H2020 – CALL FOR TENDERS (CLOSED)

21.08.2020

IRRCS Galeazzi Orthopedic Institute (Milan) has been awarded the call for tender to assist PlusValue in the coordination of start-ups and SMEs to support the acquisition of the CE mark (clinical validation phase) in relation to the T-Factor project.

18.09.2020
The call for Tenders is now closed.

TENDER PROCEDURE FOR THE SELECTION OF AN ORGANISATION TO ASSIST PLUSVALUE IN THE COORDINATION OF START-UPS AND SMEs TO SUPPORT THE ACQUISITION OF THE CE MARK (CLINICAL VALIDATION PHASE) IN RELATION TO THE H2020 T-FACTOR PROJECT

BACKGROUND INFORMATION

The H2020 T-Factor project has been approved by the European Commission under Grant Agreement number: 868887 —T-Factor —H2020-SC5-2018-2019-2020/ H2020-SC5-2019-2, entitled "Unleashing future-facing urban hubs through culture and creativity-led strategies of transformative time". T-Factor challenges the waiting time in urban regeneration – i.e. the (often long) time in between the adoption of the regeneration masterplan, and its actual realization and delivery. It will explore and demonstrate how heritage, culture and creativity can drive collective and collaborative urban transformation in the waiting time and contribute to unleash vibrant urban hubs for inclusive urban regeneration, social innovation and enterprise. The project has a duration of 48 months, starting from 1st June 2020. It brings together a wide partnership of 25 partners including universities, grassroot organizations, public bodies and businesses across Europe and China.

T-Factor's mission is to turn historic urban areas across Europe into vibrant hubs for inclusive urban (re)generation, social innovation and enterprise, harnessing culture, creative collaboration and wide engagement to steer radically new, transformative approaches of 'meanwhile' (i.e. the period in-between the approval of the regeneration masterplan, and its actual realization and delivery). The project will pilot this 'transformative time' approach in a diversity of historic areas in Milan, London, Kaunas,Amsterdam,Bilbao,Lisbon. In these areas, huge financial investments have been already approved by various configurations of public-private partnerships (PPPs): T-Factor will complement these efforts by focusing on the activation of the software component (i.e. social, relational and cultural capital) which shall unleash transformative waiting times towards effective, sustainable and inclusive regenerations. These initiatives will be backed and supported by 'advance cases' of meaningful meanwhile approaches, contributing to the creation of an international community of practice that will support knowledge co-creation, sharing of practices and collective capacity-building. By comparing and contrasting the development of the regenerations across pilot sites, the project will produce evidence-

based yet adaptable knowledge, strategies, methods and tools to support multi-stakeholder, collaborative and participatory city-making throughout the meanwhile. Besides, the set-up of an international think tank and a community of practice focused on public value creation in the meanwhile will help go beyond the pilot sites, contributing to turn Europe into a seedbed of generative urban regenerations.

ROLE OF PLUSVALUE IN T-FACTOR

In the framework of EU project T-Factor, PlusValue is leading on engaging with relevant stakeholders to make sure that MIND – Milan Innovation District, the 1million sqm urban regeneration project being implemented in the former EXPO area in Milan, will answer the needs of, and create opportunities for, current and future communities who will live, work and play in the new area.

The new district will have a focus on the Life Sciences, due to the strong presence of both public and private research institutions, hospitals, and large companies active in this field in the precinct and the broader Lombardy region.

In this regard, start-ups and SMEs active in this area are a key target audience for the district, which set-out to develop, pilot and – in case of success – scale a broad set of services and facilities to accelerate their innovation and impact capacities.

In this framework, MIND partners are joining forces to support start-ups and SMEs in the medical device area in aquiring the CE mark under the new European Medical Devices Directive (MDD), In Vitro Diagnostic Devices Directive (IVDD) and Active Implantable Medical Devices Directive (AIMDD) – which imply that the sector will introduce various phases of clinical testing to assess the quality of its products, as it already happens for drugs. This is a very onerous process for SMEs and start-ups, which represent 95% of the Italian entrepreneurial population in the sector, but only 5% of the turnover, and which will face a great risk once the new directives will come into force (according to MedTech Europe many products might be retrieved from the market because of the 10-15% raise in their price due to the new accreditation mechanisms, causing unfair merge and acquisition processes).

Support at the regulatory level has been identified through desk research and 70 interviews to regional and national life sciences experts and practitioners conducted by PlusValue in 2019 as a key barrier for start-ups and SMEs in the medical device area, which represent a regional excellence in Lombardy.

The idea is to create in MIND, with the support of qualified consultants, researchers and clinicians, a structure that will allow to carry out mono and multi-centre experiments in structures that have great experience, many patients and therefore specific quality activities with top professionals, which would lead to a quicker EU marking and then marketing. This initiative could channel together several pros around it: companies, associations, IRCSS and universities that want to join, the Lombardy region and national agencies. This would mean the creation of a “Primary site” (with the transfer of all clinical trials activities to a single place even if connected to the entire national IRCCS network), which today exists only for drugs and not for medical devices. The economic advantage is obvious, even considering that there is no funding available to support clinical trials in the medical device area. In this way and to be competitive, the most disparate industries could get in touch not referring to personal contacts and the lowest price, which then often results in an increase in costs related to marking because of the difficulty in producing an official documentation. This gathering would increase the speed of clinical trials. There

would not be any waste of time, for example, between the approval of the ethics committee and the signature of the general manager.

WHO CAN APPLY?

To pilot the concept, PlusValue is looking for a service provider with deep expertise in the organisation of clinical trials, to support us and our partners at MIND in fully understanding the needs of 10 companies representative of this diverse sector and the costs implied by acquiring the CE mark, with the goal of building the case for the establishment of a hub providing this service at MIND.

The service provider should:

– Be available to conduct all the necessary activities in MIND – Milan Innovation District, while being connected to the whole regional and national network of research hospitals (IRCCS) in Italy;

– Show an excellent track-record in the conduction of clinical trials and health technology assessment for medical devices.

SERVICE DESCRIPTION

The contractor will:

- Interview the selected companies to determine how to build the patients' cohorts to run the clinical trials necessary to acquire the CE mark allowing to commercialise innovative medical devices;
- Define the budget needed to run the trials;
- Liaise with companies, hospitals and other relevant stakeholders as it might be required
- Support PlusValue in evaluating the impact of the new service both on the competitiveness of start-ups and SMEs, savings for public health providers and benefits from the perspective of patients, with a view of scaling-up the service at MIND
- Support PlusValue in organising a workshops with the companies and relevant stakeholders (including patients and their associations, citizens, industry associations and policy-makers) to disseminate the results of the pilot and raise awareness about the barriers faced by start-ups and SMEs in the medical device sectors, as well as their potential to increase human wellbeing.

PRESENTATION OF THE TENDERS

The following documents must be presented:

- A cover letter with a brief presentation of the organisation and a list of track records in the field
- Curriculum Vitae of the team
- Participation request form

The absence of any of the Annexes listed above will entail the exclusion of the applicant from the evaluation phase. Tenders shall be submitted by email only (with attachments) to the email address fiorenza.lipparini@plusvalue.org with the following reference in

subject: “T-FACTOR Tender”. Tenders addressed to another email address will be rejected.

The new deadline for the submission of the offer is: 18th September 2020 (H 23:59 CET)

ELIGIBILITY AND EVALUATION

The applications are considered admissible and assessable if:

- received by the date and time indicated in this tender, and duly signed;
- submitted by an organisation in possession of the above listed requirements;
- submitted in all parts listed under the article 5.

The selection will take place through the evaluation of the track records of the organisation (up to 20 points) and the curriculum of the team (up to 20 points).

The applicant scoring more than 33 points, will be invited for an interview. The interview will focus on the topics covered by this tender to ascertain the candidates’ general knowledge and professional experience. The maximum score attributed to the interview will be 30 points.

DURATION OF THE CONTRACT

14th September 2020 – 20th of January 2021

CONTRACTUAL AND FINANCIAL TERMS

Administrative details of the Contracting Authority:

PlusValue

9 Perseverance Works, Kingsland Road, E2 8DD London

VAT: GB299592134

The amount available for this consultancy services is €20.000, VAT included.

INTELLECTUAL PROPERTY

All documents produced by the selected organisation for the performance of the service referred to in this contract will be the property of PlusValue which can dispose of them fully and freely. However, this shall be without prejudice to the copyright. The selected organisation acknowledges that all the property rights relating to any intellectual work that it may have created as part of the activity carried out on behalf of PlusValue belong to the latter. The selected expert undertakes not to disclose or publish or in any case use data or news relating to the project without having obtained the prior written consent of the Manager and, in the case of publications, the prior approval of the related texts.

CONFIDENTIALITY CLAUSE

Despite the public execution of the project, part of the information exchanged for the development of the purpose of this contract between the PlusValue and the selected

expert, may be confidential. On this basis, only the documents and other pieces of information provided explicitly with the statement “confidential” will be dealt with as such. The selected expert ensures that respect its confidentiality and do not disseminate it, forward it to third parties or use it without prior written consent from PlusValue.

PRIVACY PROTECTION CLAUSE

Pursuant to the U.E. n. 679/2016, we inform you that the processing of personal data of the applicants is aimed solely at drawing up of the professional assignment; the treatment of personal data will be within the limits necessary to pursue the aforementioned purposes, with suitable methods and tools to guarantee the security and confidentiality of applicants.

TENDER INFORMATION

The person in charge of this procedure is Fiorenza Lipparini, Director of PlusValue.

For information & clarifications,
contact fiorenza.lipparini@plusvalue.org
CC elena.bologna@plusvalue.org