Załącznik nr 1 do Regulaminu Konkursu

Grant Application Template

Tab: Application record

The application form is completed automatically based on the information entered in the application. The exception is the Project start date, Project end date and indication of the type of the Project which must be completed below. The Applicant is also obliged to fill in the next pages of the application. After completing all fields, use the 'Submit' button and then confirm the operation.	
Program name	Call for enterprises on the financing of development, performance evaluation and clinical assessment of innovative medical devices
Competition short name	WM
Competition number	ABM/2022/2

Application number	
Date application filed	
Project name	
Leader	
Project type	
Projected Project implementation period Please select Project start date and Project end date. Warning: The maximum Project duration is 3 years (36 months) – without clinical trial. The maximum Project duration is 6 years (72 months) – with clinical trial.	
Date from	

Date to	
Consortium Members	
Status of Application	
Clinical trial phase (if applicable)	
International protocol for clinical trial	
Medical device specification	

A. Tab: Basic information on the Project

Project name	
Project type	
Medical device specification	
Clinical trial phase (if applicable)	
International protocol for clinical trial	
Project summary (in Polish)	
Project summary (in English)	

I.B Tab: Applicant

Basic information about Single Applicant/Consortium Leader	Name of section
Full name	
Legal form	
Status of Single Applicant / Consortium Leader	
NIP (Tax Identification Number)	
REGON (National Business Registry Number)	
KRS (National Court Register)	
ePUAP mailbox	
Office e-mail adress	
Registered office adress	Name of subsection
Country	
Street	
Building number	
Flat number	

Postal code	
City/Town	
Municipality	
District	
Voivodeship	
Person authorised to make binding decisions	Name of subsection
Name	
Last name	
Function performed	
Phone number	
e-mail adress	
Contact persons	Name of subsection
Name	
Last name	

Function performend	
Telephon number	
e-PUAP mailbox	
e-mail adress	

Applicant general activities and role in the Project	Name of section
Description of the activities of Single Applicant/ Consortium Leader	

Public aid declarations of the Applicant/Consortium Leader	Name of section
Does the Applicant apply for public aid?	

Does the enterprise apply for public aid for **fundamental research**?	

Does the enterprise apply for public aid for **industrial research**?	
Does the enterprise apply for public aid for **experimental development**?	
Does the enterprise apply for increased intensity of public aid for **industrial research/experimental development**?	

Declarations of the Single Applicant/Consortium Leader on the use of bonuses in the field of industrial research/experimental development	Table name
Does the project involve **effective collaboration**: between undertakings, which are independent of each other, among which at least one is an SME, or is carried out in at least two Member States, or in a Member State and in a Contracting Party of the EEA Agreement, and no single undertaking bears more than 70% of the eligible costs?	
Does the project involve **effective collaboration**: between an undertaking and one or more research and knowledge-dissemination organisations (an organisation which conducts research and spreads knowledge), where the latter bear at least 10% of the eligible costs and have the right to publish their own research results?	
Are the results of the **project widely disseminated** and within 3 years from the completion of the project:	
• through at least 3 scientific and technical **conferences**, of which at least 1 will be a national conference?	

• through **publications** in at least 2 scientific or technical journals (included in the list of journals published by the Ministry of Science and Higher Education (MNiSW), valid as at the date on which the article is accepted for publication)?	
• through **open access repositories** - they will be publicly available in databases ensuring free access to the test results obtained (raw research data)?	
• trough **free-of-charge software or open source software**?	

Does the Single Applicant/Consortium Leader apply for public aid for **advisory services** for SMEs?	

Will the Single Applicant/Consortium Leader incur Indirect expenses/Flat rate 5%	

Public aid description	Name of section
Description of public aid for which the entity applies	
Public aid received in respect of the same eligible costs related to the Project described in the application	

Description of the connection between the project and other Projects of the entity	

II.B Tab: Consortium Members

Consortium Members	Name of section
Consortium Member	
No.	
Full name	
Legal form	
Status of Consortium Member	
NIP (Tax Identification Number)	
REGON (National Business Registry Number)	
KRS (National Court Register)	

Adress	Name of subsection
Country	
Street	
Building number	
Flat number	
Postal code	
City/Town	
Municipality	
District	
Voivodeship	
Person authorised to make binding decisions	Name of subsection
Name	

Last Name	
Function performed	
Telephone number	
e-mail adress	
Contact persons	Name of subsection
Name	
Last name	
Function performed	
Telephone number	
e-mail adress	

Consortium Member general activities and role in the Project	Name of section
Description of activities of the Consortium Member	
Description of the selection of the Consortium Member and its role in the Project	

Public aid declarations of Consortium Member	Name of section
Does the Consortium Member apply for public aid?	

Does the Consortium Member apply for public aid for **fundamental research**?	

Does the Consortium Member apply for public aid for **industrial research**?	
Does the Consortium Member apply for public aid for **experimental development**?	

Does the Consortium Member apply for increased intensity of public aid for **industrial research/experimental development**?	

Declarations of the Consortium Member on the use of bonuses in the field of industrial research/experimental development	Table name
Does the project involve **effective collaboration**: between undertakings, which are independent of each other, among which at least one is an SME, or is carried out in at least two Member States, or in a Member State and in a Contracting Party of the EEA Agreement, and no single undertaking bears more than 70% of the eligible costs?	
Does the project involve **effective collaboration**: between an undertaking and one or more research and knowledge-dissemination organisations (an organisation which conducts research and spreads knowledge), where the latter bear at least 10% of the eligible costs and have the right to publish their own research results?	
Are the results of the **project widely disseminated** and within 3 years from the completion of the project:	
• through at least 3 scientific and technical **conferences**, of which at least 1 will be a national conference?	
• through **publications** in at least 2 scientific or technical journals (included in the list of journals published by the	

Ministry of Science and Higher Education (MNiSW), valid as at the date on which the article is accepted for publication)?	
• through **open access repositories** - they will be publicly available in databases ensuring free access to the test results obtained (raw research data)?	
• trough **free-of-charge software or open source software**?	

Does the Consortium Member apply for public aid for **advisory services** for SMEs?	

Will the Consortium Member incur Indirect expenses/Flat rate 5%	

Public aid description	Nazwa sekcji
Description of public aid for which the entity applies	
Public aid received in respect of the same eligible costs related to the Project described in the application	
Description of the connection between the Project and other Projects of the entity	

C. Tab: Project location

Please select minimum 1 location for Single Applicant/Consortium Leader and each Consortium Member.	

Project location	Table name
Name of entity	
Voivodeship	
District	
Municipality	

D. Tab: Description and justification of the implementation of the Project

Purpose of the Project	
Description of current knowledge regarding the designed solution, including the results of preliminary tests obtained by the Applicant (state-of-the-art)	
Description of scientific and technological risks	
Description of market potential of the solution to be implemented in the future	
Description of functionality and mechanism of action	
Comparative technologies (if applicable)	

Description of the impact of the Project on the improvement of public health, including: - life saving and achieving full recovery; - life saving and improving health condition; - preventing early deaths; - improving the quality of life.	
The planned way of establishing and verifying the clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements.	
Demonstrating the lack of barriers to the implementation/ commercialization of the results of R&D works	
Expected class of the device	
Describe rules/rule of classification applicable to device	
Relevant existing standards, common specifications, guidelines (e.g. harmonised European standards, WHO international standards, best practice documents) applicable to device	
Regulatory strategy with timeline	
The planned way of establishing and verifying the clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements	
The planned way of establishing and verifying the scientific validity, analytical performance and, where applicable, clinical performance of the device (outline of performance evaluation plan)	

E. Tab: The Applicant's potential to implement the Project (Single Applicant or Consortium Leader and Consortium Members)

Human resources necessary for the implementation of the Project at the Applicant's disposal – the experience of management staff	
Human resources necessary for the implementation of the Project at the Applicant's disposal or necessary for hiring – the experience of R&D team	
Human resources necessary for the implementation of the Project at the Applicant's disposal – the experience of administrative staff	
Technical resources necessary for the implementation of the Project at the Applicant's disposal – real estate	
Technical resources necessary for the implementation of the Project at the Applicant's disposal – machines and devices	
Intangible assets necessary for the implementation of the Project at the Applicant's disposal	
Standards applied by the Applicant – including GLP, GMP, ISO or other	
Documentation of potential for commercialization – e.g. patents, other proof of implementation (if applicable)	

F. Tab: Innovation and intellectual property rights

Innovative character of the Project	
Description of current technology advancement	
Owner of rights to Project results	
Description of the potential use of the Project outcomes in the healthcare system	
Comparison of the proposed solution in terms of costs and health outcomes with appropriate comparative technology currently	

used as a standard of care (benefits of applied treatment in relation to costs)	
Economic rationale for technology implementation – health care system perspective	
Economic rationale for technology implementation – company perspective	

G. Tab: Project stages

In this part, please include planned project activities and their implementation method. A maximum of ten stages may be added. Each stage can consist of minimum 1 task and of maximum 5 tasks. This module is a table to be completed. It is necessary to add separate items for each stage.	
Project activities	Name of section
Stage No…	
Stage name	
Type of work	
Entity responsible for performing the stage	
Beginning of execution period	
Completion of execution period	

Tasks	Name of subsection
Task name	

Description of tasks work to be performed as part of the stage	

Milestone name – enter milestone name. **Parameter value** – enter numbers only. Rounding up to 2 decimal places is permitted. Decimal separator ',' (comma). **Parameter unit of measurement** – a unit of measure should be determined, e.g. pcs., kg, m2. **Please note that there must be minimum 1 milestone and maximum 5 milestones per task added**.	
Description of final task results – milestones	Table name

No.	Milestone for particular task	Parameter value	Parameter unit of measurement
…			
…			

Infrastructure/apparatus intended to be purchased or produced as part of the Project	Name of subsection

Infrastructure/apparatus held	Table name

Name	
Intended use	

Infrastructure/apparatus intended to be purchased or produced as part of the Project	Table name
Name	
Intended use	

Stage description	Name of section
Final results to be archived	
Risks/threats/limitations	
Assessment of safety and identification of risks (description of the procedure for identification, reporting and assessment of safety)	
The purchased R&D infrastructure be made available to other entrepreneurs and scientific institutions on preferential terms (if applicable)	
Description of subcontracting (if applicable)	
Description of conformity with the relevant general safety and performance requirements.	
Description of the clinical investigation including: • Study design: randomised controlled trial, other pivotal trial, short-term feasibility study, other; and the duration of the follow-up • Primary and secondary endpoint(s) • Inclusion/exclusion criteria for subject selection • Number of enrolled subjects	

• Study population: main baseline characteristics of each study group, including gender and age of enrolled subjects • Summary of study methods	

H. Tab: Work Schedule

Work schedule – Gantt Chart	Name of section

[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]	[quarter] / [year] or [year]
Stage no. [no. of stage]: [Stage name]							

I.I Tab: Project budget

Calculation of the cost for the Project	Name of section
This part of the application defines the anticipated costs for each pre-defined Stage.	

If any Stage involves no costs, the entry accompanying the Stage may be deleted. If the Stage involves more cost items, new lines may be added to the respective Stage. For the costs provided, provide: • Name of cost • Cost category • Entity to which cost item is assigned (Single Applicant/Consortium Leader/Consortium Member) • Rate/unit price • Unit of measurement – a field defining the measurement unit of the cost (e.g. hour, examination, piece) • Number – field defining the number of instances of the cost • Description of how the cost is calculated – describe how the calculation has been made. The description of how the cost is to be calculated should refer to the values provided in the following fields: rate/unit price, unit of measurement, number, total cost of the item. Please describe in detail how the calculation has been made. Please provide a precise description of the method of calculation that will confirm the unit rate to the total value of the budget item. • Nature of support - whether the support is covered by the rules of public aid, if yes, in the field select "Public aid", if not select "Not applicable". • VAT within eligible amount (PLN) • % of funding – should be selected from 0% to 100% bearing in mind that the intensity of support depends in particular on the size of the enterprise and the type of work (Fundamental research, industrial research, Experimental development, advisory services) - applies to entities defined as entrepreneurs. Other entities (meeting the definition of a research and knowledge-dissemination organisation) select 100%.	

• Information on how the total cost is distributed across the particular years of Project execution – combined cost of the Stage shall be divided into particular time ranges. For the ranges in which no cost will be incurred, enter 0. Please make sure that the proposed expenditures are justified in the presented schedule of Stages under the Project. Should "kit" be selected as the unit of measurement, the description of the calculation should list the items comprising the kit. You can add maximum of 100 cost items.	

Budget of stage	Name of subsection. Fields repeatable for each stage
Stage no. [Stage number]: [Stage name]	
Type of work	

+	Subsection for each cost item in the Stage. Possibility of adding a new cost item using "+"
No.	
Name of cost	
Cost category	
Entity, to which cost item is assigned (Single Applicant/Consortium Leader/Consortium Member)	
Rate/unit price	
Unit of measurement	
Other – provide name	
Number	
Description of how the cost is calculated	
Nature of support	
Value of eligible cost /item (PLN)	

VAT within eligible amount (PLN)	
% of funding	
Funding (PLN)	
Own contribution (PLN)	

Cost, by year	Name of subsection
Please provide the total cost of item, by year.	
Rate/unit price	
Number	
Eligible cost (PLN)	
Sum of the numbers from each year	

Sum of values from each year (Eligible cost (PLN))	
Eligible cost of the stage (PLN)	

II.I Tab: Project summary

After making changes to the 'II.I Project budget' section, the Budget summary must be recalculated. Please use the button 'Recalculate summary' and check all the values. Before submitting your application, please make sure that all values are correct.

Recalculate summary

Total budget of the Project Single Applicant/Consortium Leader by source of funding and type of work	Table name

Type of work	**Cost category**	**Single Applicant / Consortium Leader:**			
		Eligible cost (PLN)	**Funding (PLN)**	**Own contribution (PLN)**	**% of funding**

fundamental research	Remuneration	0,00	0,00	0,00	0,00
	Subcontracting costs	0,00	0,00	0,00	0,00
	Costs of instruments and equipment	0,00	0,00	0,00	0,00
	Costs of buildings and lands	0,00	0,00	0,00	0,00
	Other direct costs	0,00	0,00	0,00	0,00
	Costs of licenses to use/manufacture elements of a medical device	0,00	0,00	0,00	0,00
	Indirect expenses/Flat rate 5%	0,00	0,00	0,00	0,00
Total value for fundamental research (PLN)		0,00	0,00	0,00	0,00
industrial research	Remuneration	0,00	0,00	0,00	0,00
	Subcontracting costs	0,00	0,00	0,00	0,00
	Costs of instruments and equipment	0,00	0,00	0,00	0,00
	Costs of buildings and lands	0,00	0,00	0,00	0,00
	Other direct costs	0,00	0,00	0,00	0,00
	Costs of licenses to use/manufacture elements of a medical device	0,00	0,00	0,00	0,00

	Indirect expenses/Flat rate 5%	0,00	0,00	0,00	0,00
Total value for industrial research (PLN)		0,00	0,00	0,00	0,00
experimental development	Remuneration	0,00	0,00	0,00	0,00
	Subcontracting costs	0,00	0,00	0,00	0,00
	Costs of instruments and equipment	0,00	0,00	0,00	0,00
	Costs of buildings and lands	0,00	0,00	0,00	0,00
	Other direct costs	0,00	0,00	0,00	0,00
	Costs of licenses to use/manufacture elements of a medical device	0,00	0,00	0,00	0,00
	Indirect expenses/Flat rate 5%	0,00	0,00	0,00	0,00
Total value for experimental development (PLN)		0,00	0,00	0,00	0,00
advisory services	Subcontracting costs	0,00	0,00	0,00	0,00
Total value for advisory services (PLN)		0,00	0,00	0,00	0,00
Total value (PLN)		0,00	0,00	0,00	0,00

Total budget of the Project Consortium Member no., by source of funding and type of work	Table name

Type of work	**Cost category**	**Consortium Member no. ...:**			
		Eligible cost (PLN)	**Funding (PLN)**	**Own contribution (PLN)**	**% of funding**
fundamental research	Remuneration	0,00	0,00	0,00	0,00
	Subcontracting costs	0,00	0,00	0,00	0,00
	Costs of instruments and equipment	0,00	0,00	0,00	0,00
	Costs of buildings and lands	0,00	0,00	0,00	0,00
	Other direct costs	0,00	0,00	0,00	0,00
	Costs of licenses to use/manufacture elements of a medical device	0,00	0,00	0,00	0,00
	Indirect expenses/Flat rate 5%	0,00	0,00	0,00	0,00
Total value for fundamental research (PLN)		0,00	0,00	0,00	0,00
industrial research	Remuneration	0,00	0,00	0,00	0,00
	Subcontracting costs	0,00	0,00	0,00	0,00

	Costs of instruments and equipment	0,00	0,00	0,00	0,00
	Costs of buildings and lands	0,00	0,00	0,00	0,00
	Other direct costs	0,00	0,00	0,00	0,00
	Costs of licenses to use/manufacture elements of a medical device	0,00	0,00	0,00	0,00
	Indirect expenses/Flat rate 5%	0,00	0,00	0,00	0,00
Total value for industrial research (PLN)		0,00	0,00	0,00	0,00
experimental development	Remuneration	0,00	0,00	0,00	0,00
	Subcontracting costs	0,00	0,00	0,00	0,00
	Costs of instruments and equipment	0,00	0,00	0,00	0,00
	Costs of buildings and lands	0,00	0,00	0,00	0,00
	Other direct costs	0,00	0,00	0,00	0,00
	Costs of licenses to use/manufacture elements of a medical device	0,00	0,00	0,00	0,00
	Indirect expenses/Flat rate 5%	0,00	0,00	0,00	0,00
Total value for experimental development (PLN)		0,00	0,00	0,00	0,00

advisory services	Subcontracting costs	0,00	0,00	0,00	0,00
Total value for advisory services (PLN)		0,00	0,00	0,00	0,00
Total value (PLN)		0,00	0,00	0,00	0,00

Total budget of the Project, by source of funding and type of work	Table name

Type of work	**Cost category**	**Total value (PLN):**		
		Eligible cost (PLN)	**Funding (PLN)**	**Own contribution (PLN)**
fundamental research	Remuneration	0,00	0,00	0,00
	Subcontracting costs	0,00	0,00	0,00
	Costs of instruments and equipment	0,00	0,00	0,00
	Costs of buildings and lands	0,00	0,00	0,00
	Other direct costs	0,00	0,00	0,00
	Costs of licenses to use/manufacture elements of a medical device	0,00	0,00	0,00

	Indirect expenses/Flat rate 5%	0,00	0,00	0,00
Total value for fundamental research (PLN)		0,00	0,00	0,00
industrial research	Remuneration	0,00	0,00	0,00
	Subcontracting costs	0,00	0,00	0,00
	Costs of instruments and equipment	0,00	0,00	0,00
	Costs of buildings and lands	0,00	0,00	0,00
	Other direct costs	0,00	0,00	0,00
	Costs of licenses to use/manufacture elements of a medical device	0,00	0,00	0,00
	Indirect expenses/Flat rate 5%	0,00	0,00	0,00
Total value for industrial research (PLN)		0,00	0,00	0,00
experimental development	Remuneration	0,00	0,00	0,00
	Subcontracting costs	0,00	0,00	0,00
	Costs of instruments and equipment	0,00	0,00	0,00
	Costs of buildings and lands	0,00	0,00	0,00

	Other direct costs	0,00	0,00	0,00
	Costs of licenses to use/manufacture elements of a medical device	0,00	0,00	0,00
	Indirect expenses/Flat rate 5%	0,00	0,00	0,00
Total value for experimental development (PLN)		0,00	0,00	0,00
advisory services	Subcontracting costs	0,00	0,00	0,00
Total value for advisory services (PLN)		0,00	0,00	0,00
Total value (PLN)		0,00	0,00	0,00

Total budget of the Project, by eligible costs	Table name

Cost category	**Single Applicant / Consortium Leader (PLN):**	**Consortium Member no. ... (PLN):**	**Total value (PLN):**
Remuneration	0,00	0,00	0,00
Subcontracting costs	0,00	0,00	0,00
Costs of instruments and equipment	0,00	0,00	0,00

Costs of buildings and lands	0,00	0,00	0,00
Other direct costs	0,00	0,00	0,00
Costs of licenses to use/manufacture elements of a medical device	0,00	0,00	0,00
Indirect expenses/Flat rate 5%	0,00	0,00	0,00
Total value (PLN):	0,00	0,00	0,00

Total budget of the Project, by cost category and by type of work	Table name

Cost category	**fundamental research (PLN):**	**industrial research (PLN):**	**experimental development (PLN):**	**advisory services (PLN):**	**Total value (PLN):**
Remuneration	0,00	0,00	0,00	0,00	0,00
Subcontracting costs	0,00	0,00	0,00	0,00	0,00

Costs of instruments and equipment	0,00	0,00	0,00	0,00	0,00
Costs of buildings and lands	0,00	0,00	0,00	0,00	0,00
Other direct costs	0,00	0,00	0,00	0,00	0,00
Costs of licenses to use/manufacture elements of a medical device	0,00	0,00	0,00	0,00	0,00
Indirect expenses/Flat rate 5%	0,00	0,00	0,00	0,00	0,00
Total value (PLN):	0,00	0,00	0,00	0,00	0,00

Total budget of the Project, by Stage	Table name

Stage number	**Single Applicant / Consortium Leader (PLN):**	**Consortium Member no. … (PLN):**	**Total value (PLN):**
Stage no. …	0,00	0,00	0,00

Indirect expenses/Flat rate 5%	0,00	0,00	0,00
Total value (PLN):	0,00	0,00	0,00

Total budget of the Project (eligible costs), by Stage, broken down by years	Table name

Stage number	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**Total value (PLN):**
Stage no. …	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
Stage no. …	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
Stage no. …	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
Stage no. ...	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
Total value (PLN):	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00

Value of direct eligible costs (PLN)

Value of direct eligible costs (PLN)

Including VAT (PLN)

Including VAT (PLN)

VAT – ineligible. Please enter the value 0,00.

Indirect expenses (PLN)

Indirect expenses (PLN)

Funding support applied for (PLN)

Funding support applied for (PLN)

Own contribution (PLN)

Own contribution (PLN)

Total Project value (PLN)

Total Project value (PLN)

J. Tab: Commercialization of Project results

Information on commercialization	Name of section
Description of commercialization	
Expected commercialization date	

Declarations on commercialization	Name of section
Introduction of Project results to the Single Applicant/Consortium Leader's own enterprise (in the Consortium - min. 1 Consortium Member being an enterprise) through launching serial production of the device and placing it on the market.	checkbox

Granting a license (on market terms) for the use of the Single Applicant/Consortium rights to the project results in business activities conducted by other enterprise with the obligation of such third party to manufacture and place the device on the market.	checkbox
Sale (on market terms) of the rights to project results in order to introduce them into the economic activity of another enterprise, with the obligation of such third party to manufacture and place the device on the market, and with the provision that the sale of these results for the purpose of their further resale shall not be regarded as commercialization of the results.	checkbox
Is the commercialization of the project results planned on the territory of the Republic of Poland?	checkbox

K. Tab: Indicators

Indicators for the project duration	Table name

Indicator	**Target value**	**Target value achievement year**
Number of enterprises receiving the funding		

Number of completed R&D works		
Number of developed and implemented analytical methods for the product quality control associated with the medical device release		
Number of national and/or foreign consortia established to implement the project		
Publications, conference abstracts		

L. Tab: Statements

General statements	Name of section	
I represent that: I am aware of criminal liability for providing false information or making false statements.	**YES/NO**	
I represent that: the information contained in this Grant Application is true.	**YES/NO**	
I represent that: I represent that the Project is compliant with the applicable regulations of EU and national law, including those governing public procurement and public aid.	**YES/NO**	
I represent that: I am aware that the content of this Grant Application with appendices may be made available to other institutions and experts performing assessments, evaluations and inspections, and I hereby undertake to take part in any evaluation measures necessary to assess the Programme.	**YES/NO**	
I represent that:	**YES/NO**	

the application submitted via the system constitutes a statement of intent of the Applicant, and the information contained therein and the documents attached thereto is compliant with the facts and the legal framework.		
I represent that: 1) if the funding for the implementation of a project has been granted, it does not result in a violation of the principle of prohibition of double funding, meaning that the same expenditure cannot be reimbursed, in whole or in part, from public funds (EU or national) twice; 2) the tasks covered by the application are not financed from any other sources and the applicant does not apply for funding from other sources.	**YES/NO**	
I represent that: the subject of pre-implementation work does not constitute an activity excluded from aid based on the regulations listed in Article 1 of Regulation 651/2014.	**YES/NO**	
I represent that: the project has not begun and will not begin earlier than on the day following the date of submission of this Grant Application.	**YES/NO**	
I represent that: no conflict of interest occurs during the implementation of the project, i.e.: the R&D manager, project manager and persons performing duties in their stead are not at the same time contractors of any work on the part of the subcontractor, including any other form of cooperation with the subcontractor (concerns employment relationship, civil law relations or other forms of cooperation) and the remaining R&D staff and project management staff does not perform the same project work on the part of the applicant and the subcontractor at the same time.	**YES/NO**	
I represent that: Pursuant to Article 105(4a) and 105(4a)' of the Act of 29 August 1997 – Banking Law in conjunction with Article 13 of the Act of 9 April 2010 on Disclosure of Business Information and Exchange of Business Data, I hereby authorize the Medical Research Agency to submit, on behalf of the applicant/consortium members whom I represent, through Biuro Informacji Gospodarczej InfoMonitor S.A. with its registered office in Warsaw, at Biuro Informacji Kredytowej S.A. and the Polish Bank Association, an unlimited authorization to make available economic data processed by these institutions, to the extent necessary to assess payment reliability and credit risk for the purpose of their disclosure by Biuro Informacji Gospodarczej InfoMonitor S.A. with its registered office in Warsaw to the Medical Research Agency.	**YES/NO**	

I represent that: 1) **Products developed in the project or medical device subject to clinical evaluation** in the project will be or are medical devices within the meaning of article 2 of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC and are or will be classes IIa, IIb or III medical devices according to the classification in the Annex VIII of the Regulation. 2) All my actions regarding medical devices being developed in the project or medical devices subject to clinical evaluation in the project will comply with requirements of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.	**YES/NOT APPLICABLE**	
I represent that: 1) **Products developed in the project or in vitro diagnostic medical device** subject to performance evaluation in the project will be or are in vitro diagnostic medical device within the meaning of article 2 of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU and are or will be classes B, C or D medical devices according to the classification in the Annex VIII of the Regulation. 3) All my actions regarding in vitro diagnostic medical device being developed in the project or in vitro diagnostic medical device subject to performance evaluation in the project will comply with requirements of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.	**YES/NOT APPLICABLE**	
I hereby represent that:		

the required consents / positive opinions / permits / approvals of relevant bioethics and ethics commission and competent committee will be obtained, if the project covers clinical investigations:		
– which are medical experiments within the meaning of Article 21 of the Act of 5 December 1996 on the Profession of Doctor and Dentist;	**YES/NO**	
– which are pre-clinical investigations;	**YES/NO**	
– which are clinical investigations referred to in article 62 of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC;	**YES/NOT APPLICABLE**	
– which are performance study referred to in article 66 of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU;	**YES/NOT APPLICABLE**	
– requiring animal experiments;	**YES/NO**	
– on species of plants, animals and fungi under species protection or in protected areas;	**YES/NO**	
– on genetically modified organisms or using such organisms.	**YES/NO**	
I agree to provide information for the purposes of evaluations carried out by the ABM, UOKiK or another authorized entity.	**YES/NO**	
I represent that: an effective consortium agreement has been concluded, the wording of which is compliant with the guidelines provided for in the Regulations of the Competition.	**YES/NOT APPLICABLE**	

Single Applicant statements	Name of section
I represent that: the tasks covered by the application are not funded or applied from public funding from other sources.	**YES**
I represent that: the entrepreneur which applies for funding is not in arrears with payment of taxes or contributions to social and health security, the Labour Fund, the State Fund for Rehabilitation of Disabled People, or other mandatory charges required by specific regulations.	**YES**
I represent that: I am entitled to represent the beneficiary in the scope covered by the application.	**YES**
I represent that: I represent that the entity which applies for funding support is not subject to exclusion from the possibility of receiving funding support, including the exclusion referred to in Article 207(4) of the Act of 27 August 2009 on Public Finance (uniform text: Journal of Laws no. 2021, item 305, 1236, 1535, 1773, 1927, 1981, 2054, 2270).	**YES**
I represent that: I have read the Regulations and I fully accept its terms and conditions as well as the content of the funding agreement.	**YES**
I represent that: the Grant Application does not violate any rights of third parties and there are no legal obstacles to the submission of the Application or the implementation of the Project in accordance with the Grant Application, in particular, I represent that no other agreements or contracts have been concluded which would prevent or limit the participation of the Applicant in the Project covered by the Grant Application.	**YES**

I represent that: I have read the information clause (“Information clause for the Applicant”) and hereby undertake, on behalf of the Data Controller (the Medical Research Agency), to meet the notification obligation towards all individuals whose details are contained in the Grant Application (“Information clause for natural persons identified by the Applicant in the application”).	**YES**
I represent that: no court, administrative, enforcement, fiscal or criminal tax proceedings are pending against the Applicant, the outcome of which may affect the performance of the tasks specified in the Grant Application.	**YES**

Multiple Applicant statements	Name of section
I represent that: The Leader and Consortium Members do not fund and do not apply for public funding from other sources for the tasks covered by the application.	**YES**
I represent that: The Leader and Consortium Members are not in arrears with payment of taxes or contributions to social and health security, the Labour Fund, the State Fund for Rehabilitation of Disabled People, or other mandatory charges required by specific regulations.	**YES**
I represent that: I am authorised to represent the Applicant within the scope covered by the Grant Application and to submit this Application for and on behalf of the Leader and all Consortium members.	**YES**

I represent that: The Leader and Consortium Members have read the Regulations and they fully accept its terms and conditions as well as the content of the funding agreement.	**YES**
I represent that: the Grant Application does not violate any rights of third parties and there are no legal obstacles to the submission of the Application or the implementation of the Project in accordance with the Grant Application, in particular, I represent that no other agreements or contracts have been concluded, except for a consortium agreement, which would prevent or limit the participation of the Leader and Consortium Members in the Project covered by the Grant Application.	**YES**
I represent that: The Leader and Consortium Members have read the information clause ("Information clause for the Applicant") and hereby undertake, on behalf of the Data Controller (the Medical Research Agency), to meet the notification obligation towards all individuals whose details are contained in the Grant Application ("Information clause for natural persons identified by the Applicant in the application").	**YES**
I represent that: no court, administrative, enforcement, fiscal or criminal tax proceedings are pending against the any of the Consortium members, the outcome of which may affect the performance of the tasks specified in the Grant Application.	**YES**
I represent that: an effective consortium agreement has been concluded, the content of which is compliant with the minimum provisions contained in the template of the Consortium Agreement.	**YES**

Information clause for the Applicant	Name of section

Under 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) – GDPR (OJ L 119/1 of 4/05/2016), we hereby inform you that:

1) The Controller of your personal data is the Medical Research Agency, based in Warsaw 00-014, S. Moniuszki 1A,
2) The Controller has appointed a Data Protection Officer who can be contacted at the following e-mail address: iod@abm.gov.pl.
3) Your personal data are processed for the following purposes:
    a) take all steps prior to entering into a contract, to process the conclusion and performance of a contract for the execution and funding support for the Project under Article 6(1)(b) GDPR,
    b) evaluation of the application submitted in the competition titled "Development of innovative therapeutic solutions using RNA technology", and if funding support is granted, project evaluation, inspection, audit, assessment of information and promotional measures, its acceptance, assessment and financial settlement, and building resources of the clinical research search engine, which will provide patients with information about clinical research that has been given a positive opinion by the Bioethics Committee and consent from the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, within the scope necessary to perform tasks connected with the search engine and in order to conduct the search engine statistical analyses, based on Article 6(1)(e) 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 the Act of 21 February 2019 on the Medical Research Agency (Journal of Laws of 2020, item 2150) and Article 6(1)(c) GDPR, the need to fulfil legal obligations arising from the provisions of law,

c) protection of legitimate interest of the Controller, i.e. potential establishment or investigation of, or defence against, claims based on Article 6(1)(f) GDPR.

4) Your personal data may be processed for the purpose of the proceeding of providing you with public aid in accordance with Article 6(1)(c) GDPR.
5) Your personal data may be made available to public authorities and offices or other entities authorised in compliance with the law in force or performing tasks carried out in the public interest or in the exercise of official authority. Your personal data may be made available to entities that operate the controller's ICT systems or provide ICT tools, and provide the controller with hosting, cloud services or postal services, as well as institutions and experts that carry out evaluation or assessment.
6) We do not process your personal data in an automated way, including in the form of profiling.
7) Your personal data shall be processed for the period necessary for the assessment of your application, and, in case you are awarded funding, for the period of the contract implementation, supervision of the project implementation, its receipt, financial assessment and accounting, project evaluation, supervision and audit, and informational-promotional assessment unless it is necessary to process the data for a prolonged period, e.g. due to archiving obligations or claims barred by statute of limitations.
8) You have the right to request the Controller to provide you with access, rectify, restrict the processing of your personal data, and the right to data portability.
9) You also have the right to raise an objection.
10) You have the right to lodge a complaint with a supervisory authority, i.e. President of the Personal Data Protection Office.
11) Provision of personal data is required to assess the application. Refusal to provide personal data shall result in inability to assess the application and select it as one to be used in connection with the implementation of the project, to enter into a

contract, to implement the project and finance it, to supervise its implementation, to evaluate, supervise and audit it, to assess informational-promotional activities, to allow its receipt, and financial evaluation and accounting, or to build resources of the clinical research search engine, which will provide patients with information about clinical research that has been given a positive opinion by the Bioethics Committee and consent from the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. Failure to provide the data will result in the inability to obtain public aid.

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 identified by the Applicant in the application	Name of section

In compliance with Art. 14 of the 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 – GDPR, OJ L 119 of 2016), we hereby inform that:

1) The Controller of personal data of the natural persons indicated by the Applicant is the Medical Research Agency, based in Warsaw 00-014, S. Moniuszki 1A.
2) The personal data of the persons referred to in paragraph 1 have been obtained from our Applicant.
3) The Controller has appointed a Data Protection Officer who can be contacted at the following e-mail address: iod@abm.gov.pl.
4) The personal data of the persons referred to in para 1 will be processed by the Controller based on:

a) Article 6(1)(b) GDPR, performing all activities that fall within the conclusion and implementation of the Agreement prior to the implementation of the Agreement;
b) Article 6(1)(e) GDPR, in conjunction with the Act of 21 February 2019 on the Medical Research Agency (Journal of Laws of 2020, item 2150), 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;
c) Article 6(1)(c) GDPR, the need to fulfil legal obligations resulting from legal provisions;
d) Article 6(1)(f) GDPR, protection of legitimate interest of the Controller, i.e. potential establishment or investigation of, or defence against, claims.

5) The data categories include ordinary data – first name, last name, job or function, place of work, job e-mail, telephone number, fax number, educational background, academic degree, professional experience.
6) Your personal data may be made available to public authorities and offices or other entities authorised in compliance with the law in force or performing tasks carried out in the public interest or in the exercise of official authority. Your personal data may be made available to entities that operate the controller's ICT systems or provide ICT tools, and provide the controller with hosting, cloud services or postal services, as well as institutions and experts that carry out evaluation or assessment.
7) The Controller will not make automated decisions based on the personal data of the persons referred to in para. 1, including any decisions resulting from profiling within the meaning of the GDPR.
8) Your personal data shall be processed for the period necessary for the assessment of your application, and, in case you are awarded funding, for the period of the contract implementation, supervision of the project implementation, its receipt, financial assessment and accounting, project evaluation, supervision and audit, and informational-promotional assessment unless it is necessary to process the data for a prolonged period, e.g. due to archiving obligations or claims barred by statute of limitations.

9) Those mentioned in para 1 have the right to request the Controller to access, rectify, delete or restrict the processing of their personal data, and the right to data portability.
10) Those mentioned in para 1 shall also have the right to raise an objection.
11) Those mentioned in para 1 have the right to lodge a complaint with a supervision authority, i.e. the President of the Personal Data Protection Office.
12) Provision of personal data is required to assess the application. Refusal to provide personal data shall result in inability to assess the application and select it as one to be used in connection with the implementation of the project, to enter into a contract, to implement the project and finance it, to supervise its implementation, to evaluate, supervise and audit it, to assess informational-promotional activities, to allow its receipt, and financial evaluation and accounting, or to build resources of the clinical research search engine, which will provide patients with information about clinical research that has been given a positive opinion by the Bioethics Committee and consent from the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. Failure to provide the data will result in the inability to obtain public aid.
13) Data of the persons mentioned in para 1 shall not be transferred to a third country/ international organization, unless the Controller is required to do so by law.

M. Tab: Appendices

Mandatory appendices – to be attached as pdf files

1. **Document confirming the authorisation to submit an application, signed with a qualified electronic signature, in the case of a Multiple Applicant signed by the Consortium Leader (.pades signature with a graphic symbol).**

.PAdES signature format with a graphic symbol. The allowed format of attachments is .pdf; maximum attachment size: 5 MB. Please attach the current KRS excerpt if the authorization results from it. There is no need to sign KRS excerpt.

2. **Document confirming holding own contribution (separate for each Single Applicant/ Consortium Leader and Consortium Members applying for public aid and declaring own contribution) in the required amount, signed with a qualified electronic signature (.pades signature with a graphic symbol).**

.PAdES signature format with a graphic symbol. The allowed format of attachments is .pdf; maximum attachment size: 5 MB.

3. **Statement of the status of entrepreneur/institution (separate for each Single Applicant/Consortium Leader and Consortium members). Declaration on the template attached to the Competition Regulations – signed with a qualified electronic signature (.pades signature with a graphic symbol).**

.PAdES signature format with a graphic symbol. The allowed format of attachments is .pdf; maximum attachment size: 5 MB.

4. **Financial situation of the Single Applicant and Consortium Members (together with the Consortium Leader) that apply for public aid – financial statements for the last three reporting periods, signed with a qualified electronic signature by individual entities submitting them (.pades signature with a graphic symbol). In some cases, micro and small enterprises are only required to submit declarations that they are not required to prepare financial statements or submit financial statements under the competition.**

.PAdES signature format with a graphic symbol. The allowed format of attachments is .pdf; maximum attachment size: 5 MB.

5. **Consortium Agreement signed with a qualified electronic signature of the Consortium Leader and other Consortium Members (.pades signature with a graphic symbol) – if applicable. The consortium agreement must be substantially compliant with the template attached to the Competition Regulations.**

   .PAdES signature format with a graphic symbol. The allowed format of attachments is .pdf; maximum attachment size: 5 MB.

6. **Statement of revenue from the sale of products. Declaration on the template attached to the Competition Regulations, signed with a qualified electronic signature (.pades signature with a graphic symbol).**

   .PAdES signature format with a graphic symbol. The allowed format of attachments is .pdf; maximum attachment size: 5 MB.

7. **Form with information presented when applying for public aid, submitted on a template attached as an Appendix to the Regulations of the Competition, filled out by Single Applicant/Consortium Leader and each Consortium Member separately – signed with a qualified electronic signature (.pades signature with a graphic symbol)**

.PAdES signature format with a graphic symbol. The allowed format of attachments is .pdf; maximum attachment size: 5 MB.

Additional Appendices – to be attached as pdf files

1. **EU declaration of conformity of medical device/ in vitro diagnostic medical device** (if applicable)

   .PAdES signature format with a graphic symbol. The allowed format of attachments is .pdf; maximum attachment size: 5 MB.

2. **Relevant certificate of medical device/ *in vitro* diagnostic medical device** (if applicable)

   .PAdES signature format with a graphic symbol. The allowed format of attachments is .pdf; maximum attachment size: 5 MB.

3. **Other** (max. 5)

.PAdES signature format with a graphic symbol. The allowed format of attachments is .pdf; maximum attachment size: 5 MB.