Annex no. 1 to the Regulation of the Call

Template of the Grant Application

GRANT APPLICATION FORM FOR PROJECT TYPE: RESEARCH EXPERIMENTS

Tab: Application Details

Implementation under	Open call for research experiments
Recruitment symbol	EB26
Recruitment No.	ABM/2026/3
Application Number	
Application submission date	
Project title	
Applicant	
Project type	Research experiment

Planned period of implementation of the Project	Note: The project must start in between September 1, 2027 and November 2, 2027. In addition, the following rules must be taken into account: • the minimum duration of the Project is 3 years (36 months); the maximum duration of the Project is 5 years (60 months).
Start of Project implementation	
End of Project implementation	
Consortium Members	
Principal Investigator/ Head of Research Experiment/ R&D Manager/ Project Manager	
Application status	

Tab I.A Single Applicant/Consortium Leader

Research experiment entity (Applicant/Consortium Leader)	
Type of the Single Applicant/Consortium Leader	Mandatory field, single choice from among the following values: 1. Entity as defined in Article 7(1)(1–6) and (8) of the Act of 20 July 2018 – Law on Higher Education and Science;

	2. The Centre of Postgraduate Medical Education (pl. Centrum Medycznego Kształcenia Podyplomowego), referred to in the Polish Act of 13th September 2018 on the Centre of Postgraduate Medical Education; 3. Entity for which the constituent entity is: a public medical university or a university conducting teaching and research activities in the field of medical sciences, or the Centre of Postgraduate Medical Education; 4. The following entities performing Scientific Research and Experimental Development. a) an organisational unit with legal personality and registered office in the territory of the Republic of Poland. Next to the field, under the "i" icon, there is a hint: **1) entity referred to in Article 7(1)(1-6; 8) of the Polish Act of 20 July 2018 on higher education and science;** higher education institutions; federations of entities of the higher education system and science; the Polish Academy of Sciences acting on the basis of the Act of 30 April 2010 on the Polish Academy of Sciences, hereinafter referred to as "PAN"; scientific institutes of the PAN operating under the Act on the PAN; research institutes, operating under the Act of 30 April 2010 on research institutes; international scientific institutes established on the basis of separate acts and operating on the territory of the Republic of Poland; other entities conducting mainly scientific activities on an independent and continuous basis.

Single Applicant/Consortium Leader Full Name	
Field for specifying another name	
NIP (Tax Identification Number)	
REGON (National Business Registry No.)	
KRS (National Court Register) number	
Legal form	
Website address	
E-mail address for correspondence	
Address of the e-Delivery box	
Address	
Country	
Street	
Building No.	
Apartment No.	
Postal code	
Town / City	

Municipality	
District	
Voivodeship	
Person authorised to make binding decisions and submit an Application It is necessary to indicate in accordance with the act stating the election of the Rector, on the basis of the National Court Register or another equivalent document.	
Mr. / Ms.	
First name	
Last name	
Position	
Phone	
E-mail address	
Person authorised to working contacts	

Is this a person indicated as entitled to make a binding decision and submit the Application?	Mandatory field, single-select from the values: Yes/No.
Mr. / Ms.	
First name	
Last name	
Position	
Phone	
E-mail address	
Person authorised to represent the Applicant If the Person authorized to represent the Applicant acts on behalf of the Person authorized to make a binding decision and submit the Application by signing the documentation submitted with the Grant Application, the relevant power of attorney signed with a qualified electronic signature (compliant with the eIDAS Regulation (EU) No 910/2014; with the use of a graphic symbol) by the Person authorized to make a binding decision and submit the Application should be attached.	
Is this a person indicated as entitled to make a binding decision and submit the Application?	Mandatory field, single-select from the values: Yes/No.

Mr. / Ms.	
First name	
Last name	
Position	
Phone	
E-mail address	

The Applicant's revenues for the previous financial year	
Value (in PLN)	
Year	

Total number of full-time employees (number of persons employed in the previous year)	
Value	

Year	

Total number of employees employed under civil law contracts (number of persons employed in the previous year)	
Value	
Year	

Applicant's potential

Scientific potential

The scientific potential of the entity in the field of conducted commercial and non-commercial clinical trials and Research experiments (m.in. the number of people with the definition of scientific degrees with experience in conducting Cinical trials or Research experiments, the number of studies conducted should be carried out with a division into commercial, non-commercial and Research experiments) In the case of clinical trials, projects verified on the basis of publicly available clinical trial databases should be taken into account (e.g. clinicaltrials.gov, EudraCT), including a description of key Cinical trials and Research experiments on similar topics.

Text field, mandatory, max. 3,000 characters

The potential of the entity responsible for the implementation of the Project – in relation to its technical, financial and administrative capacity

Owning an institutional capacity

The Applicant has the resources to perform the tasks under the Project, i.e. appropriate technical and personnel resources necessary for the proper implementation of the requested Project.

Text field, mandatory, max. 1,700 characters

Financial potential

The financial capacity of the entity responsible for the implementation of the Project, including confirmation of the entity's financial ability demonstrating that, irrespective of other undertakings it carries out, it possesses the resources necessary to ensure the financial liquidity required for the proper execution of the Project and the sustainability of its results. The description should also include information regarding the entity's current financial liabilities.

Text field, mandatory, max. 1,700 characters

Administrative potential

Administrative potential (at least the Applicant's ability to implement projects financed from public funds or other funds should be confirmed by indicating which projects were implemented by the Applicant with the use of public funds. Please indicate whether the Applicant has implemented Standard Operating Procedures or has a specialised unit handling external projects, etc.).

Text field, mandatory, max. 1,700 characters

Declaration of eligibility of the tax on goods and services

3 selection options (1 out of 3 options must be selected, it is not possible to select more than 1 option):

1. In connection with the implementation of the Project entitled [title of the Project] financed by the Medical Research Agency, [name of the entity submitting the Declaration] represents that by implementing the above Project it has the legal possibility to recover the cost of tax on goods and services, the amount of which has not been included in the Project budget and also undertakes to make available financial and accounting documentation and to provide authorised control bodies with information enabling verification of the eligibility of the tax on goods and services.
2. In connection with the implementation of the Project entitled [title of the Project] financed by the Medical Research Agency, [name of the entity submitting the Declaration] represents that by implementing the above Project, it has the legal possibility to recover a part of the cost of tax on goods and services, the amount of which has not been included in the Project budgetand undertakes to return the part of the tax on goods and services reimbursed under the Project entitled [title of the Project], if within 5 years after the completion of the Project there are premises enabling the recovery of this tax [1] by [name of the entity

submitting the Declaration] [2] within the time limit not longer than 90 days from the date of submission of the VAT declaration [3]. At the same time, [name of the entity submitting the Declaration] undertakes to inform the Medical Research Agency about a change in the VAT tax status during the Project implementation period and for 5 years after its completion, if this will affect the legal possibility of recovering the VAT settled under the Project. [Name of the entity submitting the Declaration] also undertakes to make available financial and accounting documentation and to provide authorised control bodies with information enabling verification of the eligibility of the tax on goods and services.

3. In connection with the implementation of the Project entitled [title of the Project] financed by the Medical Research Agency, [name of the entity submitting the Declaration] represents that by implementing the above Project it does not have the legal possibility to recover the cost of tax on goods and services, the amount of which has been included in the Project budgetand undertakes to return the part of the tax on goods and services reimbursed under the Project entitled [title of the Project], if within 5 years after the completion of the Project there are premises enabling the recovery of this tax [1] by [name of the entity submitting the Declaration] [2] within the time limit not longer than 90 days from the date of submission of the VAT declaration [3]. At the same time, [name of the entity submitting the Declaration] undertakes to inform the Medical Research Agency about a change in the VAT tax status during the Project implementation period and for 5 years after its completion, if this will affect the legal possibility of recovering the VAT settled under the Project. [Name of the entity submitting the Declaration] also undertakes to make available financial and accounting documentation and to provide authorised control bodies with information enabling verification of the eligibility of the tax on goods and services.

Footnotes:

1 - Cf. Article 91(7) of the Act of 11 March 2004 on Tax on Goods and Services

2 - Article 86(13) of the Act of 11 March 2004 on Tax on Goods and Services

"If the taxpayer has not reduced the amount of tax due by the amount of input tax within the deadlines referred to in paragraphs 10, 10d, 10e and 11, he may reduce the amount of tax due by correcting the tax return:

1) for the period in which the right to reduce the tax due arose, or
2) for one of the three subsequent settlement periods, and in the case of the taxpayer referred to in Article 99, paragraphs 2 and 3, for one of the two subsequent settlement periods, after the settlement period in which the right to reduce the tax due arose
- but no later than within 5 years from the beginning of the year in which the right to reduce the tax due arose."

3 - This is applicable to VAT declaration, which shows the amount of input tax on the purchase of goods and services incurred as part of the granted co-financing.

Tab I.B Consortium Members

Consortium Members The maximum number of Consortium Members in the project = 3.	
Consortium Member	
No.	
Type of Consortium Member	Mandatory, single-selection field. Options: 1. Entity as defined in Article 7(1)(1–6) and (8) of the Act of 20 July 2018 – Law on Higher Education and Science; 2. The Centre of Postgraduate Medical Education (pl. Centrum Medycznego Kształcenia Podyplomowego), referred to in the Polish Act of 13th September 2018 on the Centre of Postgraduate Medical Education; 3. Entity for which the constituent entity is: a public medical university or a university conducting teaching and research activities in the field of medical sciences, or the Centre of Postgraduate Medical Education; 4. The following entities performing Scientific Research and Experimental Development. a) an organisational unit with legal personality and registered office in the territory of the Republic of Poland. Hint next to the field (icon "i"): **1. Entity as defined in Article 7(1)(1–6) and (8) of the Act of 20 July 2018 – Law on Higher Education and Science**

	universities, federations of entities in the higher education and science system, the Polish Academy of Sciences (PAN) operating under the Act of 30 April 2010 on the Polish Academy of Sciences, PAN research institutes operating under the Act on PAN, research institutes operating under the Act of 30 April 2010 on Research Institutes, international research institutes established under separate acts and operating on the territory of the Republic of Poland, other entities conducting mainly scientific activities independently and continuously.	
Full Name of the Consortium Member		
Field for specifying another name		
NIP (Tax Identification Number)		
REGON (National Business Registry No.)		
KRS (National Court Register) number		
Legal form		

Website address	
E-mail address for correspondence	
Address of the e-Delivery box	
Address	
Country	
Street	
Building No.	
Apartment No.	
Postal code	
Town / City	
Municipality	
District	

Voivodeship	
Person authorised to make binding decisions and submit an Application It is necessary to indicate in accordance with the act stating the election of the Rector, on the basis of the National Court Register or another equivalent document.	
Mr. / Ms.	
First name	
Last name	
Position	
Phone	
E-mail address	
Person authorised to represent the Applicant If the Person authorized to represent the Applicant acts on behalf of the Person authorized to make a binding decision and submit the Application by signing the documentation submitted with the Grant Application, the relevant power of attorney signed with a qualified electronic signature (compliant with the eIDAS Regulation (EU) No 910/2014; with the use of a graphic symbol) by the Person authorized to make a binding decision should be attached.	

Is this a person indicated as entitled to make a binding decision?	Mandatory field, single-select from the values: Yes/No.
Mr. / Ms.	
First name	
Last name	
Position	
Phone	
E-mail address	

Description of the consortium members scientific potential and justification for its participation in the project

Text field, mandatory, min. 1000, max. 5000 characters.

Declaration of eligibility of the tax on goods and services

3 selection options (1 out of 3 options must be selected, it is not possible to select more than 1 option):

1. In connection with the implementation of the Project entitled [title of the Project] financed by the Medical Research Agency, [name of the entity submitting the Declaration] represents that by implementing the above Project it has the legal possibility to recover the cost of tax on goods and services, the amount of which has not been included in the Project budget and also

undertakes to make available financial and accounting documentation and to provide authorised control bodies with information enabling verification of the eligibility of the tax on goods and services.

2. In connection with the implementation of the Project entitled [title of the Project] financed by the Medical Research Agency, [name of the entity submitting the Declaration] represents that by implementing the above Project, it has the legal possibility to recover a part of the cost of tax on goods and services, the amount of which has not been included in the Project budget and undertakes to return the part of the tax on goods and services reimbursed under the Project entitled [title of the Project], if within 5 years after the completion of the Project there are premises enabling the recovery of this tax [4] by [name of the entity submitting the Declaration] [5] within the time limit not longer than 90 days from the date of submission of the VAT declaration [6]. At the same time, [name of the entity submitting the Declaration] undertakes to inform the Medical Research Agency about a change in the VAT tax status during the Project implementation period and for 5 years after its completion, if this will affect the legal possibility of recovering the VAT settled under the Project. [Name of the entity submitting the Declaration] also undertakes to make available financial and accounting documentation and to provide authorised control bodies with information enabling verification of the eligibility of the tax on goods and services.
3. In connection with the implementation of the Project entitled [title of the Project] financed by the Medical Research Agency, [name of the entity submitting the Declaration] represents that by implementing the above Project it does not have the legal possibility to recover the cost of tax on goods and services, the amount of which has been included in the Project budget and undertakes to return the part of the tax on goods and services reimbursed under the Project entitled [title of the Project], if within 5 years after the completion of the Project there are premises enabling the recovery of this tax [4] by [name of the entity submitting the Declaration] [5] within the time limit not longer than 90 days from the date of submission of the VAT declaration [6]. At the same time, [name of the entity submitting the Declaration] undertakes to inform the Medical Research Agency about a change in the VAT tax status during the Project implementation period and for 5 years after its completion, if this will affect the legal possibility of recovering the VAT settled under the Project. [Name of the entity submitting the Declaration] also undertakes to make available financial and accounting documentation and to provide authorised control bodies with information enabling verification of the eligibility of the tax on goods and services.

Footnotes:

1 - Cf. Article 91(7) of the Act of 11 March 2004 on Tax on Goods and Services

2 - Article 86(13) of the Act of 11 March 2004 on Tax on Goods and Services, “If the taxpayer has not reduced the amount of tax due by the amount of input tax within the deadlines referred to in paragraphs 10, 10d, 10e and 11, he may reduce the amount of tax due by correcting the tax return:

1. for the period in which the right to reduce the tax due arose, or
2. for one of the three subsequent settlement periods, and in the case of the taxpayer referred to in Article 99, paragraphs 2 and 3, for one of the two subsequent settlement periods, after the settlement period in which the right to reduce the tax due arose
   - but no later than within 5 years from the beginning of the year in which the right to reduce the tax due arose.”

3 - This is applicable to VAT declaration, which shows the amount of input tax on the purchase of goods and services incurred as part of the granted co-financing.

Tab I.C. Principal Investigator/ Head of Research Experiment/ R&D Manager/ Project Manager

Head of Research Experiment - details of the Head of Research Experiment (first and last name only)

Head of Research Experiment	First name	Last name
	Text field, required, max. 50 characters	Text field, required, max. 50 characters

The data of the **Head of Research Experiment** such as his/her name and surname are public information.

Academic Title/ Academic Degree

Text field, mandatory, max. 50 characters Pursuant to the terms of the call, a PhD degree is required

Education

Text field, mandatory, max. 450 characters

Number of the Licence to practice

Text field, mandatory, max. 50 characters

Contribution to the proposed project

Text field, mandatory, max. 500 characters Please specify: Nature of contribution to the project, scope of work, Amount and length of involvement in individual tasks

Professional work experience in the conducting of clinical trials (commercial and non-commercial) in the area covered in the Project

No	Project Title	Clinical Trial Number	**Project duration**			Entity conducting Project	Role in the Project	**Period of Clinical Trial Involvement**		
			From	Ongoing?	To			From	Ongoing?	To

Date of last current GCP E6 (R3) training (max. 1 year prior to submission of Application)

Date of last current GCP E6 (R3) (max. 1 year prior to submission of Application) *(YYYY/MM/DD)* Mandatory field.	**Institution issuing the GCP E6 (R3) certification** Text field, mandatory, max. 100 characters

Current involvement in other projects (not only in publicly financed Projects)

No.	Project Title	**Project duration**			Entity conducting Project	Role in the Project	Time commitment per FTE, (e.g. 0.5 FTE)
		From	Ongoing?	To			

Key publications of Head of Research Experiment in the field of applied Project

Text field, mandatory, max. 10 000 characters Please prove the list of 1-10 most important papers published or accepted for publication in the proposal submission year or over the period of 10 years prior to the proposal submission year. 1 to 3 most important papers presented above may be attached as PDF files in section 'Attachments'.

Employment

No.	**Employment Period**			Employing Entity	Occupied position	Time commitment per FTE, (e.g. 0,5 FTE)	Type of contract
	From	Curently ongoing?	To				

Tab II.A. Project – general data

General data

Project title

Title of the Project - enter the title of the Project, which should reflect its idea/purpose. Formulate a precise and medically valid purpose of the Research experiment (in the form of statements related to clear, concise, scientifically correct clinical questions).

Text field, min. 10 characters, max. 500 characters, mandatory field

Project type

Non-editable field. The value is loaded from the “Project type” field in the “Application Details” tab.

Population

Mandatory field, selection list: adult/pediatric/mixed

Keywords (in Polish)

Please provide between 3 and 10 keywords describing the subject of the Project, separated by commas. Each keyword should be consistent with the MeSH (Medical Subject Headings) terminology.

Keywords (in Polish language)

Mandatory field, text field, max. 1000 characters Keywords should comply with the MeSH classification.

Keywords (in English)

Please provide between 3 and 10 keywords describing the subject of the Project, separated by commas. Each keyword should be consistent with the MeSH (Medical Subject Headings) terminology.

Mandatory field, text field, max 1000 characters. Keywords should comply with the MeSH classification.

Project classification

It is possible to select more than 1 Category. Be sure to select all Categories covered by the Project. It is possible to select the same Category and Subcategory multiple times.

Category

Single-choice field, mandatory

Subcategory

Single-choice field, mandatory

Sub-Subcategory

Single-choice field, mandatory

Summary of the Project (in Polish)

The Summary should not include details of the Research experiment, e.g., research experiment participant inclusion/exclusion criteria, details of the procedures performed.

Summary of the Project (in Polish)

Text field, min. 1,000, max. 3,000 characters, mandatory field The Project Summary is subject to public disclosure.

Summary of the Project (in English)

The Summary should not include details of the Research experiment, e.g., research experiment participant inclusion/exclusion criteria, details of the procedures performed.

Summary of the Project (in English)

Text field, min. 1,000, max. 3,000 characters, mandatory field The Project Summary is subject to public disclosure.

Will the Applicant use the electronic Case Report Form (eCRF) made available by the Agency as part of the Project implementation?

If the Applicant marks the answer 'YES', they will be obliged, in the case of receiving a grant recommendation, to sign the Entrustment Agreement constituting an annex to the Co-financing Agreement.

Mandatory field, selection list: YES / NO

Is the Project submitted to the MRA again?

Mandatory field, selection list: YES / NO If YES is selected, an icon with a plus sign appears and it is necessary to provide a minimum of 1 and a maximum of 10 records. Each record is a pair of fields: - No. of the call in which the Project was previously submitted selection list: ABM/2019/1 ABM/2020/1

ABM/2021/1

ABM/2021/2

ABM/2021/3

ABM/2022/1

ABM/2022/3

ABM/2023/1

ABM/2024/1

ABM/2024/2

ABM/2025/1

ABM/2025/2

ABM/2026/2

- No. of the previously submitted Application

Does the subject matter of the Project coincide with other research tasks carried out by the Applicant?

Selectable values: YES/NO, mandatory field

Description of tasks associated with other Projects

Text field, max. 2,000 characters, mandatory field

Territorial scope

In this item, information on the scope of the proposed intervention should be specified – whether it will include a strategy on a national or global scale.

Mandatory field, text field, Min. 200, Max 1000 characters

Tab II.B. Project – the substantive part

Substantive part

Identification data of the Research experiment

ICD-9 code for the key procedure(s) used and covered by the subject matter of the Project. ICD-9 codes are chosen from a selection list.

Please indicate the ICD-9 code corresponding to the key medical procedure addressed by the Project. The code must be taken from the official ICD-9 list published on the website of the National Health Fund (NFZ): https://www.nfz.gov.pl/dla-swiadczeniodawcy/slowniki/pliki-icd-9-pl/, as of the date the Call for proposals was announced.

Code number	
Code name	

Analysis of the research problem

Health problem

Please specify:

- Aetiology and pathogenesis of the disease entity
- Clinical picture, natural course, complications and prognosis
- Epidemiology and disease burden

Health problem

Text field, min. 1000, max. 15,000 characters, mandatory field

Does the health problem concern rare diseases?

Mandatory field, dropdown list with YES/NO options

ORPHAcode

Text field, Min. 1 character, Max. 50 characters Hint: The Applicant is required to provide a valid ORPHAcode in the Application.

Arms of the study

Arm No. 1 - please specify the planned procedure

Mandatory text field max. 200 characters

Description of the scientific value of the Project (please refer to the Regulations)

Description of the scientific value of the Project

Text field, mandatory, min. 1000, max. 5,000 characters A detailed description of the issues assessed in the specific criteria is included in the Annexes to the Call Regulations – the Substantive Evaluation Sheet and the Panel Evaluation Sheet.

Description of the Research experiment according to the PICOS (population, intervention, comparison, outcome, study design) scheme:

P - population in which the intervention will be used

A detailed description of the target population must be provided, including the justification for its selection, an estimation of the sample size (described in a manner that allows verification of the calculations), and the inclusion and exclusion criteria for participants

in the Research experiment. An estimated recruitment rate must be presented based on at least three published sources concerning the same disease entity or a similar intervention, a comparable population, or analogous research activities. The sources used should include information enabling an assessment of recruitment feasibility, particularly regarding population size, recruitment period, number of participants, or number of study sites. The data sources should be indicated in a manner that allows their identification and verification (e.g., scientific publication, entry in a public clinical trial registry, study protocol, or another publicly available document). If no published data are available, an alternative basis for estimating the recruitment rate should be described, such as data from disease registries, healthcare service databases, experience from previous projects, analyses of the number of patients treated at the study site, or other reliable data sources.

Text field, min. 1000, max. 35,000 characters, mandatory field

I –proposed intervention

Please specify: A description of the proposed intervention, the ICD-9 code for the key procedure(s) used that are related to the subject matter of the Project in accordance with the Identification data of the Research experiment field, and the characteristics of the procedures to which the study participants will be subjected.

Text field, mandatory, min. 1000, max. 10,000 characters

Statements regarding the use of Medical devices and *in vitro* diagnostic Medical devices

Does the planned intervention involve the use of a Medical device or an *in vitro* diagnostic Medical device (e.g. algorithm, software, tool, apparatus) including those that are intended to support a medical decision, including a specialist's decision, that may have consequences for the health and/or life of the participant? (Does not apply to products routinely used in standard care, such as syringes, test tubes or infusion sets.)

☐ YES
☐ NO

Medical devices and *in vitro* diagnostic medical devices”

Question	Field type
Trade name and type of Medical device/*in vitro* diagnostic Medical device.	Text field
T**he product has a valid certificate of conformity issued by a notified body or an EU declaration of conformity**.	YES / NO
T**he use of the Medical device in the Research experiment consistent with its intended use as specified in the Instructions for Use (IFU)?**	YES / NO
The purpose of the project is to test, evaluate performance, validate or calibrate a product.	YES / NO
T**he results obtained after the Project completion are planned to be used to obtain CE marking, register a Medical device or an *in vitro* diagnostic Medical device in the Office for Registration of Medicinal Products, or in the commercialization process**. **Commercialization is understood as activities aimed at introducing a product to the market, including, among others, preparation for sale, acquiring an investor, licensing, validating the product in market conditions or developing a marketing strategy.**	YES / NO

Content of the declaration:

☐ I declare that no Medical device has been included in the planned Project or that the Medical device/*in vitro* diagnostic Medical device included in the Project has an EU declaration of conformity (is marked with the CE mark) and/or has a valid certificate of conformity issued by a notified body. In the event that a Medical device/*in vitro* diagnostic Medical device is included in the study, it is placed on the market and used within the Project in accordance with the current standard of therapy. At the same time, the planned Project is not intended to assess the safety or effectiveness of the Medical device/*in vitro* diagnostic Medical device.

Description of the intervention used in the Project

The Applicant is obliged to demonstrate that the intervention indicated in the section Description of the study according to the PICOS scheme (population, intervention, comparison, outcome, study design), in the field 'I – proposed intervention', does not meet the criteria for classifying the Project as a clinical investigation of a Medical Device within the meaning of the applicable legal provisions [4].

The explanations submitted may not consist solely of a declaration; they must demonstrate that, in accordance with the applicable regulations, the Project will not be considered a clinical investigation of a Medical Device, including a clinical investigation of a Device such as software supporting a physician's decision-making, nor of an In Vitro Diagnostic Medical Device.

The justification in this respect must be detailed and comprehensive, and must take into account all relevant legal regulations. The information provided by the Applicant will be subject to verification by the Agency, including at the stage of the formal assessment of the application.

Text field, mandatory, min. 1000, max. 10,000 characters The inclusion in the Project of a Medical device or a Medical device in in vitro diagnostics without a certificate of conformity or an EU declaration of conformity contra to its intended use results in a negative formal assessment under criterion 14 (Does the project concern an investigational experiment?)"

Footnotes:

4 - Medical device – within the meaning of Article 2. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC is a tool, apparatus, device, software, implant, reagent, material or other article intended by the manufacturer to be used, individually or in combination, in humans for one or more of the following specific medical applications:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or mitigation of the disease,
- diagnosing, monitoring, treating, mitigating or compensating for an injury or disability;
- Study, replacement or modification of an anatomical structure or process or physiological or disease state.
- the provision of information by in vitro testing of samples taken from the human body, including those taken from donors of organs, blood and tissues, and which does not achieve its essential intended effect by pharmacological, immunological or metabolic agents in or on the human body, but whose action may be aided by such agents.

A medical device for in vitro diagnostics – within the meaning of Article 2 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on medical devices for in vitro diagnostics and repealing Directive 98/79/EC and Commission

Decision 2010/227/EU, is a medical device that is a reagent, reagent product, calibrator, control material, kit, tool, instrument, equipment, software or system, used singly or in combination, intended by the manufacturer for in vitro use for the examination of samples taken from the human body, including blood and tissues collected from donors, solely or principally for the purpose of providing information:

(a) a physiological or disease process or condition;

(b) with a congenital physical or mental developmental defect;

(c) predisposed to a disease or disease;

(d) to determine safety and compliance with potential recipients;

(e) to predict responses or responses to treatment or

(f) to identify or monitor therapeutic activities.

C – proposed comparators (comparative technologies)

The following should be specified: a description of the comparator, the rationale for its selection, the time and method of administration/application of the comparator, or a justification in the absence of a comparator in the Research experiment.

Text field, mandatory, min. 1000, max. 5,000 characters In this Call of proposals, only Research experiments with two arms (intervention and control/comparison) are possible, in accordance with the requirement of formal criterion. An exception are projects concerning only Research experiment participants with rare diseases (according to www.orpha.net), where a control/comparison group is not required.

O – health effects

Please specify: endpoints including primary and secondary, with rationale for their selection and the adopted methodology for their assessment, clinical significance of the main endpoints with justification.

Text field, mandatory, min. 1000, max. 5,000 characters

S – type of proposed Research experiment

Please specify: The type of proposed Research experiment along with a description (if applicable) of randomization and allocation of patients to groups, blinding concept for statistical analysis of data, and duration of the Research experiment (in months), with the indication of the patient's participation time in the study, including the maximum treatment period and the patient's observation period and conditions of early termination of the Research experiment.

Text field, mandatory, min. 1000, max. 7,000 characters

Has participant randomization been applied in the project?

☐YES
☐ NO

The applicant should make sure that the above field have been filled in correctly **before moving on to completing the milestones.**

The number and names of the sites in which the Research experiment will be conducted along with a description of their technical potential (the number of sites, including equipment and personnel resources necessary for the implementation of the Project) owned by individual sites.

Moreover, the Applicant should demonstrate that they are able to implement the Project to the optimum degree. Please describe the key scientific and research personnel (indicate the academic title, name, surname) necessary for the proper implementation of the Project, along with their competencies. The Applicant should demonstrate whether they currently has adequate human resources to conduct the study or plan to employ additional personnel.

Text field, mandatory, max. 5,000 characters

Clinical analysis

Description of the current clinical knowledge in the field of the planned Research experiment (evidence-based medicine)

Identification of risks in the design of the Research experiment, e.g. scientific, legal, administrative, financial (description of the procedure for identifying, reporting and assessing patient safety in the trial.)

Text field, mandatory, min. 500, max. 3,000 characters

Ethical, social and legal aspects of the conducted Research experiment, as well as identification and determination of risks associated with research activities (project risks), with financial aspects and taking into account legal and administrative requirements

Text field, mandatory, min. 500, max. 3,000 characters

The Applicant's declaration that in the case of biobanking, it will take place in a biobank operating in accordance with the Quality Standards for Polish Biobanks v. 2.00[5]

[5] Quality Standards for Polish biobanks v. 2.00 (2021)
https://wydawnictwo.umw.edu.pl/upload/files/standardy_jakosci_dla_biobankow_polskich_2.0.pdf

In accordance with the provisions of the **Regulation** (**section on Banking of biological material**), if the Applicant plans to collect whole peripheral blood samples from patients in the Project, provided that the patient has given his/her informed and voluntary consent, the Applicant is obliged to submit one blood sample to the biobank (divided into 4 test tubes / vials). The quantity of the collected biological material should enable sequencing of the genome of the sample donor.

Text field, mandatory, min. 11 characters, max. 1,000 characters

Description of the impact of the Project on improving the health of citizens, including (please refer to the provisions of the Regulation):

- Saving life and achieving full recovery and/or Saving life and achieving health improvement
- Preventing premature death;
- Improving the quality of life.

Text field, mandatory, min. 500, max. 1 000 characters

A detailed description of the issues assessed in the specific criteria is included in the Annexes to the Call Regulations – the Substantive Evaluation Sheet and the Panel Evaluation Sheet.

Description of the innovativeness of the Project (please refer to the Regulations).

Description of the innovativeness of the Project

Text field, mandatory, min. 1000, max. 2,000 characters A detailed description of the issues assessed in the specific criteria is included in the Annexes to the Call Regulations – the Substantive Evaluation Sheet and the Panel Evaluation Sheet.

Description of the anticipated economic effects (please refer to the provisions of the Regulation).

Text field, mandatory, min. 1000, max. 5,000 characters A detailed description of the issues assessed in the specific criteria is included in the Annexes to the Call Regulations – the Substantive Evaluation Sheet and the Panel Evaluation Sheet.

Description of the possibility of applying the results of the Project in the healthcare system (please refer to the provisions of the Regulation).

Text field, mandatory, min. 1000, max. 9,000 characters A detailed description of the issues assessed in the specific criteria is included in the Annexes to the Call Regulations – the Substantive Evaluation Sheet and the Panel Evaluation Sheet.

Possession by the Applicant of material resources necessary for the implementation of the Project (please refer to the provisions of the Regulation).

Text field, mandatory, min. 2 500, max. 7,500 characters A detailed description of the issues assessed in the specific criteria is included in the Annexes to the Call Regulations – the Substantive Evaluation Sheet and the Panel Evaluation Sheet.

Possession by the Applicant of human resources necessary for the implementation of the Project (please refer to the provisions of the Regulation).

Text field, mandatory, min. 2 500, max. 7,500 characters A detailed description of the issues assessed in the specific criteria is included in the Annexes to the Call Regulations – the Substantive Evaluation Sheet and the Panel Evaluation Sheet.

Bonus criteria specific to the Call

Text field, not mandatory, max. 5,000 characters A detailed description of the issues assessed in the bonus criteria is included in the Annexes to the Call Regulations – the Substantive Evaluation Sheet and the Panel Evaluation Sheet.

Indicators

Number of validated innovative therapeutic developed within Research experiment

Text field, mandatory, it is possible to enter an integer greater than 0 (at least 1).

Number of participants included in Research experiment

Text field, mandatory, it is possible to enter an integer greater than 0 (at least 1).

Number of Research experiments initiated in Poland in line with regulatory requirements

Text field, mandatory, it is only possible to enter an integer equal to 1.

Number of sites involved in the implementation of Research experiments under the Project

Text field, mandatory, it is only possible to enter an integer equal to 1.

Please provide the total number of all sites involved in conducting the study, including the Applicant. The applicant should make sure that the filed below have filled in correctly before moving on to completing the milestones”

Number of biobanked biological material samples for the purposes of the Medical Research Agency (ABM)

The total number (greater than 0) should be entered if the Applicant has planned to collect biological material. The data provided in the indicator should be consistent with the description provided in part II. B of the Application in the field “The Applicant’s declaration that in the case of biobanking, it will take place in a biobank operating in accordance with the Quality Standards for Polish Biobanks v. 2.00”, where the Applicant should describe the assumptions on the basis of which it estimated the number of biological material samples (reasons and estimates for the assumption of obtaining biological material samples from, for example, 50% of patients or 25% of patients should be indicated).

As an exception, it is permissible to indicate “zero” for the above indicator when the Applicant does not plan to collect any biological material, which is based on the assumptions of the Project.

Text field, mandatory, it is possible to enter an integer (including 0).

Number of publications with the results of Research experiment

Text field, mandatory, it is possible to enter an integer greater than 0 (at least 1).

Tab II.C. Project – implementation schedule

Planned project activities and the method of their implementation

In this section, please include the project activities. The obligatory tasks are already defined:

- Research experiment management
- Implementation of the clinical part

Up to 4 tasks can be added.

Each task should contain a defined, parameterised milestone. Reference should be made to the provisions in the Regulation. The milestones should be defined in such a way as to refer to the research issues undertaken at a given stage and allow for an objective assessment of the degree of achievement of the research objectives assumed at a given stage.

This module takes the form of a table that must be completed. It is necessary to add more items for each task separately.

Note: Entering changes in the fields:

• Indicators: Number of sites involved in the implementation of Research experiment under the Project

and

• S – type of proposed Research experiment: Has participant randomization been applied in the project?

may result in deletion of previously entered data in this section. The applicant should make sure that the above fields have been filled in correctly **before moving on to completing the milestones**. Otherwise, in the event of changes in the above fields - the data will be permanently lost.

No.	Task list	

	Task No. ...	
	Task name	Text field, mandatory, max. 1,000 characters. The following obligatory tasks are already specified and cannot be deleted. As regards the required order: if there is an option to use separate dictionaries of tasks, with separate numbering. In order: 1. Research experiment management 2. Implementation of the clinical part and the ability to add more, defined by yourself (up to 4, because the maximum is 6)
	Start of the task implementation period	
	End of the task implementation period	
	Name of the Applicant / Consortium Member responsible for the implementation of the task	

	Description of the task	max. 5,000 characters
	Milestones	Repeatable section.
	No.	Number for the milestone, completed automatically.

<table>
<tr>
<td>Name of the milestone</td>
<td>
<table>
<tr>
<td>For the task “Research experiment management”</td>
<td>Milestones are:
a) Preparation of the Research experiment protocol (Development of the Research experiment documentation);
b) Obtaining consents and approvals – obtaining a positive opinion from the Bioethics Committee regarding the Research experiment</td>
</tr>
<tr>
<td>For the task “Implementation of the clinical part”</td>
<td>Milestones are:
a) First Site Activation (FSA);
b) Activation of 50% of sites;
The milestone is considered achieved only after the required number of sites has been activated
c) Activation of the last site; 100% of sites activated (Last Site Activated, LSA);
d) First Patient Randomized (FPR);
e) Inclusion of 25% randomized participants;
f) Inclusion of 50% randomized participants;
g) Inclusion of 75% randomized participants;
h) Last Patient Randomized (LPR); 100% of randomized participants included;
i) Inclusion of the first participant;
j) Inclusion of 25% participants;</td>
</tr>
</table>
</td>
</tr>
</table>

		k) Inclusion of 50% participants; l) Inclusion of 75% participants; m) Inclusion of the last participant in the Research experiment; 100% of participants included; n) Database lock: completion of data entry, verification, and approval processes; o) Final analysis and submission of the final report on the Research experiment to the Medical Research Agency	
	For the remaining tasks (with names entered manually by the Editor)	In each task: possibility to add custom milestones (max. 2, at least 1 is mandatory)	
Date of reaching the milestone			

Implementation schedule

[quarter] / [year] or [year]	[quarter] / [year] or [year]	[quarter] / [year] or [year]	[quarter] / [year] or [year]	[quarter] / [year] or [year]	[quarter] / [year] or [year]	[quarter] / [year] or [year]	… etc., max. 12 columns
Task no. [task no.]: [task name]							

Milestone: [name of the milestone]							

Tab III. Detailed budget of the Project

Cost calculation in the Project
In this part of the Application, the planned costs should be specified for each previously defined task, taking into account the period of implementation of a given task. If a given task does not require costs, you can delete the entry for the task. If a given task involves more costs, you can add additional lines for the task. For the reported cost, please provide: • Cost name • Cost category • A description of the cost calculation method – please describe in detail how the calculation was made, e.g.: – For the "Remuneration" category, indicate the planned number of positions, the form of involvement, and the amount of remuneration, FTE or number of hours (if applicable, depending on the form of involvement) and period of involvement (number of months) - For the "Purchase of medical equipment, including research infrastructure" category, list the components of the kit (if applicable). • Total cost of the item (PLN) Please make sure that the planned expenses are justified in the presented schedule of activities/tasks in the Project. You can add up to 100 cost items.

Task budget	
Task no. [task number]: [task name]	
+	Subsection for each cost item in the task. + possibility to add subsection for each cost item in the task
No.	
Cost name	Text field, mandatory, max. 100 characters
Cost category	Mandatory field, single-choice. Selectable values: • Remunerations; • Drug; • Medical service; • Other; • Specialist services commissioned; • Insurance costs; • Medical device; • CRO involvement; • Purchase of medical equipment, including research infrastructure.
Institution to which the cost item is assigned (Applicant / Consortium Member)	Mandatory field. The field is visible if any Consortium Members have been added to the Application.

Description of the cost calculation method	Text field, mandatory, min. 300 characters, max. 3000 characters. Please describe in detail how a given cost was calculated, e.g.: • for the “Remuneration” category, indicate the planned number of positions, the form of involvement, and the amount of remuneration, FTE or number of hours (if applicable, depending on the form of involvement) and period of involvement (number of months) • for the “Purchase of medical equipment, including research infrastructure” category, list the components of the kit (if applicable). A summary of all costs reported in the costing must be the same as the total cost of the item.
Total cost of the item (PLN)	
Total cost of the task (PLN)	

The total budget of the Project by type of eligible cost	The table consists of the following columns: • Cost category – names of all cost categories. • Applicant (PLN) – total costs allocated to the Applicant for a given cost category from all tasks. The fields always presents 2 decimal places. • Consortium Member(s) (PLN) – total costs allocated to all Consortium Members for a given cost category from all tasks. The fields always presents 2 decimal places. • Total (PLN) – the sum of the “Applicant (PLN)” and “Consortium Member(s) (PLN)” values. The fields always presents 2 decimal places.

The total budget of the Project by task	The section contains the table presented below.

Task (according to tasks from the detailed budget of the Project)	Applicant (PLN)	Consortium Member(s) (PLN)	Total (PLN)
Task No. 1: [name of the task]			
Task No. 2: [name of the task]			
…. etc.			
		Total (PLN):	

Direct costs – actual (PLN)

Non-editable field, value calculated automatically.

It is the sum of all cost categories.

Indirect costs (PLN)

The flat-rate (%) of indirect costs

15%

Indirect costs (flat-rate)

Non-editable field containing an automatically calculated amount.

Total eligible costs of the Project (PLN)

Total eligible costs of the Project (PLN)

Non-editable field, value calculated automatically. It is the sum of all categories of costs as well as indirect costs and the incentive bonus. The Project does not have a defined minimum value. The maximum possible value of the Project – PLN 12 million

Amount of the co-financing

100%

Grant requested (PLN)

Grant requested (PLN)

Non-editable field, value calculated automatically.

<u>Tab IV. Attachments</u>

Mandatory attachments – to be attached in the form of a file with the format specified next to a given field

1. The Consortium Agreement in Polish - to a significant extent compliant with the template constituting Annex to the Regulations - signed with a qualified electronic signature by the Consortium Leader and the Consortium Members signed with a qualified electronic signature (Signature format in accordance with eIDAS Regulation (EU) No 910/2014) or certified in electronic form (qualified electronic signature in PAdES signature format using a graphic symbol) as a true copy of the original by a notary in accordance with Article 97(2) of the Act of 14th February 1991 – the Notarial Law - if applicable
2. A document confirming possession of an EU declaration of conformity or a certificate of conformity for the Medical device/*in vitro* diagnostic Medical device used in the Project (if applicable). Signature format compliant with the eIDAS Regulation (EU) No 910/2014; with the use of a graphic symbol

3. Document confirming the authorisation to represent the Single Applicant/Consortium Leader (if applicable) – signed with a qualified electronic signature (Signature format in accordance with eIDAS Regulation (EU) No 910/2014) by a person authorised to make a binding decision and submit the Application – e.g. power of attorney to represent the entity

Optional attachments – to be attached as a pdf file

4. Report on research and development (R&D) activities submitted to the Central Statistical Office (GUS) on form PNT-01 for 2025
5. A document confirming possession of an EU declaration of conformity or a certificate of conformity for the Medical device/in vitro diagnostic Medical device used in the Project
6. Key publications of Head of Research Experiment in the scope of the proposed Project
7. Documentation confirming active international scientific and network cooperation
8. Other formal documents; the content of these attachments will not be subject to substantive evaluation (maximum of 20).

Tab: V. Declarations

General Declarations	
I declare that the clinical trial planned under the Project include activities that:	
- require the use of human embryos;	YES/NO
- require the use of tissues or cells derived from human embryos or foetuses;	YES/NO
- require the use of human embryonic stem cells;	YES/NO
- require the use of human genetic material;	YES/NO
- require the use of commercially available human cells or tissues, other than those specified above;	YES/NO
- require the use of human biological samples obtained in the project or sourced from non-commercial origins;	YES/NO

- involve genetically modified organisms or the use of such organisms;	YES/NO
- are associated with research conducted in non-EU countries and may raise ethical concerns;	YES/NO
- include plans for the import or export of research materials to/from non-EU countries;	YES/NO
- involve the use or production of dual-use goods (e.g., pathogens, technologies) that require export authorisation in accordance with EU Regulation;	YES/NO
- have the potential to be a source of abuse, crimes, or terrorist attacks.	YES/NO

Declarations and Clauses

1. I am aware of the criminal liability for providing false data or submitting false statements.
2. I declare that the information contained in this Grant Application is true.
3. I declare that the Project complies with the relevant provisions of EU and national laws, including those concerning public procurement and public aid.
4. I am aware that the content of this Grant Application and its annexes may be made available to other institutions and experts performing assessment, evaluation and control, and I undertake to participate in evaluation studies aimed at evaluating the Project.
5. I declare that the Application submitted via the system constitutes a statement of intent by the Applicant, and the information contained therein, as well as in the documents attached to it, is factually and legally accurate.
6. I declare that:

- in the event of receiving funding for the implementation of the Project, the principle of prohibition of double funding will not be violated, meaning that it is prohibited to receive full or partial reimbursement of the same expense twice from public funds (EU or national);
- the tasks covered by the Application are not funded from other sources, and the Applicant is not seeking funding from other sources for these tasks.

7. I declare that no conflict of interest arises during the implementation of the Project, i.e.: Head of Research Experiment and persons substituting for them in their duties are not simultaneously performing any work on behalf of subcontractors. This includes no employment relationship or other form of cooperation with subcontractors (employment contracts, civil law agreements, or other forms of collaboration). Furthermore, other R&D staff and Project management staff do not perform the same tasks in the Project on behalf of both the Applicant and the subcontractor.

Single Applicant

1. I declare that I am entitled to represent the Applicant within the scope covered by the Application and to submit this Grant Application.
2. I declare that I do not receive or apply for financing of the tasks covered by the Application from public funds from other sources.
3. I declare that the institution applying for the grant is not in arrears with the payment of taxes, as well as with the payment of social and health insurance contributions, the Labor Fund, the State Fund for the Rehabilitation of the Disabled, or other charges required by separate regulations.
4. I declare that the entity applying for the grant is not subject to exclusion from the possibility of receiving funding, including the exclusion referred to in Article 207(4) of the Act of 27 August 2009 on public finances (Journal of Laws of 2025, items 1483, consolidated text).
5. I declare that I have read the Regulation and accept its terms in full, including the content of the Co-financing Agreement, which is attached as Appendix to the Regulation.
6. I declare that the Grant Application does not infringe the rights of third parties and that there are no legal obstacles to submitting the Application and implementing the Project in accordance with the Co-financing Application; in particular, I declare that no other agreements or contracts have been concluded that would prevent or limit the Applicant's participation in the Project covered by the Grant Application.
7. I declare that I have read the information clause ("Information clause for the Applicant") and undertake, on behalf of the Personal Data Controller (Medical Research Agency), to fulfill the information obligation towards persons whose data are contained in the Grant Application ("Information clause for natural persons indicated by the Applicant in the Application").
8. I declare that there are no court, administrative, enforcement, fiscal or penal-fiscal proceedings pending against the Applicant, the outcome of which could affect the implementation of the tasks specified in the Grant Application.
9. I declare that the Applicant does not conduct business activities within the scope covered by the financing granted by the Agency.

Multi-entity Applicant

1. I declare that I am entitled to represent the Applicant within the scope covered by the Grant Application and to submit this Grant Application for and on behalf of the Leader as well as all Consortium Members.

2. I declare that a Consortium Agreement has been effectively concluded with the content taking into account the minimum provisions contained in the template of the Consortium Agreement constituting Annex to the Regulation.
3. I declare that the Leader and the Consortium Members do not receive or apply for financing of the tasks covered by the Application from public funds from other sources.
4. I declare that the Leader and the Consortium Members are not in arrears with the payment of taxes, as well as with the payment of social and health insurance contributions, the Labor Fund, the State Fund for the Rehabilitation of the Disabled, or other charges required by separate regulations.
5. I declare that the Leader and the Consortium Members are not subject to exclusion from the possibility of receiving funding, including the exclusion referred to in Article 207(4) of the Act of 27 August 2009 on public finances (Journal of Laws of 2025, items 1483, consolidated text).
6. I declare that the Leader and the Consortium Members have read the Regulation and accept its terms in full, including the content of the Co-financing Agreement, which is attached as Appendix to the Regulation.
7. I declare that the Grant Application does not infringe the rights of third parties and that there are no legal obstacles to submitting the Application and implementing the Project in accordance with the Co-financing Application; in particular, I declare that no other agreements or contracts, subject to the Consortium Agreement, have been concluded that would prevent or limit the participation of the Leader and the Consortium Members in the Project covered by the Grant Application.
8. I declare that the Leader and the Consortium Members have read the information clause (“Information clause for the Applicant”) and undertake, on behalf of the Personal Data Controller (Medical Research Agency), to fulfill the information obligation towards persons whose data are contained in the Grant Application (“Information clause for natural persons indicated by the Applicant in the Application”).
9. I declare that there are no court, administrative, enforcement, fiscal or penal-fiscal proceedings pending against any of the Consortium Members, the outcome of which could affect the implementation of the tasks specified in the Grant Application.
10. I declare that the Leader and the Consortium Members do not conduct business activities within the scope covered by the financing granted by the Agency.
11. I declare that within the framework of the Project, no substantive services will be commissioned by the Consortium Leader to the Consortium Members and vice versa. The tasks performed in the Project will result from the Consortium Agreement, and no other civil law agreements related to this Project will be concluded between the Consortium members.
12. I declare that in the case of a person employed by both the Consortium Leader and the Consortium Member(s), that person's involvement in the Project may only be through one of these entities.

Information clause for the Applicant

In accordance with Article 13 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation – the "GDPR", Official Journal of the EU L 119/1 of 4 May 2016) we would like to inform you that:

1. The Controller of your personal data is the Medical Research Agency, ul. Chmielna 69, 00-801 Warsaw.
2. The Controller has appointed a Data Protection Officer whom you can contact at iod@abm.gov.pl.
3. Your personal data is processed for the following purposes:

a) to perform all activities required before the conclusion of the agreement, the process of conclusion and implementation of the agreement for the performance and financing of the Project; pursuant to Article 6(1)(e) of the GDPR, processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the Controller, in conjunction with the Act of 21 February 2019 on the Medical Research Agency (consolidated text, Journal of Laws of 2023, item 2064),

b) to evaluate the Application submitted under the Open call for non commercial clinical trials, and in the case of obtaining the grant, to evaluate the Project, control, audit, assessment of information and promotion activities, its acceptance, assessment of financial credibility and organisational and legal situation, as well as financial assessment and settlement, building resources of a clinical trial search engine, through which information on clinical trials that have received a positive opinion of the Ethics Committee and the approval of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products will be disseminated to patients, to the extent necessary to perform the tasks related to the search engine and for the purpose of statistical analyses of the search engine; your personal data will also be processed in order to set up and maintain an account allowing access to the secured system, which will be used for substantive monitoring of the financial part of the project co financed by the Medical Research Agency; pursuant to Article 6(1)(e) of the GDPR, processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the Controller, and pursuant to the Act of 21 February 2019 on the Medical Research Agency, and pursuant to Article 6(1)(c) of the GDPR, processing is necessary for compliance with a legal obligation,

c) to protect the Controller's legitimate interests, that is, a possible determination, investigation or defense against claims pursuant to Article 6(1)(f) of the GDPR.

4. Your personal data may be processed for the purpose of concluding and implementing an agreement on the collection and storage of material, including biological material for scientific research purposes and using the PSBK system (Polish Clinical Trials Network) with the eCRF MRA module (Electronic Case Report Form), which is an electronic questionnaire specifically used in clinical trials).
5. Your personal data may be transferred to public authorities and state offices or other entities authorised to receive such data by law or performing tasks carried out in the public interest or in the exercise of official authority vested in them. Your personal data may be transferred by the Controller to entities that operate the Controller's ICT systems and provide ICT tools, providing an IT system for submitting and considering Grant Applications or provide hosting, cloud storage, documentation disposal and postal services to the Controller, as well as entities assessing the financial credibility and the organisational and legal situation, and to institutions and experts performing evaluation, assessment, control, or audits.
6. The Controller will not make any automated decisions based on your personal data, including decisions resulting from profiling within the meaning of the GDPR.
7. Your personal data will be processed during the Application evaluation period, and in the case of obtaining the grant, during the implementation of the agreement, supervision over the implementation of the Project, its receipt, assessment of financial credibility and organisational and legal situation, financial assessment and settlement, keeping an account allowing access to the secured system, which will serve for substantive monitoring of the financial part of the Project, as well as control, audit, and evaluation of information and promotion activities, in accordance with the archiving regulations and for the storage period specified in the Records Management Instruction and the Unified File Classification System, as well as until the limitation of potential claims.
8. You have the right to demand from the Controller access to your personal data, the right to rectify them or limit their processing.
9. You also have the right to object.
10. You have the right to lodge a complaint with the supervisory authority, i.e. the President of the Personal Data Protection Office.
11. Providing personal data is required for the evaluation of the Application. The refusal to provide personal data will result in the inability to assess and select the Application for the implementation of the Project, conclude an agreement for the implementation of the Project and its financing, as well as supervise the implementation of the Project, its evaluation, control, audit, assessment of

information and promotion activities, assessment of financial credibility and organisational and legal situation, conduct informational and analytical activities related to the performance of public tasks by the Agency, receipt, assessment and financial settlement, setting up and maintaining an account allowing access to the secured system, which will be used for substantive monitoring of the financial part of the project, or building the resources of a clinical trial search engine, through which information on clinical trials that have received a positive opinion of the Ethics Committee and the approval of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (where applicable) will be disseminated to patients.

Refusal to provide personal data may also result in the inability to conclude and implement an agreement on the collection and storage of material, including biological material for scientific research purposes, and to use the PSBK system (Polish Clinical Trials Network) with the eCRF MRA module (Electronic Case Report Form, which is electronic questionnaire specifically used in clinical trials).

12. Your personal data will not be provided to a third country/international organisation, unless the Controller is required to do so by law.

Information clause for natural persons indicated by the Applicant in the Application

In accordance with Article 14 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation – the "GDPR", Official Journal of the EU L 119 of 2016), we would like to inform you that:

1. The controller of personal data of natural persons indicated by the Applicant in the Application is the Medical Research Agency, ul. Chmielna 69, 00-801 Warsaw.
2. The personal data of the persons referred to in item 1 have been obtained from the Applicant.
3. The Controller has appointed a Data Protection Officer whom you can contact at iod@abm.gov.pl.
4. The personal data of the persons referred to in item 1 will be processed by the Controller on the following bases:
   a) pursuant to Article 6(1)(e) of the GDPR, in conjunction with the Act of 21 February 2019 on the Medical Research Agency, processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the Controller;
   b) pursuant to Article 6(1)(c) of the GDPR, processing is necessary for compliance with a legal obligation;

c) pursuant to Article 6(1)(f) of the GDPR, processing is necessary for the purposes of the legitimate interests pursued by the Controller, that is, a possible determination, investigation or defense against claims;

5. The data include the category of ordinary data – name, surname, position or function, place of work, business e mail address, telephone, fax, academic title/degree, date of birth, education, professional licence number, professional experience.
6. The personal data referred to in item 1 may be transferred to public authorities and state offices or other entities authorised to receive such data by law or performing tasks carried out in the public interest or in the exercise of official authority vested in them. The personal data may be transferred by the Controller to entities that operate the Controller's ICT systems and provide ICT tools, providing an IT system for submitting and considering Grant Applications or provide hosting, cloud, documentation disposal or postal services to the Controller, as well as entities assessing the financial credibility and the organisational and legal situation, and to institutions and experts performing evaluation, assessment, control, or audits.
7. Based on the personal data of the persons referred to in item 1, the Controller will not make automated decisions, including decisions resulting from profiling within the meaning of the GDPR.
8. The personal data of the persons referred to in item 1 will be processed during the Application evaluation period, and in the case of obtaining the grant, during the implementation of the agreement, supervision over the implementation of the Project, its receipt, financial assessment and settlement, assessment of financial credibility and organisational and legal situation, evaluation of the Project, control, audit, assessment of information and promotion activities, keeping an account allowing access to the secured system, which will serve for substantive monitoring of the financial part of the Project, unless a longer processing period is necessary, e.g. due to archiving obligations, for the storage period specified in the Records Management Instruction and the Unified File Classification System, or until the limitation of claims.
9. The persons referred to in item 1 have the right to demand from the Controller access to their personal data, the right to rectify them, erase them or limit their processing.
10. The persons referred to in item 1 also have the right to object.
11. The persons referred to in item 1 have the right to lodge a complaint with the supervisory authority, i.e. the President of the Personal Data Protection Office.
12. The provision of personal data of the individuals referred to in item 1 is required to evaluate the Application. Refusal to provide personal data will result in the inability to evaluate and select the Application related to the Project implementation, conclude the contract for the Project and its funding, as well as to supervise the Project implementation, its evaluation, control, audit, assessment of informational and promotional activities, evaluation of financial credibility and organisational-legal status, conduct informational and analytical activities related to the performance of public tasks by the Agency, acceptance, financial settlement, setting up and

management of access accounts to a secured system used to monitor the substantive and financial parts of the project, or build resources for the clinical trial search engine, which will provide patients with information about clinical trials approved by the Bioethics Committee and the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products (where applicable).

Refusal to provide personal data may also result in the inability to conclude and implement an agreement on the collection and storage of material, including biological material for scientific research purposes, and to use the PSBK system (Polish Clinical Trials Network) with the eCRF MRA module (Electronic Case Report Form, which is electronic questionnaire specifically used in clinical trials).

13. Data of the persons referred to in item 1 will not be provided to a third country/international organisation, unless the Controller is required to do so by law.