Open Call for Proposals

GUIDELINES FOR APPLICANTS

Application Submission Starts on: 21st February 2022
Submission Deadline: 21st March 2022

Application Form

www.safenmt.eu

This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under the Grant Agreement number 814607.

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Executive Summary

The Guide for Applicants contains the basic information needed to guide you in preparing a proposal for submission to the SAFE-N-MEDTECH Open Call. It gives an introduction on how to structure your proposal. It also describes how to submit the proposal and the evaluation criteria.

SAFE-N-MEDTECH gathers expertise from 28 partners around the World focused on enabling the safe translation of nano-enabled medical technologies from Proof of Concept to markets and clinical practice. It is a H2020 funded project (Grant Agreement No. 814607) and it is co-led by the Basque Foundation for Health Innovation and Research (Spain) and BioKeralty (Spain).

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1. Scope of the SAFE-N-Medtech Open Call

An Open Call within H2020 project SAFE-N-MEDTECH – Safety testing in the life cycle of nanotechnology-enabled medical technologies for health– has been launched with the objective of providing services and support to companies and other organizations with the aim of accelerating the development and commercialization of innovative MedTech solutions based on nano-enabled technology.

This call uses funds obtained within the scope of the SAFE-N-MEDTECH project funded by European Union´s Horizon 2020 Research and Innovation Program.

Please note that all information provided will be treated as confidential and is stored only for the purpose of this call.

2. Rules and Conditions

All applicants will have to abide by all general requirements described in Section 2 of this Guide for Applicants in order to be considered eligible for the Open Call.

2.1 Type of Beneficiary

Any private legal entity (consortiums not allowed) headquartered in any part of the EU or associated countries eligible under H2020 can apply to this call, ensuring that:

- They are legally recognised (have 'legal personality');
- They are recognized as Small or Medium Enterprise (including start-ups)
- The organisation should not have had convictions for fraudulent behaviour, other financial irregularities, unethical or illegal business practices;
- The participating organisation should not have been declared bankrupt or have initiated bankruptcy procedures;
- It is not under liquidation or is not an enterprise under difficulty according to the Commission Regulation No 651/2014, art. 2.18.
- The applicant cannot be a partner or affiliate of the consortium

In case of selection for support, official documents issued by the relevant national authorities to prove compliance with these conditions should be provided as part of the contracting process with the SAFE-N-MEDTECH project.

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2.2 Support

This call uses funds obtained within the scope of the SAFE-N-MEDTECH project funded by European Union´s Horizon 2020 Research and Innovation Program.

The applicants will not receive funds but will benefit from services provided by SAFE-N-MEDTECH partners at no cost for the selected proposal (s) (Section 2.3 of this document).

2.3 Services provided by SAFE-N-MEDTECH Partners

SAFE-N-MEDTECH with its key expertise and extensive knowledge in nano-enabled medical technologies, offers characterization, pre-clinical validation, access to biobanks and patient samples, scale up and regulatory support, technology assessment and horizon scanning.

Examples of support services for product/technology development/validation:

- **Nanoparticle Characterisation**
  - Chemical Composition
  - Physical properties
  - Drug loading/release
  - RNA quantification and integrity
  - Sterility and Toxicity

- **Pre-Clinical Development**
  - Antibody production
  - Peptide/Protein synthesis
  - Oligonucleotide synthesis
  - Immune response monitoring
  - Cellular assays
  - Biological evaluation
  - Nanoparticle development
  - Design and optimisation of biosensor platforms
  - Access to human samples and Biobanks
  - In vivo experiments

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- **In Silico**
  - In silico modelling

- **Clinical Validation**
  - RNA extraction
  - RNA/DNA sequencing
  - Binding affinity measurement
  - Immune response monitoring

- **Assistance in prototyping and qualification of manufacturing facilities**

- **Business development coaching, links with business angels, investors, capital risk, etc**

- **Regulatory Assessment**
  - Regulatory support to Europe and US approval

- **Health Technology Assessment**
  - First evaluation of the project/product based on Health Technology Assessment (HTA) and Healthcare system needs
  - Technology scanning to identify redundancies/synergies

3. Proposal Submission

3.1 Submission

Proposals for the SAFE-N-MEDTECH Open Call are submitted in a single stage through the platform, available at www.safenmt.eu. Applicants will be required to complete the form directly in the platform. Each applicant will be able to send one proposal.

Submission deadline: March 21st 2022, 23:59 CET

Applicants will be informed about the outcome of their application by the end of May 2022. Activities are planned to start in June 2022, depending on the signature of the necessary contracts.

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3.2 Language

The proposal has to be written in English. Proposals in any other language or format will not be considered eligible. English is also the only official language during the whole length of the support process. This means that all communication will be in English, and all deliverables will only be accepted if in English.

3.3 Other

Do not wait until the last minute to submit the final version of your proposal. Failure of your proposal to arrive on time for any reason, including communication delays, is not acceptable as a delay circumstance.

A receipt of a successfully submitted proposal will be issued to the email address used at the time of proposal registration. The sending of an acknowledgement of receipt does not imply that the proposal has been accepted as eligible for evaluation.

4. Proposal Evaluation and Selection

4.1 Overall Process

The selection of the open call proposals will be realised in a three-stage process and will start immediately after the call cut-off date. Stage one will consist of general eligibility check against the rules and conditions established in Section 4.2 of this document. Proposals considered eligible will pass to stage two, which will comprise the in-depth evaluation according to five criteria (described in 4.3) by an Evaluation Committee. The applications will be ranked according to the overall score in descending order and, on a third stage, the results will be submitted to the SAFE-N-MEDTECH Project Management Committee for review and decision.

Feedback on the evaluation will be provided within 60 working days after the cut-off date. If any delays in the evaluation process occur for reasons outside the control of SAFE-N-MEDTECH Consortium, this will be promptly communicated to the Applicants via email.

If the application is successful, the SAFE-N-MEDTECH consortium partners will enter into contract negotiations with the successful applicant with regard to the specific terms of the service and confidentiality agreements.

Two to three applications are expected to be selected finally.

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4.2 General Eligibility Check

In order to be considered eligible for evaluation, a proposal needs to meet the following conditions:

- The online application form has been completed as required;
- The proposal description is written in English
- The proposal was submitted by the closing date;
- The eligibility criteria and rules set out in section 2 were met
- The overall concept is aligned with SAFE-N-MEDTECH scope (medical technologies-Medical devices or In vitro diagnostics) that are based/use nanotechnology

Proposals that do not fulfil all of the above conditions will not be considered for the next step of the evaluation process and will get a rejection letter including the reasons for being declared as non-eligible.

4.3 Expert Evaluation

Proposals will be evaluated by a panel composed of 3 members with wide expertise in the technological areas envisaged in SAFE-N-MEDTECH. The evaluators are members of the Consortium. The selection decisions are based on a balance of objective criteria, experience and professional judgement of the evaluators.

The evaluation will comprise, in a first step, the in-depth analysis of the proposal by each evaluator against 5 criteria, as follows:

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No	NAME AND EXPLANATION	SCORE
1	**Aim of the call** Innovative medical devices/IVDs based on nanotechnology at adequate TRL (4 or above)	YES/NO If NO, proposal is not assessed further
2	**Impact on Call objectives and patient/health system requirements** The proposal must contribute to the overall objectives of the Call and the product described in the proposal must have a high impact on the needs of the patient/health system. SME participation is strongly encouraged and valued	Range 0-5
3	**Excellence of the idea and approach** The objectives of the application must be SMART (specific, measurable, assigned, realistic, time-bound) and must demonstrate a clear vision from the defined start to finish. it should contribute to the advancement of the respective field. The use of services needs to suit the objectives and support the path towards market deployment. Regulatory and certification strategy aspects should be addressed.	Range 0-5
4	**Quality and efficiency of the implementation** Coherence and effectiveness of the work plan, including extent to which the resources assigned to work are in line with their objectives. Appropriateness of the procedures, including risk and innovation management.	Range 0-5
5	**Feasibility to carry out within SAFE-N-MEDTECH OITB** It is highly recommended that each proposal already identifies which support is needed from the SAFE-N-MEDTECH project. The features of the medical device specified in the proposal fit with SAFE-N-MEDTECH and can be tested afterwards in the OITB. The institutions are sufficiently equipped to carry out the proposed activities.	Range 0-5

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Except for criteria 1, the scores must be in the range 0-5, with the following interpretation:

- **0 – Not addressed at all:** The proposal fails to address the criterion under examination or cannot be judged due to missing or incomplete information.
- **1 – Poor:** The criterion is addressed in an inadequate manner, or there are serious inherent weaknesses. Some indication given but rarely explained and unclear.
- **2 – Fair:** While the proposal broadly addresses the criterion, there are significant weaknesses;
- **3 – Good:** The proposal addresses the criterion well, although improvements would be necessary
- **4 – Very good:** The proposal addresses the criterion very well, although certain improvements are still possible. Indication on the criteria is given and some additional aspects are introduced.
- **5 – Excellent:** The proposal successfully addresses all relevant aspects of the criterion in question. It goes beyond what has been requested and has the potential to produce inspiring new results.

4.4 Consensus and Communication

The applications will be ranked according to the overall score in descending order and each Evaluation Committee will decide by consensus and based on the ranking results of the two-stage evaluation, being a joint decision for or against the proposal. The results will be submitted to the Project Management Committee for review and decision.

All proposals will receive a short evaluation summary report either accompanied with a rejection letter or an invitation to start the contract signature process.

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4.5 Other

All proposals and related data, knowledge and documents are treated in confidence. The assigned evaluators of each Evaluation Committee will sign a non-conflict and confidentiality agreement, to avoid any conflict of interest.

5. Contacts

In order to get additional support during the preparation of the proposal, such as further clarification on the type of support, feedback on certain aspects of a proposal, applicants are strongly encouraged to contact the SAFE-N-MEDTECH Open Call Communication Department at communication@cebr.net.

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