Call for enterprises for funding the development, performance evaluation, clinical evaluation of innovative medical devices

The Medical Research Agency plans to announce on 30 March 2022 a Competition for companies to finance the development, performance evaluation, clinical evaluation of innovative medical devices (ABM/2022/2). It will be possible to submit Applications for Projects at various stages of development - both those at the idea stage and Projects requiring only development work, for example.

Planned deadline for submission of applications

30th March 2022 - 30 June 2022.

Manner of application submission

Applications can be submitted via the ABM ICT system, filling in the application form in English.

Allocation for the competition

PLN 100 million

Minimum project value

3 million PLN

Maximum value of a Project

None.

Applicants

Applications under the Call for Proposals may be submitted both by independent enterprises, as single-entity Applicants, and by Consortia, where the Leader of the Consortium must be an enterprise and the remaining members may be entities referred to in Article 17(1) of the Act of 21 February 2019 on the Medical Research Agency (among others, scientific institutions and medical entities).

Subject of the competition

Financial support of the Agency is planned for R&D works concerning Projects requiring performance evaluation in cooperation with a certified notified body:

medical devices of classes IIa, IIb, III

or

in vitro diagnostic medical devices of classes B, C, D.

One Application may concern only one medical device or medical device for in vitro diagnostics. It is allowed to carry out Projects for development of Devices together with their equipment.

The subject of one Application cannot be systems or kits or

medical devices containing, as an integral part, a substance having an essential action or ancillary to that of the device, which, if used separately, would be considered a medicinal product,
medical devices intended to administer medicinal products and medicinal products, where they are placed on the market in such a way that they form a single product which constitutes an integral whole and is intended exclusively for use in a given combination and is non-reusable
medical devices that incorporate, as an integral part, non-viable tissues or cells of human origin or derivatives thereof which are intended to be used principally or ancillary to the function of the device,
product groups with no intended medical use (in accordance with Annex XVI to the Commission Regulation (EU) No 651/2014 of 17 June 2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty (Official Journal of the European Union L-187/1 of 26.06.2014 as amended).
Scope of co-financing

Co-financing is provided for:

- basic research,
- industrial research
- development works.

Additionally, enterprises from the SME sector can apply for co-financing of consultancy services.

The intensity of co-financing for particular entities for particular type of works in the Project results from the regulations on the rules of granting public aid.

Requirement to commercialize the Product

Regardless of the initial phase the Project is at, it has to end with implementation of the product into mass production within the framework of

the Beneficiary's own business activity
or
as part of a third party's business activity (granting a licence to a third party by the Beneficiary or sale of rights to a third party by the Beneficiary).
The commercialisation process (including fees related to the process of conformity testing and obtaining a CE conformity certificate) shall not be financed by the Agency.

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