

TENDER FOR SUBCONTRACTING A SPECIALIZED INTERNATIONAL FULL SERVICE LAW FIRM THAT CAN ASSIST THE CONECT4CHILDREN (c4c) CONSORTIUM WITH REGARDS TO THE SPECIFIC REQUIREMENTS FOR THE GENERATION AND IMPLEMENTATION IN NETHERLANDS OF A NON-FOR-PROFIT PUBLIC-PRIVATE FUNDED LEGAL ENTITY

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APPENDIX 1

1. INTRODUCTION TO THE PROJECT

1.1 The c4c project

The requested services are part of the **conect4children (c4c)** project that is funded by the “**Innovative Medicines Initiative 2**” Joint Undertaking (JU) 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 and infrastructure 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 1st 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 35 academic and 10 industry partners from 21 European countries, and around 200 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** activities include facilitating clinical trials through National Hubs, coordinating national networks, providing advice about the strategic feasibility of clinical trials, education and training, standards for data used in clinical trials, and communicating about the network.

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 Paediatric 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.

c4c will most probably operate as a conglomerate of independent subsidiaries and/or partner organisations, across different EU countries. This tender relates to the steps leading to the incorporation of a Central Organisation that will coordinate the services provided by the conglomerate

Sustainability of the c4c network is one of the major goals of the project. Therefore, specific tasks in the current Grant Agreement are devoted to the definition of the main features, statutes, structure, and implementation plans for a successor organisation able to take over the activities before, or immediately after, the end of the IMI2 funding. While the full consortium will decide on the proposal made on the successor form, the **c4c** Project Leadership Team (Work Package 1) is coordinating the preparations for the successor organization.

In a first step toward establishing the successor organisation, multiple forms of the successor from non-profit to profit organisations were analysed based on the findings of **c4c** Work Package 3, with the help of subcontractor Lawrencium Legal. A short list of 3 countries was agreed by the consortium. Finally, The Netherlands was selected as the country of the c4c successor organisation.

1.2 Scope of the subcontract

To support the incorporation of the successor organisation more specific expertise is needed related to two components:

1. The development of a suitable legal and governance structure for the new non-profit legal entity in The Netherlands to act as the Central Organization that coordinates services provided by the pan-European paediatric clinical trials network, including comprehensive memorandum on all relevant legal, tax and governance aspects; drafting of the documentation needed to incorporate the new legal entity in the Netherlands, including internal governance documents and basic operating documents. Registration and formation of the new legal entity under Dutch law. Support for implementation of the legal, tax, governance aspects, and basic operating documents after the legal entity has been registered.
2. The framework of agreements within the network including a) templates of the agreements that regulate interactions between the Central Organisation based in The Netherlands and the National Hubs in all 21 countries (including the Dutch National Hub that will be separate from the Central Organisation), and b) templates of the agreements that regulate interactions between the Central Organisation and organisations that provide the network's services when those organisations are not the Central Organisation.

all in close cooperation and alignment with c4c.

1.3 Collaborators within c4c

The work covered by the subcontract will be done in collaboration with a core team of c4c Beneficiaries:

- Fondazione Penta – ONLUS (Penta): Coordinator of the c4c project
- Bayer Aktien Gesellschaft (BAYER): Co-lead of the c4c project, Industry lead for sustainability of the c4c project
- Janssen Pharmaceutica NV (Janssen): c4c Project Leader
- Servizo Galego de Saude (SERGAS): Academic co-lead for sustainability of the c4c project
- Helsingin Ja Uudenmaan Sairaanhoidopiirin Kuntayhtyma (HUS): Academic co-lead for sustainability of the c4c project
- UCB Biopharma (UCB): Industry co-lead for sustainability of the c4c project
- University of Liverpool (ULIV): Co-coordinator of the c4c project
- Stichting Radboud Universitair Medisch Centrum (SRUMC): Host of the Dutch c4c National Hub

2. SUBCONTRACTING SERVICE AND DELIVERABLES

2.1. SUBCONTRACTING SERVICE

The c4c Description of Activities (DoA) describes the c4c Work Packages (WP) and Tasks, and includes specific activities to be supported by the External Provider sought through this Tender:

***“Task 1.10. Cross-cutting activity to define appropriate arrangements after IMI2 JU support. This task will be devoted to the definition of the main features, statutes, structure, and implementation plans for a successor form able to take over the activities immediately after the end of the IMI2 project.*”**

Sub-task 1.10.3. Definition of a start-up plan

Once the most suitable form of the successor form is approved by the governing bodies, a comprehensive work plan will be developed, including: a) incorporation of the appropriate form that will support the network after IMI support;... d) main services and contracts to be developed during this period.”

To carry out the above-mentioned comprehensive legal activities it is necessary to involve an external organization with the right expertise.

Component 1 of the Tender requires, in particular, expertise in the fields of corporate law (drafting and negotiations of corporate agreements (contract law), including drafting of incorporation/formation documents such as Corporate Articles of Incorporation, Bylaws, drafting of Board member agreement), tax law, policies related to public funding and mixed public-private funding of non-for-profit organizations at European level and on a country level in The Netherlands as well as registration and formation of the new legal entity under Dutch law. Expertise in advising on 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/IHI) will be considered in the evaluation process. Experience of support for implementation of articles, bylaws and agreement after registration has been completed will also be included in the evaluation process.

Component 2 of the Tender requires, in particular, expertise in in the fields of corporate law, tax law, policies related to public funding and mixed public-private funding of non-for-profit organizations among countries in geographical Europe including The Netherlands. This component relates to agreements between the central organisation based in The Netherlands and components of the network that are currently based in 21 countries.

2.2. DELIVERABLES

- a) Comprehensive memorandum on all relevant legal, tax and governance aspects of the central non-profit entity and of the network, including on membership and membership rights, corporate bodies, governance structure, taxation of formation, funding and operations, employment matters, contractual arrangements with National Hubs and with other service providers
- b) Formation of the new legal entity: documentation for incorporation and internal legal matters of the non-profit entity (articles of association, bylaws/ rules of procedure, templates for accession of members, service agreements with directors and officers, template of employment agreement),
- c) Support for implementation of articles, bylaws and agreement after registration has been completed
- d) External: all relevant filing documents (corporate, tax, etc.), leading the registration process
- e) Template(s) of Agreement(s) relating to work with National Hubs, support implementation of agreements with NHs

- f) Template(s) of Agreement(s) relating to services that are not provided by the Central Organisation

2.3. MILESTONES

- a) Comprehensive memorandum (cf. supra) for setup of the legal entity that provides central services in The Netherlands, to be developed in close cooperation and alignment with c4c (4 months after execution of subcontract)
- b) Drafting of documentation for incorporation and internal legal matters (2 months after finalization of the memorandum)
- c) Filing for registration of the new legal entity (2 months after finalization of the documentation for incorporation)
- d) Drafting of templates for agreements between the legal entity that provides central services and other components of the network (4 months after finalization of memorandum)
- e) Progress Reports (including update on fees) each month after the execution of the subcontract and at other times as required by c4c.

Workplans will cover actions to be taken by the organisation engaged for this subcontract and the members of the c4c consortium.

We hope to start the process of incorporation by the end of 2022.

3. REQUIREMENTS FOR THE APPLICANT AND FOR THE TECHNICAL PROPOSAL

3.1. REQUIREMENTS FOR THE APPLICANT

A team with proven expertise, led by a partner / senior consultant, and with a Netherlands-based key contact person/s to be directly involved in the project.

Component 1.

- Established international full-service law firm-with proven expertise in advising on corporate, tax and public law across Europe;
- Local offices in The Netherlands
- Experience in advising cross European non-profit company, association, foundation, charitable limited co-operation, or research institution
- Track record of supporting the incorporation of non-profit organizations in The Netherlands including development of documents within the non-profit organizations and documents relating to the registration of the non-profit organizations (including for tax purposes);
- Desirable but not essential: experience in working with public-private partnership consortia, in particular IMI JU (Innovative Medicines Initiative-Joint Undertaking), as consortia transition to sustainable legal forms
- Solid understanding of the political and economic environment related to European Research and Health Care sector public funding (HORIZON 2020; Horizon Europe); IHI (Innovative Health Initiative) 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 Netherlands, including impact on cross funding between different European countries)

- Operative agreements and laws covering legal issues of cross-border funding in EU
- Employment laws in the Netherlands, with special emphasis on free movement and/or remote work environments across Europe
- Corporate law with focus on Dutch public/private non-for-profit organisations (company, associations, foundations, charitable limited)
- Interdisciplinary teamwork, working with large public-private consortia; ability to manage and to work within multi-cultural teams
- Providing tailored solutions for complex cases and deliver seamless services across jurisdictions.

Component 2.

- Experience with developing contractual agreements across multiple jurisdictions for multiple business functions.

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 under the lead of Penta supported by BAYER, Janssen, SERGAS, HUS, ULIV, UCB, SRUMC, and other relevant partners.

The technical proposal needs to include the scope of work with all the relevant information included to perform tasks detailed in this tender, including:

- Detailed planning of activities and objectives
- Calendar with key activities and milestones
- Budget: The maximum amount of money available to hire a subcontractor to perform all the activities detailed in this document is 250,000 Euros. Please provide a detailed budget setting forth the budget for each component and deliverable, and confirm that you are prepared to accept the agreed budget as a fixed cap. 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 June 3rd, 2022

4.2 Documentation to be submitted:

4.2.1 Documentation about the applicant

- Demonstrate the capability and capacity of the applicant law firm with respect to the required work. Detail the:
 - Composition of the team. Description of the staff involved in the activities, including distinctive skills, past works regarding the topic of this proposal
 - Specific expertise and experience in working with European funded projects (e.g. HORIZON 2020) and/or public-private consortia, including IMI, as they transition to a sustainable non-

profit legal entity. Illustrate requirements laid out in Section 3 with practical examples of work done by the applicant.

4.2.2. Documentation about the technical proposal

- Technical proposal of tasks detailed in the Subsection 1.2 and Section 2 using the capabilities described in Section 3.
- Budget
- Timetable

The applicant should accept the attached draft procurement contract or provide detailed comments in which regard an amendment of the contract is requested, when submitting their tender proposal.

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

4.3 Evaluation process

Evaluation will be done by the interdisciplinary team of c4c partners included in the core team listed in Subsection 1.3.

Criteria for selection

Type of company:

Minimum requirement: Law firm or consultancy company with substantial legal expertise.

Established company:

Minimum requirement: 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:

Minimum requirement: Localization of main office in EU with permanent office in the Netherlands.

Composition and expertise of the team:

Minimum requirements: Central project manager with some legal expertise, 1 senior legal expert, supported by junior legal experts.

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 the Netherlands (5 points) or

Over 5 years' experience of the responsible person in corporate, taxation and employment laws of the Netherlands (10 points).

Other experience:

Minimum requirement of company's experience: involved in the evaluation of legal requirements for non-for-profit organizations with multinational operations within the last 3 years

Points given from one of the following filled criteria:

Directly involved in the evaluation of legal requirements for non-for-profit organizations with multinational operations – no direct experience with registering a non-profit legal entity in the past 3 years (up to 10 points)
or

Directly involved/ have created a non-for-profit legal entity with multinational operations within the last 3 years in an EU country (up to 20 points)

Additional points:

Direct experience with IMI and/or other EU funding schemes (up to 5 points)

Direct experience of Research and Health Care sector (up to 10 points)

Experience with support after registration of a non-profit with multinational operations (up to 10 points).

Budget:

Minimum requirement: Total budget 250 000 euros or less including planned meeting arrangements and travels (up to 20 points).

Working methodology

Minimum requirement: Description of working hours needed, types of communication with Task 1.10 team and Penta and timetable for the work (up to 25 points).

5. CONTRACT DURATION

Contract will start when both parties have signed the contract and will end after successful incorporation and initial implementation of the byelaws and governance of the new legal entity, with a maximum duration of 18 months.

6. WORKING METHODOLOGY

The subcontractor selected will work under the coordination of Penta, who is leading WP1 task 1.10 in the c4c project, and in close collaboration with the responsible partners in the core team (BAYER, JANSSEN, SERGAS, HUS, UCB, ULIV, SRUMC). Regular telephone conferences will be established across the project as well with face-to-face meetings if needed.

Penta 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/IHI.

7. ADDITIONAL INFORMATION

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

- Penta (Silvia Faggion, silvia.faggion@pentafoundation.org)
- ULIV (Mark Turner, mark.turner@liverpool.ac.uk)
- Bayer (Heidrun Hildebrand, heidrun.hildebrand@bayer.com)

Appendix 1

List of the 21 countries that are part of c4c and which need to be covered by Component 2 of the Tender

Austria
Belgium
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Iceland
Ireland
Italy
The Netherlands
Norway
Poland
Portugal
Spain
Sweden
Switzerland
United Kingdom