COVID-19 Call

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INTRODUCTION TO COVID-19 CALL

The novel coronavirus disease, COVID-19, was firstly reported at the end of last year in China (Wuhan). The main characteristic of COVID-19, in contrast to similar viruses such as SARS-CoV and MERS-CoV, is the low fatality rate and higher transmissibility, in so far as it has spread to over 210 countries, infected more than 18.5 million people, and claimed over seven hundred thousand lives in the last months. Medical devices containing Key Enabling Technologies could fulfil the promise of solving a wide range of problems regarding the prevention, diagnosis, and treatment of the coronavirus. TBMED aims to develop an Open Innovation Test Bed (OITB) for high risk medical devices that provides a single entry point to services along the whole value chain from preclinical development to clinical testing. The OITB has the capacity to increase patients' access to high-risk medical devices by helping SMEs to minimize time-to-market and the reimbursement process time, thus optimizing the process of transforming a prototype into a valuable innovative medical device boosting the fight against COVID-19.

Services to be provided:

- Webinar/s education addressing the perspective of the HTA about medical devices[1].
- Early dialogues between the Basque HTA office and companies that develop COVID-19 related medical devices ([1]).
- Expert advice for regional (Basque Country[1]) and/or multinational[1,2], clinical trials on COVID-19.

Scope

The open call - offered in the framework of TBMED - is addressed to help SMEs in the development of high risk medical devices with a focus on, included but not limited to, the characterization, prevention, diagnosis, treatment, follow up, and the forecast of the patient prognosis related to the COVID-19. The call supports with advisories and/or consultancies to SMEs within the test bed with a real live scenario, engaging national and/or international experts in healthcare systems and clinical trials – according to the details of services included bellow-.

Selected projects, should present innovative solutions based on a solid scientific and technological background, demonstrated proof of concept, a defined indication and a preliminary definition of the product under development for a productive interaction with the experts (TRL4-TRL6).

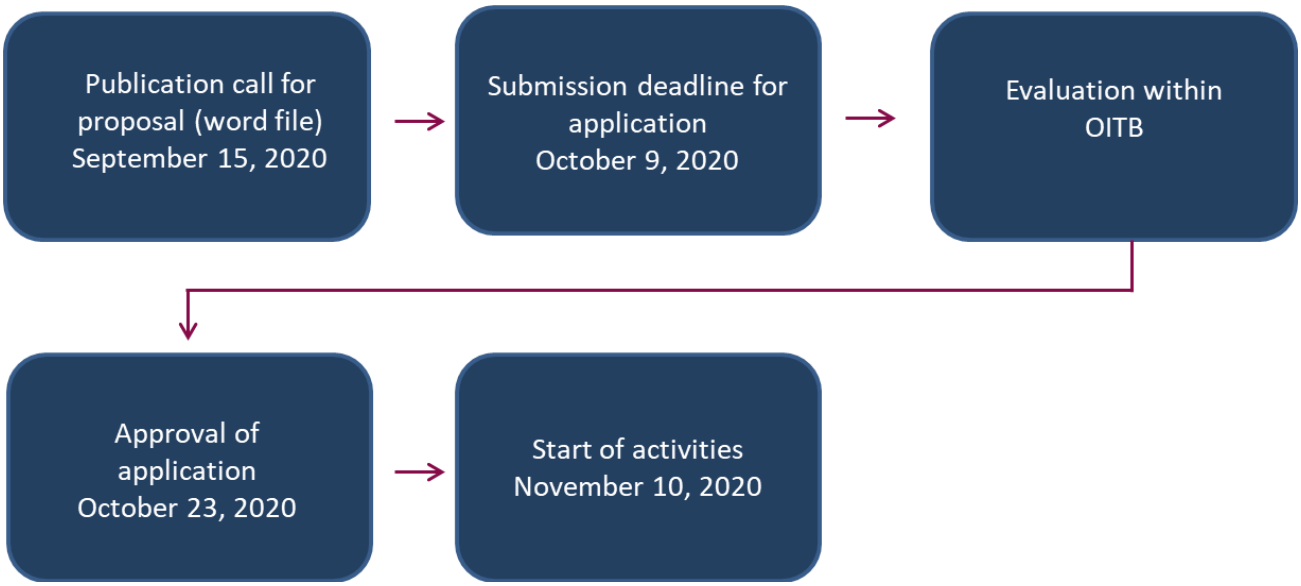
[1] A detailed definition of services and the budget will be prepared along the process depending on the needs of the companies and services available.

[2] European Clinical Research Infrastucture Network (ECRIN, https://ecrin.org/) is ready and able to provide expert advice and resources for multinational clinical investigations with medical devices related to COVID-19. In the same line, ECRIN and its national partners will be able to provide different services to support the implementation of any clinical investigation with medical devices related to COVID-19 in Europe. These activities include support in the development of the protocol, regulatory submissions and interactions with competent authorities and ethics committees in close collaboration with the sponsor in all participating countries other than the sponsor country, site initiation and set-up; routine on-site monitoring according the monitoring plan, global and local materiovigilance and data and statistics management. ECRIN is committed to participate in Covid-19 Call, however the possibility to perform the tasks will be limited to the budget available and the cost of these services.

Submission:
Applicants will be required to complete the form attached to this document[3] (available as a separate Word document for download) and send it to opencall@tbmed.eu.

Extended submission deadline: **October 11, 2020, 5:00 p.m. CEST**

Applicants will be informed about the outcome of their application by mid-October 2020. Activities are planned to start at the beginning of November 2020.



[3] Please note that all information provided will be treated confidentially and is stored only for the purpose of this call.

SERVICE DETAILS

Webinar/s education addressing the perspective of the HTA about medical devices

The Basque Foundation for Health Innovation and Research (BIOEF) will provide a webinar – with those companies that request this service – that will be focused on the aspects that Health Technology Assessment (HTA) agencies take into account when assessing the value of a new medical device in order to inform health decision makers. This will help companies to have a first contact with an HTA office in order to learn about the requirements from the perspective of public health systems – most often client for COVID-19 products – to be successful when entering into the reimbursement process of their product**.**

Early dialogues between the Basque HTA office and companies that develop COVID-19 related medical devices

Early dialogue as a non-binding scientific advice before the start of a proof of concept study. The purpose of this meeting will be to improve the quality and appropriateness of the data and/or the design of the study produced by the developers in view of future HTA assessment/re-assessment. This service includes the assessment of the product taking the HTA office's point of view and a meeting between the applicant and the HTA office after receiving the feedback of the evaluation.

Expert advice for regional (Basque Country,[4]) and/or multinational ([4,5]), clinical trials on COVID-19.

Dialogue to address the design of a clinical proof of concept (CPoC) or a clinical trial (CT). This support will assess the feasibility of developing a CPoC or a CT taking two different approaches into account: a) the regional (Basque Country) scenario, or b) the international scenario (according to the needs of the applicant). BIOEF will be in charge of providing expert advice and managing the regional approach. ECRIN will provide consultancy for the development of multinational clinical medical device investigations. In particular ECRIN will provide the necessary information regarding the regulatory and ethical requirements relevant for a specific clinical investigation in various countries. ECRIN will provide access to experts for advice in methodology and the review of the clinical investigation plan (CIP). Consultancy will also be offered for the development of funding applications and especially for all aspects regarding the organisation of the management and logistical aspects of multinational clinical investigation. *At the end of this service BIOEF and/or ECRIN will provide a quote/proposal in respect of launching the CPoC or the CT. Neither BIOEF nor ECRIN will cover the cost of the delivery, conduction or execution of the CPoC or the CT in any kind of manner.*

[4] A detailed definition of services and the budget will be prepared along the process depending on the needs of the companies and services available.

[5] European Clinical Research Infrastucture Network (ECRIN, https://ecrin.org/) is ready and able to provide expert advice and resources for multinational clinical investigations with medical devices related to COVID-19. In the same line, ECRIN and its national partners will be able to provide different services to support the implementation of any clinical investigation with medical devices related to COVID-19 in Europe. These activities include support in the development of the protocol, regulatory submissions and interactions with competent authorities and ethics committees in close collaboration with the sponsor in all participating countries other than the sponsor country, site initiation and set-up; routine on-site monitoring according the monitoring plan, global and local materiovigilance and data and statistics management. ECRIN is committed to participate in Covid-19 Call, however the possibility to perform the tasks will be limited to the budget available and the cost of these services.

TERMS AND CONDITIONS

Funds

This call uses funds obtained within the scope of the TBMED project funded by the European Union´s Horizon 2020 Research and Innovation Programme under GA no. 814439. No additional funding will be dedicated to support this call.

Process of application

Any Small and Medium-Sized Enterprise (SME) (consortiums not allowed) headquartered in the European Union can apply to this call. The language of the application forms is English. In this call only one application per applicant SME will be allowed. The process includes the completion of the application form (filled out Word file) and dispatch to the TBMED consortium under the following address: opencall@tbmed.eu. It is recommended to merge all documents into one single PDF file.
All documentation provided in the application form must be truthful, and the applicant declares, by submitting it, its authenticity singing the specific part in the document "AUTHORIZATION".

Assessment of the application

Evaluation of each application submitted will be carried out by a Selection Board consisting of 6 experts from the TBMED consortium partners. They will have specific expertise in the different areas of knowledge and/or highly specialized staff belonging to TBMED institutions (ECRIN, BIOEF, CIDETEC and EURICE). To evaluate each application the following factors will be taken into account:

- Technical advance
- Impact on the call objectives
- Feasibility of the project to progress in the TRL scale
- Feasibity to be carried out by the TBMED consortium partners
- Feasibility with regard to R&D&I
- Bussiness viability
- Expertise and resources

The scoring will take into account the median score of the members of the Selection Board. At least 75% of the members of the selection board need to participate in the evaluation in order for the decision to be made.

The decisions of the Selection Board shall be final and, upon proposal of the Board, TBMED coordinator CIDETEC may declare the call null and void, without the obligation to assign the established services, when the applications submitted do not fulfill the expectations in terms of completeness, excellence and fitness to the call. The applicants will be informed about the decision made by the Selection Board by mid-October. The decisions taken with regard to the applications of the call will also be published on the TBMED website (www.tbmed.eu) and, if applicable, disseminated through such media that are considered appropriate by the TBMED consortium partners. No further correspondence or communication will be entered into with unsuccessful applicants. Under no circumstance will separate or individualized information be provided on the application forms received, nor on the deliberation of the Selection Board. If the application is successful, the TBMED consortium partners will enter into contract negotiations with the successful applicant with regard to the specific terms of the service.

TBMED partners committment

The TBMED partners will not be obliged to provide any funding to the applicants. Services will be defined and addressed during contract negotiations.

Applicants committment

The applicants shall comply with the following requirements:

1) Each applicant can select all or only one service proposed in the portfolio of the TBMED Covid-19 call. If certain services are not required they can be assigned to other applicants.
2) The applicants will not transfer or assign directly or indirectly any portion of the support to other medical devices not included in the initial application.
3) The applicants will take part in the project in accordance with the rules and requirements of the call and in accordance with the agreed support for each project according to the contract to be concluded;
4) The applicants will designate a person to lead the communication between the applicant and the TBMED consortium partners throughout the duration of the project. In addition, a principal investigator will be responsible for the management of the project and replying to any request of information within the scope of the project;
5) The applicants will supply any information requested by the TBMED consortium partners for the purpose of ensuring that these requirements are complied with and comply with any written request or direction received from the European Commision concerning the proper management of the project;
6) The applicants will not be entitled to require further supporting for the mere reason that they disagree with the results of the support by the TBMED consortium partners;
7) The applicant will comply with dissemination and communication requirements as described in the Confidentiality and Communication Rules relating to the open call published together with the application documentation of the Covid-19 call. All applicants are aware that the TBMED consortium partners are obliged to comply with the Open Data and Open Access rules of the EC provided for in the European Union's Horizon 2020 research and innovation programme. Details can be found in the Annotated Model Grant Agreement.

For more information:
Email: opencall@tbmed.eu
https://tbmed.eu/

Application form

Instructions:

*Fill out the information **that is applicable to your product, company and knowledge**. Each applicant may only fill out and submit one application form.*

*Complete the fields in this questionnaire **as applicable.***

- *Tick or place an X in any of the boxes that are true/applicable.*
- *Add rows to tables to include requested information. Alternatively, you may attach information in a separate sheet using the same format requested.*
- *In some cases it may be required to duplicate rows, copy the section and paste as needed.*
- *Update the table of contents when completed.*

SUBMISSION QUESTIONNAIRE

A. APPLICANT INFORMATION

*The information in this questionnaire will be shared with the members of the Selection Board for the purpose of assessing the application. You will be asked to confirm that you are okay with this at the end of the application form under "***AUTHORIZATION".**

Questionnaire Submission Date *(DD/MM/YYYY)*		
Company Name		
Physical address		
Postal address		
Country		
Telephone number		
Fax		
Website		
Email		
Type of service required (according to the services offered) **Please review the call for more details about the support that each service offers.*	☐ Webinar/s education addressing the perspective of the HTA with regard to medical devices. ☐ Early dialogues between the Basque HTA office and companies that develop COVID-19 related medical devices. ☐ Expert advice for regional (Basque Country) and/or multinational, clinical trials on COVID-19.	
Type of innovation related to COVID-19	☐ Medical device ☐ Medical device- Software	☐ Medical device- *In-vitro* Diagnostics
Typology / Clasification area	☐ Biotechnology ☐ **I**nnovation assistance ☐ ICT Health (Information and Communication Technologies)	☐ Material and device ☐ Image ☐ Other
Impact	☐ Society ☐ Patients ☐ Professionals ☐ Health System sustainability	☐ Image and/or prestige ☐ Economic return for the system ☐ Business sector

Provide contact information for each of the following:

	Queries with regard to the application form (such as **Principal Investigator**)	Technical Specifications and Quality Assurance	General Inquiries
Name:			
Telephone:			
Cell phone:			
Email:			

Product FEATURES

Brand name (if any)	
Website (if any)	
Generic name of the product (if any)	
In case of medical device, please add the EU classification	☐ Class I ☐ Class I (Special function) ☐ Class IIa ☐ Class IIb ☐ Class III ☐ Not assessed yet
State of the development process (approximate TRL - Technology Readiness Level) More details are available here.	☐ 1-3 ☐ 4-6 ☐ 7-9
Intended Use *(300 characteres)*	*State the intended use of the device and/or provide a general description of the disease or condition that the device will diagnose, treat, prevent, cure or mitigate.*
Target Population *(300 characteres)*	*Describe the target patient population for which the device is intended. Specify if the device is for pediatric use.*
	☐ Pediatric use ☐ Not for pediatric use
Time to be introduced in the market	☐ ≥ 4 years ☐ 1-3 years ☐ < 1 year ☐ Adaptive pathway
Competitors	☐ Similar products/technologies/services are close to the market. ☐ Similar products/technologies/services are far from entering the market. ☐ Similar products/technologies/services have not been identified yet.
Feasibility of the project	☐ The company has not developed a business plan yet. ☐ The company has developed a business plan. ☐ The company developed a business plan and also has a financial plan.
Use	*Identify if the device is intended for single use or is reusable*
	☐ Single Use ☐ Reusable

Product INFORMATION

Product Description and Design *(Maximum one A4 page)*

Attach copies of the design drawings, diagrams, photos, if applicable.

Provide a general description of design, characteristics and performance of the medical device that you have designed.

Device Composition *(Maximum one A4 page)*

Provide a summary of the composition of the device, including at minimum, the material specification and/or chemical composition of the materials that have direct or indirect contact with the user/patient.
Indication of biological material or derivate used in the medical device.
☐ Biological material or derivate is used in the medical device. (If yes, specify origin (human, animal, recombinant or fermentation products or any other biological material; source (blood, bone, heart, any other tissue or cells) and the intended reason for its presence and if applicable, its primary mode of action. ☐ Not applicable

Safety and Efficacy of the product

Tick or place an X here ☐ if there is no information available

Clinical Assessment (if applicable)

Provide a summary of the clinical evaluation of the product, if applicable.
☐ Not applicable

Risk management[6]

Attach a copy of the results of risk management, per product medical device, if applicable.

Provide a summary of the risks identified during the risk analysis process and how these risks have been controlled to an acceptable level. The results of the risk analysis should provide a conclusion with evidence that remaining risks are acceptable when compared to their benefits. When a standard is followed in the risk assessment, describe the standard.
☐ Not applicable

[6] This information is optional, you are not obliged to provide the information requested.

Regulatory and licensing status

CE Marking Status (if applicable)

Provide a copy of the relevant CE Mark certificate for each applicable variant, if applicable.

☐ Product is CE Marked
☐ Product is not CE Marked
☐ Product submitted for CE Mark evaluation, but is still to be approved.
Date of Submission *(DD/MM/YYYY)*:
☐ Comments:

FDA Marking Status (if applicable)

Provide a copy of the relevant FDA Mark certificate for each applicable variant, if applicable.

☐ Product is approved by the US FDA: (specify authorization number)
- ☐ PMA#
- ☐ 510K#
- ☐ Other (Specify):

☐ Product submitted for US FDA evaluation. Waiting for registration approval.
Date of Submission *(DD/MM/YYYY)*:
☐ Comments:

Other Regulatory Bodies (if applicable)

Provide a copy of the relevant Regulatory certificate, if applicable.

Comments:

☐ Not applicable

CERTIFICATES (PRODUCT and/or company)

Tick or place an X here ☐ if there is no information available

Inspections/Authorizations/Certifications/Quality Controls

Add rows to the table if you need to include more information.

Type of document (Inspections/ Authorizations/ Certifications/ Quality Controls)	**Authority**	**Certificate No.**	**Date Issued** *(DD/MM/YYYY)*	**Valid until** *(DD/MM/YYYY)*

SPECIFIC DETAILS OF THE PROJECT

B. PROJECT OUTLINE

State of the art

Describe scientific and methodology features that justify the development of the product. *How will the device help in the fight against COVID-19?*

Technological insight

Technological Development Envisaged (approximately one A4 page)

Describe the state-of-the-art of the technology and the technological developments envisaged. *Describe the needs identified to progress in the development of the medical device.* *Describe the concrete results expected at the end of the project (design of the Clinical Proof of Concept or Clinical Investigation, process, etc.)*

Expertise and resources

Approximately one A4 page

Describe your expertise and core business. *What is the total number of Full-Time Equivalents working on R&D (figures).* *Describe your managerial expertise with regard to the market addressed.* *Does the company have enough resources to complete the innovation cycle of the medical device development and achieve bringing it to the market (Yes/No). Please justify.*

Market scenario

Market Application and Exploitation (approximately one A4 page)

What is the market envisaged (description)? *What is the estimated market size and expected market share?* *Describe the position of the partners in the market(s)?* *What is the status of the competition in the market(s)?* *What are the revenues foreseen at the end of the first year?*

C. AUTHORIZATION

Authorization for sharing information

I, the undersigned [ENTER FULL NAME], CERTIFY that the information stated above is true, correct and complete to the best of my knowledge. Likewise, I confirm that the company has no objection to the information contained herein being shared with the Selection Board.

Name	Signature	Date *(DD/MM/YYYY)*
Full title/Position	Company name	

D. CHECKLIST OF ATTACHMENTS

Product Information

- ☐ Copy of design drawings, diagrams, photos
- ☐ Flow diagram and brief narrative describing the manufacturing and control process of this product with relevant parameters.

Safety and Efficacy and/or Therapeutic Equivalence (if any)

- ☐ Clinical Evaluation Report

Risk Management (if any)

- ☐ Copy of results of risk management, per medical device

Regulatory and Licensing Status (if any)

- ☐ CE mark Certificate
- ☐ FDA mark Certificate
- ☐ Other regulatory bodies

Certificates (if any)

- ☐ Recent/valid system certificates (ISO 9001, ISO 13485, other)

Authorization

- ☐ Authorization to share information signed