilling the specific criteria given. The selection process includes identification of applicants, evaluation of the applicants focused on criteria for selection, evaluation of the proposals and comparison of the tenders.

Comparison and final selection:

45% of evaluation will cover quality criteria:

$(\text{applicants quality points} / \text{highest given quality points among applicants}) \times 45$ .

55% of evaluation will cover budget:

$(\text{lowest suggested budget among applicants} / \text{applicants suggested budget}) \times 55$ .

The applicant given highest total evaluation score of quality plus budget (max. 100) will be selected.

The applicant should accept the procurement contract as such when submitting their tender proposal.

There will be no payments for applicants against submitting their proposal and taking part in the tendering process.

**5. CONTRACT DURATION**

Contract will start when both parties have signed the contract and will end after 6 months.

**6. WORKING METHODOLOGY**

The subcontractor selected will work under the coordination of HUS, who is leading WP3 task 3.3.2 in the c4c project, and in close collaboration with the responsible partners (SERGAS, BAYER, HUS, PENTA, ULIV). Regular telephone conferences will be established across the project as well

face-to-face meetings if needed.

HUS/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 reports to IMI.

## **7. ADDITIONAL INFORMATION**

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

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