

## NOTICE FOR PROVIDER SELECTION

This notice is made in the framework of the 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 (<https://conect4children.org/>) 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. 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.

FGB needs to identify a list of economic operators to be invited to provide a proposal for the executive design, development and deployment of an **IT platform**, compliant with industry standards and covering both functional (processes workflow, metrics, reports, dashboards, archiving, storage, etc.) and non-functional (regulatory, security, privacy, system support service levels, system availability & performance) requirements to measure c4c performance.

The solution will be provided in SaaS (software as a service) for 55 (fifty-five) months, it should include the latest cloud file systems available with leading cloud providers and it should have abilities to linear scalability, encryption and backup encryption. Data shall be stored in EU.

The IT platform must be ready for testing by September 2019. The total maximum amount available for the executive design, development and deployment of the IT platform, including its corrective and evolutionary maintenance, is equal to € 400,000 (fourhundredthousand/00), excluding VAT.

This notice is to be understood as a mere pre-selective, non-binding procedure, aimed at the collection of non-binding expressions of interest, in compliance with the principles of non-discrimination, equal treatment, proportionality and transparency.

Fondazione Benzi reserves the right to suspend, modify or cancel, in whole or in part, the procedure initiated, without the requesting parties being able to make any claim.

Interested parties must send their expression of interest, accompanied by the following documents, to the e-mail address [c4c.tender@benzifoundation.org](mailto:c4c.tender@benzifoundation.org), **by and no later than 5pm CET on the day 7 March 2019**; any additional information or clarification can be requested sending an e-mail at this same address.

A. economic and financial capacity:

- declaration concerning the turnover related to software development and maintenance and related services in the last three financial periods (it shall be not less than one million Euros on average per year);
- declaration of having achieved, in the last three financial periods, a specific turnover for supplies and services similar to those described in this notice, at least equal to 250,000 Euros.

B. technical ability:

- declaration of having an Italian-speaking project manager for the contract;



- company presentation with a:
  - general description of the company and the technologies used, with an indication of the technical staff, the distinctive skills;
  - description of the main customers and the works carried out for them.

C. maintenance activities:

- average daily price of the technical staff, per role/skill.

On the basis of the received documents, Fondazione Benzi reserves the right to select, among all the interested parties, those to be invited to present an offer.

The IT platform will integrate the following functional components:

**A. Data collection**

To gather and manage all the data needed to measure c4c performance related to network activities, including clinical trials conduction.

The following sources will directly feed information and data into the c4c IT Platform:

- Internal sources:
  - Business Process Management system;
  - Site logistics database;
  - Contact Manager;
  - Data Base - Patient Involvement
  - On line forms;
  - Manual data collection forms;
- External sources:
  - Electronic Data Capture (EDC) systems;
  - c4c e-learning Platform.

Data from various sources has to be integrated (e.g. via a database abstraction layer and API) and stored in a relational database from a leading DB provider (Azure, Oracle, etc.).

**B. Web Portal**

The WEB PORTAL, not to be confused with the actual c4c project website, will be the gateway through which all the c4c platform services will be available on Internet to all the authorised users. It is expected to be composed by two main components, 1. a public-facing website (general information,

contact modules, request information, login module, etc.), and 2. a user portal to access services reserved to authorised users according to their access privileges.

The minimal technical requirements are:

- single integrated user interface for all stakeholders and bespoke applications will be exposed through portal console using single-sign on;
- embedded editors for accessing documents in multiple formats without requiring other applications;
- support 'Drag-and-drop' file;
- accessible and operational for 250 concurrent users simultaneously at any point of time.

### **C. Business Process Management (BPM) system**

To manage and monitor the state of the activities in a workflow, such as the processing and approval of forms, and to determine the new activity to perform according to pre-defined processes (workflows).

It will monitor and support the management and coordination of most of the c4c processes, as grouped in the following 6 categories:

- Network functioning (e.g. service requests, information requests, membership requests, etc.);
- Network coordination (e.g. internal documentation delivery among all the c4c nodes, etc.);
- Site logistics for clinical trial feasibility (gathering information from clinical sites, etc.);
- Expert advice requests;
- Marketing (e.g. quote requests, etc.);
- Finance (e.g. cost monitoring, etc.).

### **D. Site logistics database**

The collection of the information related to clinical sites characteristics and organisation, useful to perform a site selection for a clinical trial.

Each clinical site shall be able to provide, verify and update information through a specific form (a specific process will be defined to be implemented in the BPMS).

### **E. Contact Manager**

Contact manager is a central communication and information web-based app to facilitate the management of the contact data of c4c stakeholders and external contacts, assuring faster and accurate communication and allowing the full track of all information and communication.



#### **F. Data Base - Patient Involvement**

This web-based app will collect the contact data of patients' organisations, to support the process to reach individual paediatric patients or parents when required, and of adult patients unaffiliated to a patient organisation.

#### **G. Performance metrics tool**

A Business Intelligence (BI) will provide meaningful and useful information to enable more effective decision-making. BI features (dashboards, reporting, performance monitoring, benchmarking) will be implemented with the aim to allow an easy interpretation of the available data, to support both the identification of new opportunities and the implementation of effective strategies based on insights.

#### **H. On line forms**

It is a simple, lightweight tool to quickly create forms, surveys and polls, to collect responses, view automatic charts to visualize the data and extract the data for future uses.