Call: H2020-NMBP-HUBS-2018
Topic: DT-NMBP-02-2018
Funding Scheme: Innovation Action (IA)

Open Call

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CALL FOR EXPRESSIONS OF INTEREST

An Open Call within TBMED – A testing bed for the development of high-risk medical devices – has been launched with the objective of providing support to developers from SMEs and other organizations which aim to perform a clinical proof of concept or clinical investigation with an innovative high risk medical device[1].

BIOEF and ECRIN, partners in the TBMED consortium, have allocated a dedicated part of their budget to cover clinical research investigation activities.

CONTEXT

Due to the entry into force of the European regulation MDR 2017/745 in May 2021, quality, safety and performance requirements along the whole technology development of medical devices have increased in order to ensure high level of health protection for patients and users.

TBMED aims to establish an Open Innovation Testing Bed (OITB) specialized in the development of high risk medical devices (MDs) (Class IIb or Class III) by providing an integral service to accelerate the development of MDs, reducing time to market, covering technology development from TRL4 (proof of concept in small animals) to TRL7 (clinical investigations) and offering at the same time additional business management services to companies that require those.

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 improving the process of optimizing the prototype into a valuable innovative medical device.

1- More information of the TBMED project in the website: https://tbmed.eu/

Services to be provided[2,]

For developers which aim to perform a clinical investigation in the Basque Country:

- Advisory sessions (including the members of the Health Technology Assessment office of the Basque Country) to address the design of a clinical proof of concept (CPoC) that demonstrates that critical design features of the medical device perform as intended. The CPoC would develop within the Basque Public Health System.
- Support for regional pilot clinical investigations in order to determine feasibility of a medical device or perform a first in human clinical investigation including the services: Design, Clinical Investigator Identification, Project Management, support the Regulatory and Ethical and AEMPS Submissions[3], Data Management, Statistics and Monitoring.

In case of a regional clinical investigation carried out in the Basque Country, the sponsor should be responsible for (items not covered by the call budget):

- Materiovigilance
- Payment of the patient's insurance
- Manufacturing and transport of the medical device
- Inclusion of the project in clinicaltrials.gov and /or EUDAMED.

For developers which aim to perform a multinational clinical investigation in at least two of the ECRIN member/observer countries (**ECRIN member and observer countries: Czech Republic, France, Germany, Hungary, Ireland, Italy, Norway, Poland, Portugal, Slovakia, Spain, Switzerland)**:

- Consultancy for the development of multinational clinical medical device investigations (minimum two European countries involved from the list mentioned above)
    - Clinical Investigation Methodology – Validation of clinical investigations through independent protocol peer-review
    - Regulatory and ethical requirements for clinical investigation authorization
    - Clinical investigation operational planning
- Support for multinational pivotal clinical investigations in order to determine performance of a medical device including central services (Project Management, Regulatory and Ethical Submissions, Data Management and Statistics, Global Materiovigilance) and distributed services (Local Monitoring, Local Materiovigilance, and Local Project Management)

In case of a multinational clinical investigation the sponsor should be responsible for (items not covered by the call budget):

- Selection and payment of the participating clinical centres and principal investigators
- Management of the contract between the sponsor and participating clinical centres
- Payment of the patient's insurance
- Manufacturing and transport of the medical device

2- If the services needed to perform the clinical investigation exceed the budget/resources of the open call,the applicant/sponsor will cover the expenses of those services.

3 - The applicant/sponsor will address the preparation of any document required to fulfill the application process to the Ethical Committee selected and / or the Spanish Agency of Medicine and Medical Device (AEMPS) according to the recommendation and the support of the TBMED partners involved. In addittion, the applicant/sponsor will be responsible for obtaining and providing any documents required to comply with the applicable legislation.

After the UK has left the European Union, it is now a Third Party Country out of the scope for ECRIN services in terms of running a multinational clinical investigation for an UK investigator.

For both Basque Country and/or multinational clinical investigation the sponsor will be responsible for obtaining and providing to the partners involved in the project any documents required to comply with the application process to the Ethical Committee and/or the Competent Authorities according to applicable legislation.

Provision of services will entirely depend on the Covid -19 pandemic situation, as it could deeply impact on the investigator's availability. In addition, TBMED partners have a limited budget for this call. Therefore, after identifying the needs of potential CPoC and CI designs, the budget for the individual application will be defined. This implies that the company might have to face additional costs about which it will be notified in advance.

Scope

The open call – offered in the framework of TBMED - is addressed to help developers in the development of high-risk medical devices class IIb and III (In vitro diagnostics excluded) with a focus on, prevention, monitoring, prediction, prognosis, diagnosis, treatment or alleviation of disease, injury or disability of patients that fall into the following healthcare areas (but not limited to):

1- Ophthalmology
2- Orthopaedics
3- Wound management
4- Neurology
5- Drug-delivery
6- Cardiology

This call is supporting developers to perform clinical investigations. The selected projects should present innovative solutions, ready to perform clinical investigations in humans with solid scientific and technological background, including all preclinical validations needed and a defined indication. This call is focused on those medical devices with enough progression in their development to be tested in the relevant clinical environment (TRL-6, proof of concept, or TRL-7, clinical investigation) helping them to progress to higher TRLs[4]. Therefore, only medical devices with a minimum TRL of 5 will be considered in the current call.

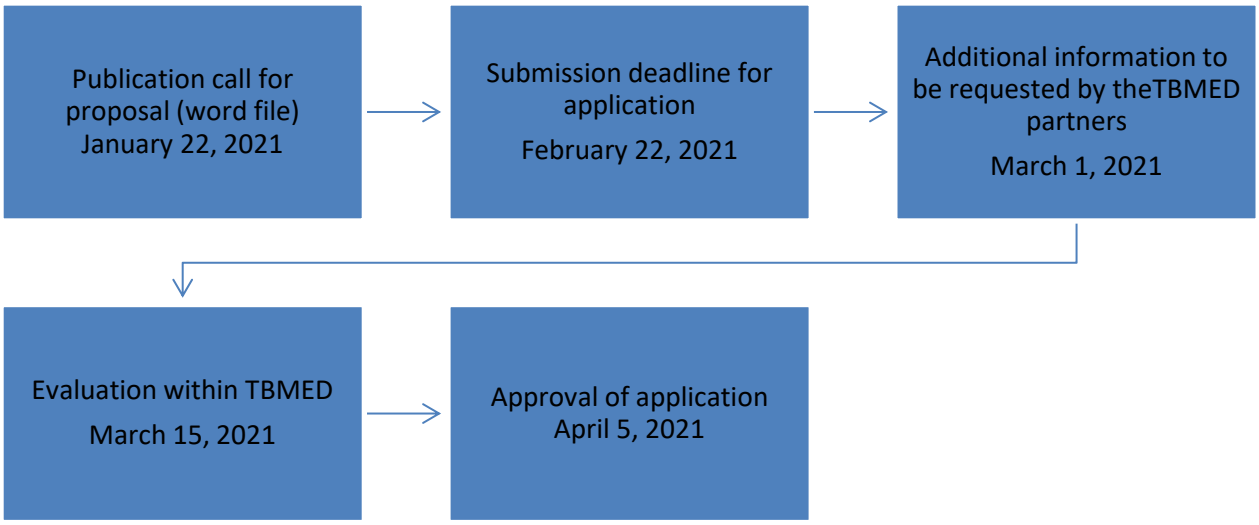
[4] **https://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2018-2020/annexes/h2020-wp1820-annex-g-trl_en.pdf**

Submission:

Applicants will be required to complete the form attached to this document[5] and send it to opencall@tbmed.eu.

Submission deadline: **February 22, 2021, 23:59 CET**

Applicants will be informed about the outcome of their application by the beginning of April 2021. Activities are planned to start in April 2021, depending on the signature of the necessary contracts.



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

TERMS AND CONDITIONS

Funds

This call uses funds obtained within the scope of the TBMED project funded by European Union´s Horizon 2020 Research and Innovation Program. No additional funding will be dedicated to support this call. The applicants will not receive funds but will profit from services provided by TBMED partners.

Process of application

Any developer such as Small and Medium-Sized Enterprise (SME), academics or research center (consortiums not allowed), that would like to perform a clinical proof of concept or clinical investigation in the European Union, is allowed to file an application. The language of the application form is English. In this call only one application per applicant 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 before sending.
All the 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 consortium partners (ECRIN, BIOEF CIDETEC and EURICE). To evaluate each application the following factors will be taken into account:

- Preclinical studies required[6] to get the enough information about safety and efficacy of the medical device must have been completed.
- Technological innovation of the proposed medical device
- Readiness to perform clinical investigations
- Feasibility of the project to progress in the TRL scale
- Feasibility with regard to R&D&I
- Impact on call objectives and health system requirements
- Business viability
- Expertise and resources

The scoring will take into account the average 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. Additional information could be requested by the TBMED partners if necessary. The applicants will be informed about the decision made by the Selection Board by the beginning of April. The decisions taken with regard to the applications of the call could also be published on the TBMED website

[6] The sponsor will follow those International Organization for Standardization (ISO) recommendations that are applicable according to the characteristics of the medical device.

(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.

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

Application form

Instructions:

Fill out the information ***that is applicable to your product, company/institution/sponsor 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 blocks 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.*
- ***Please be sure to correctly provide the information requested***

SUBMISSION QUESTIONNAIRE

SHORT TITLE of Project Proposal: ……

A. APPLICANT INFORMATION

*The information in this questionnaire will be shared with the members of the Selection Board for the purpose of assessing the applications. 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 [7]	☐ To perform a clinical investigation (Proof of Concept) in the Basque Country (TRL-6) ☐ To perform a multinational clinical investigation in at least two of the ECRIN country members[8]	
Power source	☐ Active Medical Device ☐ Non-Active Medical Device	☐ Stand-alone software as a Medical Device
Invasiveness	☐ Surgically Invasive Medical Device ☐ Implantable Medical Device	☐ Non-invasive Medical Device
Duration of contact with the patient	☐ Transient contact (less than 60 minutes) ☐ Short-term contact (up to 30 days) ☐ Long-term contact (more than 30 days)	
Medical area in which the medical device could be classified	☐ Ophthalmology ☐ Orthopaedics ☐ Wound management ☐ Neurology	☐ Drug-delivery ☐ Cardiology ☐ Other (please specify) _____
Impact	☐ Society ☐ Patients ☐ Professionals ☐ Health System sustainability	☐ Image and/or prestige ☐ Economic return for the system ☐ Business sector

[7] Please review the call for more details about the support that each service offers.

[8] ECRIN members and observers: Czech Republic, France, Germany, Hungary, Ireland, Italy, Norway, Poland, Portugal, Slovakia, Spain, Switzerland

Comments:			
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:			
E-mail:			

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 under are available here.	☐ 5-6 ☐ 7-9
Intended Use *(300 characters)*	*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 characters)*	*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 four A4 page, not including instructions for use)*

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

Provide a general description on design, characteristics and performance of the medical device that you have designed. *Provide instructions for use*

Device Composition (*Maximum three 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

Pre-Clinical Validation [9]

Proper addressing of this criteria and fulfillment is mandatory.

*Provide the biological plan evaluation according to the ISO 10993-1 and **summarize the outcome of the biological plan evaluation.***   *Provide the list of applicable standards for the medical device and a summary **justifying the compliance to those standards***

Clinical Assessment (IF ANY)

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

Risk management[10]

Attach a copy of the Results of risk management, per product medical device.

Provide a summary of the risks identified during the risk analysis process (ISO 14971) 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

[9] When necessary, more information could be asked to complete the evaluation.

[10] This information is optional, it is not mandatory to provide the information requested.

Clinical Investigation Documentation[11]

Indicate the progress of elaborating documentation related to the device for the clinical investigation in case of any.

In case the manufacturer has started to develop the clinical investigation dossier, please indicate the progress of development of essential documents related to clinical investigation					
Clinical Investigation Protocol	☐ 0%	☐ 25%	☐ 50%	☐ 75%	☐ 100%
Investigator's Brochure	☐ 0%	☐ 25%	☐ 50%	☐ 75%	☐ 100%
☐ Not applicable					

[11] When necessary, more information could be asked to complete the assessment

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´s 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

Approximately three A4 pages

Describe scientific and methodology features that justify the development of the product. *Describe the clinical indication and the solution proposed by the medical device* *Describe the advantages and impact (support needs that are not currently addressed, important advance in the field, interest of the clinicians on the medical device) of the medical device in the health system*

Technological insight

Technological Development Envisaged (approximately five A4 pages)

Describe the state-of-the-art of the technology and the technological developments envisaged[12]*.* *Describe the current state of development, including needed tests identified such as biocompatibility* *Describe the needs identified to progress in the development of the medical device* *Describe the concrete* ***results expected*** *at the end of the project* ***in this call*** *(design of the Clinical Proof of Concept or Clinical Investigation, process, etc.)* *Describe the* ***expected support*** *for the medical device coming from the TBMED partners* ***in this call***

Market scenario

Market Application and Exploitation (approximately four A4 pages)

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 is the plan to bring the product to the market?* *What are the revenues foreseen at the end of the first year?*

[12] https://www.ansm.sante.fr/var/ansm_site/storage/original/application/31ab693508ee477f4d3c201c2d888330.pdf

Expertise and resources

Approximately four A4 pages

Describe your expertise and core business. *What is the total number of Full-Time Equivalents working on R&D and regulatory affairs? (figures).* *Do you have previous experiences taking part in a clinical Proof of Concept or Pivotal clinical investigation?? (Yes/No). Please justify.* *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 accordingly to your business plan or possible European/national aids* *Does the company have pre-identified clinical investigators?* *What is the manufacturing capacity of the medical devices (i.e. manufacturing rate/day)?* *Did the company start to elaborate documentation for the clinical investigation? Please justify*

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
- ☐ Instructions for Use
- ☐ Flow diagram and brief narrative describing the manufacturing and control process of this product with relevant parameters.

Pre-clinical Assessment

- ☐ Biological Plan Evaluation
- ☐ List of applicable standards

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

- ☐ Summary of 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)

Project Outline

- ☐ State of the art
- ☐ Technological insight
- ☐ Expertise and resources
- ☐ Market scenario

Authorization

- ☐ Authorization to share information signed

Annexes

- ☐ Please specify: _____
- ☐ Please specify: _____
- ☐ Please specify: _____