

Template of the Grant Application

GRANT APPLICATION FORM FOR PROJECT TYPE: CLINICAL TRIALS

**Tab: Application Details**

Implementation under	Open call for non-commercial clinical trials
Recruitment symbol	NBK26
Recruitment No.	ABM/2026/2
Application Number	
Application submission date	
Project title	
Applicant	
Project type	Clinical trial

<b>Planned period of implementation of the Project</b> <ul style="list-style-type: none"> <li></li> </ul>	<p>Note: The project must start between March 1, 2027 and June 1, 2027.</p> <p>In addition, the following rules must be taken into account:</p> <ul style="list-style-type: none"> <li>the minimum duration of the Project is 3 years (36 months);</li> <li>the maximum duration of the Project is 6 years (72 months).</li> </ul>
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**

<b>Clinical trial entity (Applicant/Consortium Leader)</b>	
Type of the Single Applicant/Consortium Leader	<p>Mandatory field, single choice from among the following values:</p> <p>1. entity referred to in Article 7(1)(1-6; 8) of the Polish Act of 20 July 2018 on higher education and science;</p>

	<p>2. Postgraduate Medical Education Centre (pl. Centrum Medycznego Kształcenia Podyplomowego), referred to in the Polish Act of 13 September 2018 on the Postgraduate Medical Education Centre;</p> <p>3. healthcare 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;</p> <p>4. an entity performing scientific research and experimental development:</p> <p>Next to the field, under the “i” icon, there is a hint:</p> <div data-bbox="824 611 2004 1294" style="border: 1px solid black; padding: 10px;"> <p><b>1. entity referred to in Article 7(1)(1-6; 8) of the Polish Act of 20 July 2018 on higher education and science;</b></p> <p>higher education institutions;</p> <p>federations of entities of the higher education system and science;</p> <p>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”;</p> <p>scientific institutes of the PAN operating under the Act on the PAN;</p> <p>research institutes, operating under the Act of 30 April 2010 on research institutes;</p> <p>international scientific institutes established on the basis of separate acts and operating on the territory of the Republic of Poland;</p> <p>other entities conducting mainly scientific activities on an independent and continuous basis.</p> </div>
--	--

Applicant subtype	<p>Mandatory field, displayed after selecting Applicant type =5, single choice from among the following values:</p> <p>a) organisational unit having legal personality and registered office in the territory of the Republic of Poland;</p>
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	
<b>Address</b>	
Country	

Street	
Building No.	
Apartment No.	
Postal code	
Town / City	
Municipality	
District	
Voivodeship	
<b>Person authorised to make binding decisions and submit an Application</b> 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	
<b>Person authorised to working contacts</b>	
Mr. / Ms.	
First name	
Last name	
Position	
Phone	
E-mail address	
<b>Person authorised to represent the Applicant</b>	
<p>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.</p>	
Mr. / Ms.	
First name	

Last name	
Position	
Phone	
E-mail address	

The Applicant's revenues for the previous financial year	
Value (in PLN million)	
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 commercial and non-commercial clinical trials (e.g. indicate the number of persons along with the definition of academic degrees with experience in conducting clinical trials, the number of trials conducted with the division into commercial and non-commercial trials) verified on the basis of publicly available databases of clinical trials ( e.g. clinicaltrials.gov, EudraCT), including a description of the most important clinical trials on a similar subject.

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



Financial potential (as a minimum, the financial capacity of the entity responsible for the implementation of the Project should be confirmed to demonstrate that, in addition to its other activities, it is able to guarantee liquidity in terms of adequate financing of the Project in order to ensure its proper implementation and continued operation). The description should also include the amount of current financial obligations.

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 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 [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 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 [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**

<b>Consortium Members</b>	
The maximum number of Consortium Members in the project = 3 (Consortium Leader + 3 Consortium Members).	
Consortium Member	
No.	
Type of Consortium Member	<p>Mandatory, single-selection field. Options:</p> <ol style="list-style-type: none"> <li>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</li> <li>2. Center for Postgraduate Medical Education (pl. Centrum Medycznego Kształcenia Podyplomowego), referred to in the Polish Act of 13th September 2018 on the Postgraduate Medical Education Centre;</li> <li>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 Postgraduate Medical Education Centre;</li> <li>4. The following entities performing Scientific Research and Experimental Development.</li> </ol> <p>Hint next to the field (icon “i”):</p>

	<p><b>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</b></p> <p>universities,</p> <p>federations of entities in the higher education and science system,</p> <p>the Polish Academy of Sciences (PAN) operating under the Act of 30 April 2010 on the Polish Academy of Sciences,</p> <p>PAN research institutes operating under the Act on PAN,</p> <p>research institutes operating under the Act of 30 April 2010 on Research Institutes,</p> <p>international research institutes established under separate acts and operating on the territory of the Republic of Poland,</p> <p>other entities conducting mainly scientific activities independently and continuously.</p>	
Subtype of Consortium Member	<p>Mandatory, displayed after selecting Type of Applicant = 5, single-selection field. Options:</p> <p>a) An organisational unit with legal personality and registered office in the territory of the Republic of Poland;</p>	
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	
<b>Address</b>	
Country	
Street	
Building No.	
Apartment No.	

Postal code	
Town / City	
Municipality	
District	
Voivodeship	

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 [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 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 [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.C. Principal Investigator/ Head of Research Experiment/ R&D Manager/ Project Manager**

**Principal Investigator - details of the Principal Investigator (first and last name only)**

<b><u>Principal Investigator</u></b>	First name	Last name
	Text field, required, max. 50 characters	Text field, required, max. 50 characters

The data of the **Principal Investigator** such as his/her name and surname are public information.

Date of birth

Date field, mandatory,
------------------------

Academic Title/ Academic Degree, Education, number of the Licence to practice

Text field, mandatory, max. 550 characters
Pursuant to the terms of the call, a PhD degree is required

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.	Clinical Trial Title	Clinical Trial Number	Duration of the clinical trial			Sponsor Name	Principal Investigator Role in Clinical Trial	Engagement Period		
			From	Ongoing?	To			From	Ongoing?	To

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

Date of the last GCP E6 (R3) training (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 in the field of applied Project

Text field, mandatory, max. 10 000 characters

Please provide 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.

### Employment

No.	Employment Period			Employing Entity	Occupied position	Time commitment per FTE, (e.g. 0,5 FTE)	Type of contract
	From	Currently 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 clinical trial (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.

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.

Keywords (in English language)

Mandatory field, text field.

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 Clinical trial, e.g., Clinical trial 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 Clinical trial, e.g., clinical trial 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.

Does the Applicant apply for an incentive bonus?

Mandatory field, selection list: YES / NO

Pole obowiązkowe (jeśli się pojawia), lista wyboru:

1. 200 000,00 zł
2. 150 000,00 zł
3. 100 000,00 zł
4. 50 000,00 zł
5. 00,00 zł

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

- 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

- 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 investigational medicinal product**

The section and its fields below (up to and including the EAN Code) appear only for project type = clinical trial

Trade name of the medicinal product (if available)

Text field, non-mandatory, max. 200 characters

Name of the active substance

Text field, mandatory, max. 200 characters

Dosage form

Text field, mandatory, max. 200 characters

EAN code (if available)

Text field, non-mandatory, max. 500 characters

Investigational medicinal product therapeutic indication description in the Project

Text field, non-mandatory, max. 500 characters

**ICD-10 code** corresponding to the health issue addressed by the Project.

Please indicate the *ICD-10* corresponding to the health issue addressed by the Project. The code must be taken from the official ICD-10 list.

The system does not allow for direct entry of Subcategory inclusions. If needed, the relevant information should be entered in the application section **Description of the scientific value of the Project** (please refer to the *Regulations* literally).

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

The Applicant is required to provide a valid ORPHAcode in the Application.

**Arms in the Project**

**Arm no. 1** - indicate medicinal product/s

Mandatory text field max. 200 characters

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

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 clinical trial according to the PICOS (population, intervention, comparison, outcome, study design) scheme:**

**P - population in which the intervention will be used**

Please specify: a detailed description of the target population indicated in the Application, including the rationale for the selection of target population, sample size with justification (described in a manner that enables verification of the calculations presented in the Application), patient inclusion and exclusion criteria, and patient assessment scheme that includes the baseline examination and assessment during treatment with procedures that the subjects will undergo. The estimated recruitment rate should be provided based on at least three ongoing or completed clinical trials involving the same disease entity or a similar intervention being studied, taking into account the inclusion/exclusion criteria, and the source of the data should be identifiable (e.g., clinical trial number). In the absence of published data, the basis for estimating the recruitment rate should be indicated.

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

**I –proposed intervention**

Please specify: a description of the proposed intervention, the rationale for its selection, the time and method of administration of the proposed intervention, supportive treatment (if used) .

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/ <i>in vitro</i> diagnostic medical device.	Text field
The product has a valid certificate of conformity issued by a notified body or an EU declaration of conformity.	YES / NO
The use of the medical device in the Non-commercial clinical trial is consistent with its intended use as specified in the Instructions for Use (IFU).	YES / NO
The purpose of the use of medical device in the Non-commercial clinical trial is not to test, evaluate performance, validate or calibrate a product.	YES / NO
The results obtained after the Project completion are not planned to be used to obtain CE marking, register a medical device or an <i>in vitro</i> diagnostic medical device in the Office for Registration of Medicinal Products, or in the commercialization process?	YES / NO

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.	
--	--

---

### Content of the declaration

☐ I declare that no medical device is involved in the planned Project or the medical device/ *in vitro* diagnostic medical device involved in the Project has an EU declaration of conformity (is CE marked) and/or has a valid certificate of conformity issued by a notified body. If the medical device/ *in vitro* diagnostic medical device diagnostics is included in the study, it is marketed and used in the current standard of therapy. At the same time, the planned Project is not intended to evaluate the safety or efficacy of the medical device/ *in vitro* diagnostic medical device.

### 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 clinical trial.

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

In this Call of proposals, only clinical trials with two arms (intervention and control/comparison) are possible, in accordance with the requirement of formal criterion. An exception are projects concerning only clinical trials participants with rare diseases (according to [www.orpha.net](http://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 Clinical trial)**

Please specify: The type of proposed Clinical trial, along with a description (if applicable) of randomization and allocation of patients to groups, blinding (if applicable), concept for statistical analysis of data, and duration of the clinical trial (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 trial .

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 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 clinical trial (evidence-based medicine)

Identification of risks in the design of the Clinical Trial, 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 clinical trial, 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<sup>[4]</sup>

<sup>[4]</sup> Quality Standards for Polish biobanks v. 2.00 (2021)

[https://wydawnictwo.umw.edu.pl/upload/files/standardy\\_jakosci\\_dla\\_biobankow\\_polskich\\_2.0.pdf](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 literally):**

- 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 znaków

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 literally).**

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 literally).**

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 literally).**

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 literally).**

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 literally).**

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.

### **Information on possible conflict of interest – identification of Experts who should be excluded from the evaluation**

Pursuant to Article 18(1) of the Medical Research Agency Act (Journal of Laws 2025, item 259), for each competition, the President appoints a team for the evaluation of applications, consisting of Agency staff or external experts appointed by the President.

Experts are selected taking into account their competence in terms of content and their independence in assessing projects.

In order to ensure the impartiality of the evaluation process, the Applicant has the possibility to indicate up to three persons (it concerns people outside the project team) who, in their opinion, should not participate in the evaluation of this application due to a potential risk of conflict of interest. For each of these individuals, the name and affiliation must be provided.

1.	First Names	Maximum 100 characters.
	Last Name	Maximum 100 characters.

	Affiliation	Maximum 200 characters
2.	First Names	Maximum 100 characters.
	Last Name	Maximum 100 characters.
	Affiliation	Maximum 200 characters
3.	First Names	Maximum 100 characters.
	Last Name	Maximum 100 characters.
	Affiliation	Maximum 200 characters

**Indicators**

## Product indicators

Number of validated innovative therapeutic methods developed within Non-commercial clinical trial

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

Number of patients included in Non-commercial clinical trial

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

Number of patients included in Non-commercial clinical trial who were randomized (if applicable).

Text field, mandatory, integer possible (0 possible).

Number of patients included in Non-commercial clinical trial who received investigational medicinal product

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

Number of clinical trials launched in Poland in compliance with regulatory requirements

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

Number of sites conducting Non-commercial clinical trials under a given Project

Please provide the total number of all sites involved in conducting the study, including the sponsor.

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

Number of biobanked biological material samples

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).

**Result indicators**

Number of publications with the results of Non-commercial clinical trial

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:

- Obtaining a permit to conduct a clinical trial
- Obtaining medicinal product(s) for the clinical trial
- Clinical trial management
- Implementation of the clinical part

**Up to 4 tasks** can be added (a maximum of 8 tasks in total).

Each task should contain a defined, parameterised milestone. Reference should be made literally 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 Clinical trial: 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.

**The time limit related to the granting of the incentive bonus.**

In the case of applying for the incentive bonus, it should be noted that the period from submitting the clinical trial documentation to the regulatory authorities until obtaining the approval of a clinical trial should not exceed 100 calendar days.

No.	Task list	
	Task No. ...	
	Task name	<p>Text field, mandatory, max. 1,000 characters.</p> <p>The following obligatory tasks are already specified and cannot be deleted.</p> <p>As regards the required order: if there is an option to use separate dictionaries of tasks, with separate numbering.</p> <div style="border: 1px solid black; padding: 5px;"> <p>In order:</p> <ol style="list-style-type: none"> <li>1. Obtaining an authorisation to conduct a clinical trial</li> <li>2. Obtaining the medicinal product(s) for the clinical trial</li> <li>3. Clinical trial management</li> <li>4. Implementation of the clinical part</li> </ol> <p>and the ability to add more, defined by yourself (up to 4, because the maximum is 8)</p> </div>
	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	Repetitive section.
	<b>No.</b>	Number for the milestone, completed automatically.



Name of the milestone	For the task "Obtaining an authorisation to conduct a clinical trial"	<p>the milestones are:</p> <ul style="list-style-type: none"> <li>a) Developing the clinical trial dossier (Development of the clinical trial documentation);</li> <li>b) Submission of the clinical trial dossier to regulatory authorities*;</li> <li>c) Obtaining approval for the conduct of the clinical trial from regulatory authorities.</li> </ul> <p>* In the case of applying for the incentive bonus, it should be noted that the period from submitting the clinical trial documentation to the regulatory authorities until obtaining the approval of a clinical trial should not exceed 100 days.</p>
	For the task "Obtaining the medicinal product(s) for the clinical trial"	<p>Possibility to add custom milestones (min. 1, max. 2)</p> <p>Examples of milestones: signing a contract for the supply of medicinal product(s) for the study, delivery of all doses of investigational medicinal products to the Centers</p>
	For the task "Clinical trial management"	<p>the milestones are:</p> <ul style="list-style-type: none"> <li>a) First Site Activation, FSA;</li> <li>b) Activation of 50% of sites;</li> <li>c) Last Site Activated, LSA, 100% of sites activated.</li> </ul> <p>The fields b)-e) should be inactive when a numerical value 1 appears in the indicator: 'Number of sites involved in the implementation of clinical trial under the Project'.</p>

	<p><b>For the task “Implementation of the clinical part”</b></p>	<p>the milestones are:</p> <ul style="list-style-type: none"> <li>a) First Patient Randomized (FPR);</li> <li>b) Inclusion of 25% randomized participants in the Clinical trial;</li> <li>c) Inclusion of 50% randomized participants in the Clinical trial*;</li> <li>d) Inclusion of 75% randomized participants in the Clinical trial;</li> <li>e) Last Patient Randomized (LPR); 100% of randomized participants included in the Clinical trial*;</li> <li>f) Inclusion of the first participant in the Clinical trial;</li> <li>g) Inclusion of 25% participants in the Clinical trial;</li> <li>h) Inclusion of 50% of participants in the Clinical trial*;</li> <li>i) Inclusion of 75% of participants in the Clinical trial;</li> <li>j) Inclusion of the last participant in the Clinical trial; 100% of participants included*;</li> <li>k) First participant to complete all defined procedures of the Clinical trial;</li> <li>l) 25% of participants who have completed all defined procedures of the Clinical trial;</li> <li>m) 50% of participants who have completed all defined procedures of the Clinical trial;</li> <li>n) 75% of participants who have completed all defined procedures of the Clinical trial;</li> <li>o) 100% of participants who have completed all defined procedures of the Clinical trial;</li> <li>p) Database lock: completion of data entry, verification, and approval processes;</li> <li>q) Final analysis to verify the achievement of the Project's goals and submission of the findings to the Medical Research Agency.</li> </ul>
--	--	--

		<p>* Milestone affecting motivational bonus payment timing</p> <p>The fields a)-e) should be inactive if 'NO' is selected for the question 'Has participant randomization been applied in the project?' in the 'S – type of proposed Clinical trial' section of the Application.</p> <p>The fields f)-j) should be inactive if 'YES' is selected for the question 'Has participant randomization been applied in the project?' in the 'S – type of proposed Clinical trial' section of the Application.</p>
	<b>For the remaining tasks (with names entered manually by the Editor)</b>	In each task: possibility to add custom milestones (max. 2, at least 1 is mandatory)
Date of reaching the milestone		

### Implementation schedule

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

Milestone: [name of the milestone]							

**Tab III. Detailed budget of the Project**

Cost calculation in the Project
<p>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.</p> <p>If a given task does not require costs, you can delete the entry for the task.</p> <p>If a given task involves more costs, you can add additional lines for the task.</p> <p>For the reported cost, please provide:</p> <ul style="list-style-type: none"> <li>• Cost name</li> <li>• Cost category</li> <li>• A description of the cost calculation method – please describe in detail how the calculation was made, e.g.:</li> </ul>

- 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.

<b>Task budget</b>	
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.
<b>No.</b>	
<b>Cost name</b>	Text field, mandatory, max. 100 characters
Cost category	Mandatory field, single-choice. Selectable values: <ul style="list-style-type: none"> <li>• Remunerations;</li> <li>• Medical service;</li> <li>• Drug;</li> <li>• Insurance costs;</li> <li>• Medical device;</li> <li>• Other;</li> <li>• CRO involvement;</li> <li>• Purchase of medical equipment, including research infrastructure;</li> <li>• Specialist services commissioned.</li> </ul>
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	<p>Text field, mandatory, min. 300 characters, max. 3000 characters.</p> <p>Please describe in detail how a given cost was calculated, e.g.:</p> <ul style="list-style-type: none"> <li>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)</li> <li>for the “Purchase of medical equipment, including research infrastructure” category, list the components of the kit (if applicable).</li> </ul>
Total cost of the item (PLN)	
Total cost of the task (PLN)	

<b>The total budget of the Project by type of eligible cost</b>	<p>The table consists of the following columns:</p> <ul style="list-style-type: none"> <li>Cost category – names of all cost categories.</li> <li>Applicant (PLN) – total costs allocated to the Applicant for a given cost category from all tasks. The fields always presents 2 decimal places.</li> <li>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.</li> <li>Total (PLN) – the sum of the “Applicant (PLN)” and “Consortium Member(s) (PLN)” values. The fields always presents 2 decimal places.</li> </ul>
---	---

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.

#### Incentive bonus (PLN)

The field is visible if the Beneficiary applies for the incentive bonus in section Tab II.A. Project – general data.

Non-editable field, the value is completed automatically:



- the value of PLN [zgodnie z wyborem użytkownika – z listy]
  1. 200 000,00 zł
  2. 150 000,00 zł
  3. 100 000,00 zł
  4. 50 000,00 zł
  5. 00,00 zł

### **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 minimum possible value of the Project – PLN 5 million. The maximum possible value of the Project – PLN 30 million

Amount of the co-financing

100%

### **Grant requested (PLN)**

Grant requested (PLN)

Non-editable field, value calculated automatically.

#### **Tab IV. Attachments**

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

Informacje dla zespołu DEV: jeżeli w tej sekcji nie ma żadnego pola, prezentowana jest informacja: No mandatory attachments for this Application.

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. 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**

3. 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 within the Project (if applicable)
4. Report on research and development (R&D) activities submitted to the Central Statistical Office (GUS) on form PNT-01 for 2025:
5. Other formal documents; the content of these attachments will not be subject to substantive evaluation (maximum of 20).

### **Tab: V. Declarations**

<b>General Declarations</b>	
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.: Principal investigator and the Head of R&D (the Project Manager) 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.

8. I declare that the required approvals/positive opinions/permissions/authorisations from the relevant bioethical or ethical committee and competent authority will be obtained in the case where the Project includes research/trials that are clinical trials within the meaning of Article 2(2)(2) of Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.
9. I declare that the clinical trial is of a non-commercial nature, and therefore meets the conditions set out in Articles 5 and 6 of the Act of 9 March 2023 on Clinical Trials of Medicinal Products for Human Use, subject to the provisions of Article 5(2) and Article 6(4) of the above-mentioned Act (*this declaration appears only for Clinical Trial Projects*).
10. I declare that the clinical trial to which this Grant Application relates is not conducted as part of the implementation of a scientific advice concerning a clinical trial or an investigational medicinal product, carried out by the European Medicines Agency, a Member State of the European Union, or a country outside the European Economic Area, and is not part of a paediatric investigation plan referred to in Title II, Chapter 3 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004, or a pediatric investigation plan agreed with a country outside the European Economic Area (*this declaration appears only for Clinical Trial Projects*).

### **Single Applicant**

1. I declare that I do not receive or apply for financing of the tasks covered by the Application from public funds from other sources.
2. 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.

3. I declare that I am entitled to represent the Applicant within the scope covered by the Application and to submit this Grant Application.
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 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.
2. 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.
3. 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.
4. 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).
5. 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.
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, 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.
7. 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").

8. 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.
9. 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.
10. 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 no. 3 to the Regulation.
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, except for the clinical trial agreements (CTA).
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](mailto: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](mailto: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.