Template of the Grant Application

<u>Tab: Application Details</u>

Implementation under	Open call for non-commercial clinical trials and research experiments
Recruitment symbol	NBK24
Recruitment No.	ABM/2024/1
Application Number	
Application submission date	
Project name	
Applicant	
Project type	Mandatory field, drop-down list: • Clinical trial • Research experiment
Planned period of implementation of the Project	Note: The project must start in 2024, minimum 01/06/2024, maximum 31/12/2024.

	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 6 years (72 months).
Start of Project implementation	
End of Project implementation	The project duration may not be LESS than 36 months. The project duration may not be MORE than 72 months.
Consortium Members	
Application status	

Tab I.A Applicant

Clinical trial entity (Applicant/Consortium Leader)	
Applicant type	Mandatory field, single choice from among the following values: 1. entity referred to in Article 7(1)(1-6; 8) of the Polish Act of 20 July 2018 on higher education and science; 2. Postgraduate Medical Education Centre (pl. Centrum Medyczne Kształcenia Podyplomowego), referred to in the Polish Act of 13 September 2018 on the Postgraduate Medical Education Centre;

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;

4. entrepreneur having the status of a research and development centre within the meaning of Article 17(2) of the Act of 30 May 2008 on certain forms of support for innovative activity;

5. an entity performing scientific research and experimental development:

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.

Applicant subtype	Mandatory field, displayed after selecting Applicant type =5, single choice from among the following values: a) organisational unit having legal personality and registered office in the territory of the Republic of Poland; b) enterpreneur conducting activities in a different organisational form than as healthcare entity, for whom 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, and in a different organisational form than as enterpreneur having a status of a research and development centre within the meaning of Article 17(2) of the Polish Act of 30 May 2008 on certain forms of support for innovative activity.
Full name	
Full name - Other	
NIP (Tax Identification Number)	validation message: The number provided is incorrect. Remember to enter the number without spaces and dashes.
REGON (National Business Registry No.)	
Legal form	
Website address	
E-mail address for correspondence	

ePUAP mailbox address	Official correspondence from the MRA on the progress of the evaluation of the application under the call for proposals will be sent to the address provided.
Address	
Country	
Street	
Building No.	
Apartment No.	
Postal code	If country = PL is indicated, the postal code must take the format: XX-XXX (validation message: The postal code must take the following format: XX-XXX.).
Town / City	
Municipality	
District	
Voivodeship	
Person authorised to make binding decisions It is necessary to indicate in accordance with the act stating the election of the Rector, on the basis of the National Court Register[1] or another equivalent document, and attach a relevant document as an attachment to the Application.	
Mr. / Ms.	

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[1] If the representation results from the National Court Register, it is not required to attach an excerpt to the Application.

First name	
Last name	
Position	
Phone	In the case of a landline phone number, please also include the area code.
Fax	
E-mail address	In case of incorrect format, validation message = Incorrect format.
Person authorised to working contacts An appropriate power of attorney signed with a qualified electronic signature (.PAdES signature format with the use of a graphic symbol) by a person authorised to make decisions should be attached.	
Is it a person designated as entitled to make a binding decision?	After selecting Yes, the fields in the subsection become non-editable and the values from the relevant fields from the subsection "Person authorised to make binding decisions" of the Applicant are copied to them.
Mr. / Ms.	
First name	
Last name	

Position	
Phone	In the case of a landline phone number, please also include the area code.
Fax	
E-mail address	In case of incorrect format, validation message = Incorrect format.
Person authorised to represent the Applicant An appropriate power of attorney signed with a qualified electronic signature (.PAdES signature format with the use of a graphic symbol) by a person authorised to make decisions should be attached.	
Is it a person designated as entitled to make a binding decision?	After selecting Yes, the fields in the subsection become non-editable and the values from the relevant fields from the subsection "Person authorised to make binding decisions" of the Applicant are copied to them.
Mr. / Ms.	
First name	
Last name	
Position	
Phone	In the case of a landline phone number, please also include the area code.

Fax	
E-mail address	In case of incorrect format, validation message = Incorrect format.

The Applicant's revenues for the previous financial year	
Value (in PLN million)	
Year	Mandatory field, single choice from among the following values: 2022 / 2023. Default value: 2023.

Total number of full-time employees (number of persons employed in the previous year)	
Value	Only an integer can be specified.
Year	Please provide the status as of the last day of the calendar year.

Total number of employees employed under civil law contracts (number of persons employed in the previous year)	
Value	Only an integer can be specified.

Year	Please provide the status as of the last day of the calendar 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.

when this declaration is selected, another mandatory declaration will be displayed:

[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.

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.

when this declaration is selected, another mandatory declaration will be displayed:

[Name of the entity submitting the Declaration] 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[2] by [name of the entity submitting the Declaration][3] within the time limit not longer than 90 days from the date of submission of the VAT declaration[4]. 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 not been included in the Project budget.

when this declaration is selected, another mandatory declaration will be displayed:

[Name of the entity submitting the Declaration] 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[2] by [name of the entity submitting the Declaration][3] within the time limit not longer than 90 days from the date of submission of the VAT declaration[4]. 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.

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[2] Cf. Article 91(7) of the Act of 11 March 2004 on Tax on Goods and Services.

[3] 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 time limits referred to in Sections 10, 10d, 10e, and 11, the amount of tax due may be reduced by making an adjustment to the tax return for the period in which the right to reduce the amount of tax due was created, but no later than **within 5 years** from the beginning of the year in which the right to reduce the amount of tax due was created, subject to Section 13a."

[4] 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.

If the return is not made within this period, § 16 of the Co-financing Agreement will apply.

Tab I.B Consortium Members

Consortium Members	
The maximum number of Consortium Members in the project = 4.	
Consortium Member	
No.	
Full name	
NIP (Tax Identification Number)	Validation message: The number provided is incorrect. Remember to enter the number without spaces and dashes.
REGON (National Business Registry No.)	
Legal form	
Website address	
E-mail address for correspondence	In case of incorrect format, validation message = Incorrect format.
ePUAP mailbox address	Official correspondence from the MRA on the progress of the evaluation of the application under the call for proposals will be sent to the address provided.
Address	
Country	

Street	
Building No.	
Apartment No.	
Postal code	If country = PL is indicated, the postal code must take the format: XX-XXX. If another country is indicated, there is no format validation.
Town / City	
Municipality	
District	
Voivodeship	
Person authorised to make binding decisions	
Mr. / Ms.	
First name	
Last name	

Position	
Telephone number	In the case of a landline phone number, please also include the area code.
Fax	
Business e-mail address	In case of incorrect format, validation message = Incorrect format.
Person authorised to working contacts	
Is it a person designated as entitled to make a binding decision?	After selecting Yes, the fields in the subsection become non-editable and the values from the relevant fields from the subsection "Person authorised to make binding decisions" of the Consortium Member are copied to them.
Mr. / Ms.	
First name	
Last name	
Position	
Telephone number	In the case of a landline phone number, please also include the area code.
Fax	

Business e-mail address	In case of incorrect format, validation message = Incorrect format.

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.

when this declaration is selected, another mandatory declaration will be displayed:

[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.

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.

when this declaration is selected, another mandatory declaration will be displayed:

[Name of the entity submitting the Declaration] 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[5] by [name of the entity submitting the Declaration][6] within the time limit not longer than 90 days from the date of submission

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[5] Cf. Article 91(7) of the Act of 11 March 2004 on Tax on Goods and Services.

[6] 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 time limits referred to in Sections 10, 10d, 10e, and 11, the amount of tax due may be reduced by making an adjustment to the tax return for the period in which the right to reduce the amount of tax due was created, but no later than **within 5 years** from the beginning of the year in which the right to reduce the amount of tax due was created, subject to Section 13a."

of the VAT declaration[7]. 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 not been included in the Project budget.

when this declaration is selected, another mandatory declaration will be displayed:

[Name of the entity submitting the Declaration] 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[8] by [name of the entity submitting the Declaration][9] within the time limit not longer than 90 days from the date of submission of the VAT declaration[7]. 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.

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[7] 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.
If the return is not made within this period, § 16 of the Co-financing Agreement will apply.
[8] Cf. Article 91(7) of the Act of 11 March 2004 on Tax on Goods and Services.
[9] 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 time limits referred to in Sections 10, 10d, 10e, and 11, the amount of tax due may be reduced by making an adjustment to the tax return for the period in which the right to reduce the amount of tax due was created, but no later than **within 5 years** from the beginning of the year in which the right to reduce the amount of tax due was created, subject to Section 13a."

Tab II.A. Project – general data

General data

Project name

Name 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

Does the Beneficiary apply for an incentive bonus?

Mandatory field, selection list: YES / NO

Will the clinical trial be part of:

Mandatory field, selection list: domestic clinical trial / international clinical trial based on a Polish protocol / international clinical trial based on a foreign protocol / not applicable.

Please indicate in which countries the clinical trial is planned

The field appears only if in the question "Will the clinical trial be part of:" selected = international clinical trial based on the Polish protocol / international clinical trial based on a foreign protocol.

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

Will the Beneficiary 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, 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/2023/2
- 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

The field occurs only when in the question "Does the subject matter of the Project coincide with other research tasks carried out by the Applicant?" selected = YES

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

Summary of the Project (in Polish)

In the Summary, the Applicant should include: the objective of the Project, the proposed intervention along with the research methodology.

Summary of the Project (in Polish)

Text field, min. 3,000, max. 10,000 characters, mandatory field

The Summary of the Project will be made public.

The Summary should not include details of the clinical trial, e.g., drug dosage, patient inclusion/exclusion criteria, details of the procedures performed.

The Summary should contain a brief description according to the scheme:

a.   Aim of clinical trial (including the disease entity – ICD10, the assumed research hypothesis),

b.   type of clinical trial (number of arms, randomisation, etc.),

c.   brief description of the target population,

d.   description of the intervention (name of the drug or active substance / procedure),

e.   comparator description,

f.   endpoints assessed,

g.   expected benefits for the patient and the health care system from the clinical trial.

Summary of the Project (in English)

In the Summary, the Applicant should include: the objective of the Project, the proposed intervention along with the research methodology.

Summary of the Project (in English)

Text field, min. 3,000, max. 10,000 characters, mandatory field

The Summary of the Project will be made public.

The Summary should not include details of the clinical trial, e.g., drug dosage, patient inclusion/exclusion criteria, details of the procedures performed.

The Summary should contain a brief description according to the scheme:

a.   Aim of clinical trial (including the disease entity – ICD10, the assumed research hypothesis),

b.   type of clinical trial (number of arms, randomisation, etc.),

c.   brief description of the target population,

d.   description of the intervention (name of the drug or active substance / procedure),

e.   comparator description,

f.   endpoints assessed,

g.   expected benefits for the patient and the health care system from the clinical trial.

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.

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

Project classification

HINT: 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

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, non-mandatory, max. 200 characters

Dosage form

Text field, non-mandatory, max. 200 characters

EAN code (if available)

Text field, non-mandatory, max. 200 characters

Identification data of the research experiment

This section only appears for project type = research experiment

ICD-9 code for the key procedure(s) used and covered by the subject matter of the Project.

Text field, mandatory, max. 500 characters

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

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

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

- A description of the target population indicated in the Application
- Justification for the selection of the target population

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

Sample size with justification

Please indicate the sample size and the statistical tool used, and present all data allowing to replicate the sample size calculations presented in the Application.

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

Patient inclusion and exclusion criteria

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

Patient assessment scheme

a. Baseline examination

b. Assessment during treatment

c. Termination of treatment

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

I – description of the proposed intervention

Please specify:

Choice/type, time and method of administration of the intervention.

For a research experiment, provide the ICD-9 code for the procedure used in accordance with the field Identification data of the research experiment.

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

Detailed treatment protocol

- Description of the procedures that the subjects will undergo
- Supportive treatment (if used)

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

Duration of treatment at different stages

Text field, mandatory, max. 1,000 characters

C – proposed comparators (comparative technologies)

Please specify:

A description of the comparator and rationale for its choice

In the absence of a comparator in the clinical trial, indicate *not applicable*.

Text field, mandatory, max. 5,000 characters

Time and method of administration of the comparator

In the absence of a comparator in the clinical trial, indicate *not applicable*.

Text field, mandatory, max. 5,000 characters

O – health effects, i.e. endpoints against which the clinical effectiveness will be assessed, broken down into items concerning:

- **efficacy**
- **safety**

Please specify:

Name, definition and rationale for selecting a given endpoint

Text field, mandatory, max. 5,000 characters

The division of endpoints into primary and secondary (main and additional), along with a rationale for the clinical relevance of the selected endpoints

Text field, mandatory, max. 5,000 characters

S – clinical trial type (type of proposed clinical trial)

Please specify:

Type of the proposed clinical trial and a rationale for choosing this type of clinical trial with a description of:

- Randomisation and assignment to treatment groups (if applicable)
- Blinding (if applicable)
- The type of research hypothesis being tested

Text field, mandatory, max. 10,000 characters

Duration of the clinical trial (in months) and possibility of early termination of the trial

Text field, mandatory, max. 5,000 characters

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. In the case of an international clinical trial, please indicate which country is the Leader.

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

Patient Organisation and/or Scientific Society and their role in the Project.

If a Patient Organisation and/or an Organisation acting for the benefit of patients and/or a Scientific Society are not planned as a Consortium Member / Consortium Leader / Single Applicant in the Project, indicate *not applicable*.

Text field, mandatory, max. 5,000 characters

Principal Investigator / Head of Research Experiment (enter name and surname only)

Hint under the field: The data of the Principal Investigator / Head of Research Experiment such as his/her name, surname and degree or scientific title are public information.

Text field, mandatory, max. 100 characters

Description of the professional experience of the Principal Investigator / Head of Research Experiment (in the context of the assumptions of the Research Project):

1) information on the management of research projects financed under national or international calls, together with a description of the therapeutic area;

2) description of the most important publications in the field of the Project along with bibliographic information (maximum 5 items);

3) total impact factor and Hirsch index;

4) information about the conducted clinical trials (title and identification number of the clinical trial, duration of the trial, function performed in the trial, titles of publications on the trial, in which the Principal Investigator / Head of the Research Experiment is the author).

Description of the professional experience of the Principal Investigator / Head of Research Experiment

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)

Justification of the clinical trial based on scientific reports (on the basis of some of the most important and up-to-date publications on the subject of the Project).

Text field, mandatory, max. 5,000 characters

Safety assessment and risk identification (Description of the procedure to identify, report and assess patient safety in the clinical trial)

Text field, mandatory, max. 5,000 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, max. 10,000 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[1]

[1] 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, <u>provided that the patient has given his/her informed and voluntary consent, the Applicant is obliged to submit one blood sample to the biobank</u> (divided into 4 test tubes / vials). If the Applicant does not plan to collect biological material in the form of whole peripheral blood in the Project, but plans to collect another type of tissue for diagnostic purposes in the clinical trial, provided that the patient has given his/her informed and voluntary consent and the amount of collected material is sufficient, the Applicant is obliged to transfer to the biobank a part of the collected biological material in an amount enabling sequencing of the genome of the sample donor. In both cases, the quality 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 scientific value of the Project (please refer to the Regulations literally).

Please:

• Identify and precisely define the research problem and purpose of the clinical trial

• Justify the correctness of the selection of research methods and tools (methodology)

• Precisely define the final effect of each stage in the form of milestones

Text field, mandatory, min. 1000, max. 5,000 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;
- Saving life and achieving health improvement;
- Preventing premature death;
- Improving the quality of life.

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

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

The correct description and justification should include the identification and description of the current "golden standard" or current medical procedure in the field of therapy/diagnosis of a given condition offered on the national and global markets, fulfilling a function similar to that planned in the clinical trial covered by the Project.

The Application should contain basic information about the search carried out (keywords and descriptors used during the search, time period covered by the search, selected database, e.g. MEDLINE, EMBASE).

The description should provide a justification why the use/implementation of therapeutic/diagnostic solutions contained in the Project would significantly improve the existing and currently used solutions, and should present the features of innovation (breakthrough, so-called 'leap innovation', or incremental, so-called 'linear innovation').

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

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

Comparison of the proposed therapy in terms of costs and health outcomes with the appropriate comparators used in standard treatment (description of the benefits of the therapy used in relation to costs).

- Forecast of expenses and expected health outcomes (short-/long-term) compared to the current standard of treatment

- Assessment of the cost-effectiveness of the proposed technology compared to the standard therapy.

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

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

Please justify in detail:

1) Demand for the results of the Project from the healthcare sector along with the arguments as to why research is needed in the selected target group.

2) How the proposed intervention (both clinical and financial outcomes) would contribute to the increase in the effectiveness of the healthcare system, along with detailed argumentation.

3) Have any barriers been identified (e.g. systemic, financial) that could potentially hinder access of the target patient population to the use of the assessed health technology?

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

Indicators
Number of validated innovative therapeutic (treatment) or diagnostic methods developed as part of non-commercial clinical trials or research experiments
Text field, mandatory, it is possible to enter an integer greater than 0 (at least 1). The field accepts numerical values.
Number of subjects included in a non-commercial clinical trial or research experiment
Text field, mandatory, it is possible to enter an integer greater than 0 (at least 1). The field accepts numerical values.

Number of publications indicating the most clinically effective medical procedures for a given disease used at the same stage of diagnostics or treatment, aimed at optimising clinical practice guidelines
Text field, mandatory, it is possible to enter an integer greater than 0 (at least 1).   The field accepts numerical values.
Number of clinical trials and/or research experiments launched in Poland in accordance with regulatory requirements and MRA standards
Text field, mandatory, it is only possible to enter an integer equal to 1.   The field accepts numerical values.
Number of sites conducting non-commercial clinical trials or research experiments in Poland.
Text field, mandatory, it is possible to enter an integer greater than 0 (at least 1). Enter a value that represents the sum of all sites involved in the trial, including the sponsor.
Number of biobanked samples of biological material[10]
Text field, mandatory, it is possible to enter an integer (including 0).   The field accepts numerical values.
Others
Possibility to add additional indicators (i.e. field pairs: Indicator name and Value, where it is possible to enter an integer greater than 0 in the Value field).   Up to 2 indicators can be added.   When an indicator has been added – the Field accepts numerical values.

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[10] In section II.B.21 of the Application, the Applicant should describe assumptions that were the basis for estimation of the number of samples – e.g. that it is planned to collect samples from at least 70% of the participants (because not all patients consent).

Tab II.C. Project – implementation schedule

Planned project activities and the method of their implementation	Informative text on the Application
In this section, please include the project activities. The obligatory tasks are already defined: • Obtaining a permit to conduct a clinical trial – only for a Clinical Trial type Project • Obtaining medicinal product(s) for the clinical trial – only for a Clinical Trial type Project • Clinical trial management • Implementation of the clinical part **Up to 4 tasks** can be added (a maximum of 8 tasks in total for a Clinical Trial type Project, or a maximum of 6 tasks for a Research Experiment type Project). 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. **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 <u>should not exceed 100 calendar days (for a Clinical Trial type Project)</u>.	

No.	Task list	Repetitive section. In total, a maximum of 8 tasks for a Clinical Trial type Project, and a maximum of 6 tasks for a Research Experiment type Project (4 obligatory tasks for a Clinical Trial type Project and 2 obligatory tasks for a Research Experiment type Project). The Obligatory tasks cannot be deleted + the Editor may add 4 tasks regardless of the type of Project. Tasks not included in the obligatory list, added by the Editor, may be deleted, moved, etc.)
	Task No. …	Mandatory field.
	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 – depending on the type of Project.

For a Clinical Trial type Project	For a Research Experiment type Project
In order: 1. Obtaining an authorisation to conduct a clinical trial 2. Obtaining the medicinal product(s) for the clinical trial 3. Clinical trial management 4. Implementation of the clinical part and the ability to add more, defined by yourself (up to 4, because the maximum is 8)	In order: 1. Clinical trial management 2. Implementation of the clinical part and the ability to add more, defined by yourself (up to 4, because the maximum is 6) Request for the DEV: please make the *value* of these fields the same as the

		value of their counterparts for the clinical trial type (next column)	
		Note: • After selecting the "Project type", the corresponding tasks will appear with a predefined name (four or two, depending on the project type) – immediately with the appropriate milestone names (if applicable). • If the Application Editor changes the "Project type", the items on the list must be synchronised. In this case, tasks with a predefined task name are deleted and created anew at the top of the list. As a consequence, any definitions that may have been introduced will be cleared. However, all other tasks added (except the predefined ones) remain unchanged.	
	Start of the task implementation period	message text: "Task start date before the Project start date" message text: "Task start date after the Project start date" message text: "The start of the task implementation period may not be later than the end of the task implementation period"	
	End of the task implementation period	message text: "Task start date before the Project start date" message text: "Task start date after the Project start date" message text: "The start of the task implementation period may not be later than the 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. In each task, the Applicant may add a minimum of 2 and a maximum of 6 milestones within each task.
	No.	Number for the milestone, completed automatically. The milestones are numbered within a given task,that is, for each task, the numbering of the milestones starts at 1.

		For a Clinical Trial type Project	For a Research Experiment type Project
Name of the milestone	**For the task "Obtaining an authorisation to conduct a clinical trial"**	the milestones are: a. Developing the clinical trial dossier b. Submission of the clinical trial dossier to regulatory authorities c. Obtaining approval for the conduct of the clinical trial from regulatory authorities 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. + Possibility to add a custom milestone (3 more in total, because the maximum is 6)	Not applicable (no task for this type).
	For the task "Obtaining the medicinal product(s) for the clinical trial"	Possibility to add custom milestones (min. 2, max. 6)	Not applicable (no task for this type).
	For the task "Clinical trial management"	Possibility to add custom milestones (min. 2, max. 6)	Possibility to add custom milestones (min. 2, max. 6)

	For the task "Implementation of the clinical part"	the milestones are: a. Inclusion of the first patient in the clinical trial b. Inclusion of half the assumed number of patients in the clinical trial c. Inclusion of the last patient in the clinical trial + Possibility to add a custom milestone (3 more in total, because the maximum is 6) b) and c): The time limit for the conditional payment of the incentive bonus.	the milestones are: a. Inclusion of the first patient in the clinical trial b. Inclusion of half the assumed number of patients in the clinical trial c. Inclusion of the last patient in the clinical trial + Possibility to add a custom milestone (3 more in total, because the maximum is 6) b) and c): The time limit for the conditional payment of the incentive bonus.
	For the remaining tasks (with names entered manually by the Editor)	In each task: possibility to add custom milestones (max. 6, at least 2 are mandatory)	In each task: possibility to add custom milestones (max. 6, at least 2 are mandatory)
Date of reaching the milestone	message text: "Date of reaching the milestone before the start date of a given task" message text: "Date of reaching the milestone after the end date of a given task"		

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]							
If the task is to be implemented within this time frame, the field will be marked with colour or with an X	If the task is to be implemented within this time frame, the field will be marked with colour or with an X	If the task is to be implemented within this time frame, the field will be marked with colour or with an X	If the task is to be implemented within this time frame, the field will be marked with colour or with an X	If the task is to be implemented within this time frame, the field will be marked with colour or with an X	If the task is to be implemented within this time frame, the field will be marked with colour or with an X	If the task is to be implemented within this time frame, the field will be marked with colour or with an X	If the task is to be implemented within this time frame, the field will be marked with colour or with an X
Milestone: [name of the milestone]							

If the milestone is reached within this time frame, the field will be marked with colour or with an X	If the milestone is reached within this time frame, the field will be marked with colour or with an X	If the milestone is reached within this time frame, the field will be marked with colour or with an X	If the milestone is reached within this time frame, the field will be marked with colour or with an X	If the milestone is reached within this time frame, the field will be marked with colour or with an X	If the milestone is reached within this time frame, the field will be marked with colour or with an X	If the milestone is reached within this time frame, the field will be marked with colour or with an X	If the milestone is reached within this time frame, the field will be marked with colour or with an X

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.

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,

- 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	Name of the subsection. Repetitive fields for each task
Task no. [task number]: [task name]	Non-editable field, value entered automatically.
+	Subsection for each cost item in the task.
No.	The item number is completed automatically with the next integer, starting from 1. Cost items are not numbered within a given Task but are numbered within the entire Application, i.e. for each task, the item numbering does NOT start from 1 but is a continuation of item numbering from the previous task.
Cost name	Text field, mandatory, max. 100 characters
Cost category	Mandatory field, single-choice. Selectable values: • Remunerations; • Medical service; • Drug; • Insurance costs; • Medical device; • Other; • CRO involvement; • Purchase of medical equipment, including research infrastructure; • Specialist services commissioned.

Institution to which the cost item is assigned (Applicant / Consortium Member)	Single-choice field. Selection list, containing the name of the Applicant and the names of the Consortium Members defined in the Application. 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, • for the "Purchase of medical equipment, including research infrastructure" category, list the components of the kit (if applicable).
Total cost of the item (PLN)	Mandatory field, maximum 2 decimal places.
Total cost of the task (PLN)	Field completed automatically, non-editable.

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]	[total costs allocated to the Applicant for a given cost category from all tasks. The field presents the amount with exactly 2 decimal places.]	[total costs allocated to all Consortium Member(s) for a given cost category from all tasks. The field presents the amount with exactly 2 decimal places.]	[sum of values from the columns "Applicant" and "Consortium Member" of a given row. The field presents the amount with exactly 2 decimal places.]
Task No. 2: [name of the task]	as above	as above	as above
…. etc.	as above	as above	as above
		Total (PLN):	[Sum of values from the above columns]

Direct costs – actual (PLN)

Non-editable field, value calculated automatically.
It is the sum of all cost categories.
The minimum possible value of the Project – there is no limit.

Indirect costs (PLN)

The flat-rate (%) of indirect costs

15%

Indirect costs (flat-rate)

Non-editable field containing an automatically calculated amount.

Calculation of indirect costs:

Sum of the categories (Remuneration + Medical service + Drug + Insurance costs + Medical device + Other) * 15%. Mathematical rounding to 2 decimal places.

The costs of the following Categories are not included in the indirect costs: CRO involvement, Purchase of medical equipment, including research infrastructure, Specialist services commissioned.

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 depending on the selected Project type (Tab II.A. Project – general data):

- For a Clinical Trial type Project, the value of PLN 200,000.00 (according to the field selected in the "Project type" field in the "Application Details" tab);

- For a Research Experiment type Project, the value of PLN 100,000.00 (according to the field selected in the "Project type" field in the "Application Details" tab);

Total cost of the Project (PLN)

Total cost 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 – there is no limit. The maximum possible value of the Project – PLN 18 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

1. A document confirming the authorisation to submit the Application signed with a qualified electronic signature, in the case of a multi-entity Applicant signed by the Consortium Leader (.PAdES signature format with the use of a graphic symbol).

2. CV of the Principal Investigator / Head of the Research Experiment in accordance with the MRA template from Appendix No. 7 to the Regulation.

3. The Consortium Agreement, signed with a qualified electronic signature by the Consortium Leader and the Consortium Members (.PAdES signature format with a graphic symbol) to a significant extent consistent with the template constituting Annex No. 3 to the Regulation.

4. Draft protocol of the clinical trial or research experiment.

5. Positive opinion of the Ethics Committee for the conduct of the research experiment (obligatory attachment in the case of research experiment projects).

Optional attachments – to be attached as a pdf file

1. Decision approving the conduct of the clinical trial (if already available).
2. Resolution of the Ethics Committee containing an ethical review of the Application to start a clinical trial (if already available).
3. The Statute/KRS or another equivalent document of the Organisation acting for the benefit of patients / Patient Organisation – for Applications submitted in a Consortium with an Organisation acting for the benefit of patients / Patient Organisation.
4. The Statute / KRS or another equivalent document of the Scientific Society – for Applications submitted in a Consortium with a Scientific Society.
5. Other (up to 5).

Tab: V. Declarations

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 no medical device is involved in the planned Project or that the medical device involved in the Project is certified, placed on the market, has the CE mark and is used in the current standard therapy. At the same time, the planned Project is not aimed at assessing the safety or efficacy of the medical device.

6. 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*).

7. 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 2023, items 1270, 1273, 1407, 1429, 1641, 1693, 1872, 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 2a 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 2023, items 1270, 1273,1407, 1429, 1641, 1693, 1872, 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 2b 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.

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. Stanisława Moniuszki 1A, 00-014 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 call for non-commercial clinical trials and research experiments, 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 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, or provide hosting,

cloud or e-mail 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 and assessment.

5. We do not process your personal data in an automated manner, including in the form of profiling.

6. 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 provisions on archiving, the Office Instruction and the Uniform Material List of Files, as well as until any claims are time-barred.

7. You have the right to demand from the Controller access to your personal data, the right to rectify them or limit their processing.

8. You also have the right to object.

9. You have the right to lodge a complaint with the supervisory authority, i.e. the President of the Personal Data Protection Office.

10. 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, 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 will be disseminated to patients.

11. 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. Stanisława Moniuszki 1A, 00-014 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, or provide hosting, cloud or e-mail 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 and assessment.

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, Office Instruction, Uniform Substantive List of Files, or until any claims are time-barred.

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. Providing personal data referred to in item 1 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, 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 will be disseminated to patients.

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.