Appendix No. 1 to Competition Regulations

Template of Funding Application

Tab: "Application Data Sheet"

Recruitment number	
Application number	
Date of Application	
Project name	
Applicant	
Expected project performance period	Date from Date to
Partners	
Status of application	
Type of project	

Tab I "Leader and Partners"

Sponsor of study (Leader)	Name of section
Type of applicant	
Full name	
Full name - Other	
NIP (tax identification number)	
REGON (National Business Registry Number)	
Business status:	
Website address:	
E-mail address for correspondence	
Address:	Name of subsection
street	
building no.	
unit no.	
postal code	
town/city	

commune	
county	
province	
Person authorised to make binding decisions	Name of subsection
First and last name:	
Title:	
Phone	
Fax	
E-mail address	
Person authorised to working contacts	Name of subsection
Is it a person authorised to make binding decisions?	
First and last name:	
Title:	
Phone	

Fax	
E-mail address	

Leader's revenues for the prior financial year	Name of subsection
Amount (PLN million)	
Year	

Total number of Labour-Code employees (number of people employed in the prior year)	Name of subsection
Number	
Year	

Total number of people employed under civil-legal contracts (number of people employed in the prior year)	Name of subsection
Number	
Year	

Medical and research potential

Research potential of the entity for commercial and non-commercial clinical trials (among others, provide the number of people with science degrees and experience in conducting clinical trials, number of trials conducted, split into commercial and non-commercial ones)

Potential of the Leader for conducting research for Adoptive Therapies and conducting commercial and non-commercial clinical trials. Please describe, among others

- conducted research on the development of Adoptive Therapies, immunology and oncology;

- annual number of transplants of hematopoietic cells (if applicable) with reference to the figures that support that number;

- number of clinical trials conducted, split into commercial and non-commercial ones;

- number of employees with experience in conducting clinical trials, with their science degrees;

- provide the number of employees holding specialist knowledge who are employed by the Leader and assigned to conduct this Project

- whether the Leader holds a specialised unit dealing with the organisation and management of clinical trials.

Text field, mandatory, max. 20,000 characters

Leader's technical, financial and administrative capacities

Technical capacity

Technical capacity(provide, among others: specialist infrastructure at disposal, medical and research equipment important for the achievement of Project objectives).

Text field, mandatory, max. 5000 characters

Financial capacity

Financial capacity (demonstrate that the Leader responsible for carrying out the Project is able to ensure financial liquidity for the funding of its Project tasks in order to ensure correct execution and continued operation). The description should provide the amount of the current financial liabilities.

Text field, mandatory, max. 1700 characters

Administrative capacity

Administrative capacity (demonstrate operational and administrative preparedness of the Leader to carry out Projects receiving public funding or other resources by specifying which projects have been carried out by the Entity. Demonstrate the Entity's capacity to operationally manage the Project or the assigned tasks, specifying, among others:

- whether the Leader has implemented Standard Operating Procedures,
- whether it hold a specialised unit to handle third-party projects, etc.,
- how operational management of the Project will be conducted,
- competencies of the workers dedicated to the administration of the Project).

Text field, mandatory, max. 1700 characters

Project administrative manager

Project administrative manager (describe: first name and last name and professional experience of the Project Administrative Manager to manage the Project on behalf of the Applicant)

Text field, mandatory, max.1700 characters

Partners	Name of section

	Minimum number of project Partners – five, taking into account the required roles in the Project For each Partner, fields from section I.A. are repeated

Full name	
Full name - Other	
Role of the Partner in the Project in accordance with the Competition Regulations	
NIP (tax identification number)	
REGON (National Business Registry Number)	
Business status	
Website address:	
E-mail address for correspondence	
Address:	Name of subsection
country	
street	

building no.	
unit no.	
postal code	
town/city	
commune	
county	
province	
Person authorised to make binding decisions	Name of subsection
First and last name:	
Title:	
Phone	
Fax	

E-mail address	
Person authorised to working contacts	Name of subsection
Is it a person authorised to make binding decisions?	
First and last name:	
Title:	
Phone	
Fax	
E-mail address	

Name of subsection

Medical and research potential

Potential of the Partner in conducting research for Adoptive Therapies and conducting commercial and non-commercial clinical trials (describe, among others:

- conducted research on the development of Adoptive Therapies, immunology and oncology;

- annual number of transplants of hematopoietic cells (if applicable) with reference to the data to confirm that number;

- number of clinical trials conducted, split into commercial and non-commercial ones;

- number of people with experience in conducting clinical trials, with their science degrees;

- provide the number of employees holding specialist knowledge who are employed by the Applicant and assigned to conduct this Project,

- whether the Partner holds a specialised unit to deal with the organisation and management of clinical trials)

Text field, mandatory, max. 5000 characters

Name of subsection

Partner's technical, financial and administrative capacities

Technical capacity

Technical potential (provide, among others: specialist infrastructure held, medical and research equipment important for the achievement of Project objectives)

Text field, mandatory, max. 5000 characters

Financial capacity

Financial capacity (demonstrate that the Partner responsible for carrying out the Project is able to ensure financial liquidity in funding its Project tasks in order to ensure correct execution and continued operation). The description should provide the amount of the current financial liabilities.

Text field, mandatory, max. 1700 characters

Administrative capacity

Administrative capacity (demonstrate operational and administrative preparedness of the Partner to carry out projects receiving public funding or other resources by specifying which projects have been carried out by the Entity. Demonstrate the Entity's capacity to operationally manage the Project or the assigned tasks, specifying, among others:

- whether the Partner has implemented Standard Operating Procedures,
- whether it holds a specialised unit to handle third-party projects, etc.,
- how operational management of the project will be conducted,
- competencies of the workers dedicated to the administration of the Project).

Text field, mandatory, max. 1700 characters

II.A. Project - data sheet

Data sheet
Project name

Text field, mandatory, max. 500 characters)

Is the Project re-submitted to the MRA?

(Values to choose from: YES/NO, mandatory field)

- Reference no. of the Competition under which the Project was previously submitted
  (field appears following the choice of YES in question II.A.2; text field, mandatory; format as per field "Reference of the competition under which the application is made")
- Reference no. of the previously submitted Funding Application
  (field appears following the choice of YES in question II.A.2; text field, mandatory; format as per field "Project reference")

Plain language summary of the Project (in Polish)

Text field, mandatory, max. 5000 characters

Plain language summary of the Project (in English)

Text field, mandatory, max. 5000 characters

Territorial range (Project location)

Text field, mandatory, max. 5000 characters

OECD classification of the project

Tab II.B. Project – substantive part

Name of section

Analysis of the proposed Adoptive Therapy

Name of subsection

Short description of the trial according to PICOS criteria (population, intervention, comparison, outcome, study):

Name of sub-subsection

P – population in which Adoptive Therapy is to be applied

Text field, max. 5000 characters, mandatory field

I – proposed intervention as part of the developed CAR/CAR-T therapy (as per ICD-9-CM and ICD-10 codes)

Text field, mandatory, max. 10,000 characters. More than one field can be added.

C - proposed comparators (comparative drugs)

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

O – health outcomes of the proposed Adoptive Therapy, or end points, by which clinical efficacy will be assessed (adverse events described ICD-9-CM and ICD-10 codes)

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

S – type of included medical procedures (events described by ICD-9-CM and ICD-10 codes. Please indicate the type of planned procedures and their frequency)

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

Health problem addressed by the proposed CAR/CAR-T Therapy

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

Choice of target population (specify and justify the selection of one or more populations intended to be treated with CAR/CAR-T Therapy, with a split into patients intended to be treated with the available commercial therapies and those intended to receive a therapy developed under the Project)

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

Description of the proposed intervention

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

Pattern of patient assessment

a. Baseline examination
b. Mid-treatment assessment
c. End of treatment
d. Monitoring of patient status upon the application of Adoptive Therapy

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

Duration of treatment

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

Concomitant treatment (additional treatment necessary to conduct the trial)

Text field, mandatory, max. 5000 characters

Study Patient Exclusion Criteria

Text field, mandatory, max. 5000 characters

Expected health outcomes (relatively detailed short- and long-term analysis in comparison with the current standard of treatment)

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

Procedure of randomisation and assignment to treatment groups

Text field, mandatory, max. 5000 characters

Principal investigator (full name, description of professional experience of the principal investigator of the proposed clinical trial for CAR/CAR-T adoptive therapy)

Text field, mandatory, max. 5000 characters

Duration of the trial and possibility of early conclusion of trial (in months)

Text field, mandatory, max. 5000 characters

Description and number of centres intended for inclusion to the proposed clinical trial (describe the number of centres, their technical capacity, equipment, personnel experience, etc.)

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

Assessment of safety and identification of risks (analysis of potential risks for the proposed clinical trial of the developed CAR/CAR-T Therapy. Analysis of risks for patients included to the clinical trial launched for the proposed CAR/CAR-T Therapy. Exact description of the procedure for identification, reporting and assessment of safety of patients in the study.)

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

Clinical Analysis

Name of subsection

Description of current scientific and clinical knowledge for the proposed trial (evidence based medicine)

Description of major reports underlying the proposed Project.

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

Assessment of safety and identification of risks (description of the procedure for identification, reporting and assessment of safety of patients in the study)

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

Economic analysis

Comparison of the proposed Adoptive Therapy in terms of costs and health outcomes with appropriate comparators used in standard treatment (detailed economic analysis should be based on current market data and expected development of Adoptive Therapies. The description should present economic benefits of using the proposed CAR/CAR-T Adoptive Therapy with regard to costs)

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

Analysis of the impact of the proposed CAR/CAR-T Adoptive Therapy on the healthcare system (the analysis should describe the current status of healthcare in the therapeutic area where the proposed CAR/CAR-T Therapy shall be used, and demonstrate how the therapy to be developed will impact on the changes in the healthcare system)

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

Ethical, social, legal aspects of the trial

Text field, mandatory, max. 5000 characters

Description of the research value of the Project (describe the research value of both the main theme of the Project aimed at developing a CAR/CAR-T Therapy. Also describe the proposed paths of development of research on the potential for applying CAR/CAR-T technologies in the treatment for other conditions.

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

Description of how the Project will improve public health, including

- life saving and achieving full recovery;
- life saving and achieving better health;
- preventing early deaths;
- improving the quality of life

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

Description of innovative nature of the Project

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

Description of the potential for using the outcomes of the Project in the healthcare system

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

Description of the potential for using the outcomes of the Project in the healthcare system taking into account a plan of establishing a Polish network of healthcare facilities able to manage the CAR/CAR-T technology (describe the area of the healthcare system which will benefit the most from the proposed Adoptive Therapy. Describe a plan for establishing a Network of Healthcare Facilities dealing with the management and conduct of Adoptive Therapy using CAR/CAR-T cells)

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

Process analysis

Description of the proposed technology process to prepare CAR/CAR-T cells, including the geographical location of particular parts of the process (describe the entire process to prepare CAR/CAR-T cells, taking into account geographical location of particular production stages. Describe quality control procedures during the entire process from acquisition of the material, to the production and transport of the product, to administration, aimed at ensuring high quality and safety of CAR/CAR-T therapies. Define the measures aimed at reducing the average time between apheresis and administration of a CAR/CAR-T product)

Text field, mandatory, max. 10,000 sings

Description of the plan to obtain approvals and certificates for the process of production of CAR/CAR-T cell preparations to be used in therapy

Text field, mandatory, max. 7000 sings

Description of the plan of implementation of a training programme for centres and personnel administering CAR/CAR-T Therapies (describe the plan for development and implementation of a programme of training for centres and healthcare personnel involved in the treatment of patients using CAR/CAR-T cells, aimed at ensuring the safety of the therapy and optimising its process, and preparing new centres wishing to roll out CAR/CAR-T Therapies)

Text field, mandatory, max. 5000 characters

Description of the process of management of intellectual property created under the project (describe the process of management of intellectual property created by all Partners under this project from identification of potential invention to obtaining its patent protection. Describe the competencies and experience of the people responsible for the management of intellectual property. Also specify the rules for the management of intellectual property upon project completion)

Text field, mandatory, max. 5000 characters

Indicators	Name of subsection

Number of non-commercial clinical trials registered under the Project

Number of people covered by the trial (size of the population covered by intervention)

Number of healthcare providers conducting the clinical trial

Other indicators selected by the Applicant

II.C. Project – delivery schedule

	In this part, please include project activities. A total of max. ten tasks can be added, including nine obligatory tasks specified in the Competition Regulations. This module is a table to be completed. It is necessary to add separate items for each tasks.	
	Task list	
	Task no.	Task number automatically completed with the subsequent whole number, beginning from 1, e.g. "Task 1", "Task 2", etc. Mandatory field.
	Name of task	Text field, mandatory, max. 10,000 characters.
	Start of the task execution period	
	End of the task execution period	
	Name of the Consortium Member responsible for task execution	

	Description of task	max. 5000 characters

	Execution schedule	Name of section. The section contains the table presented below.

Task / execution date	[Year]	[Year]	[Year]	[Year]	[Year]	[Year]	[Year]
Task [task number]: [task name]							

Quarter 1/Year	If the task is to be executed in this time frame - the field will be marked with colour or with X	If the task is to be executed in this time frame - the field will be marked with colour or with X	If the task is to be executed in this time frame - the field will be marked with colour or with X	If the task is to be executed in this time frame - the field will be marked with colour or with X	If the task is to be executed in this time frame - the field will be marked with colour or with X	If the task is to be executed in this time frame - the field will be marked with colour or with X	If the task is to be executed in this time frame - the field will be marked with colour or with X
Quarter 2/Year	as above	as above	as above	as above	as above	as above	as above
Quarter 3/Year	as above	as above	as above	as above	as above	as above	as above
Quarter 4/Year	as above	as above	as above	as above	as above	as above	as above

III. Detailed budget of the Project

General information	Name of section

This part of the application defines the anticipated costs for each pre-defined task. If any task involves no costs, the entry accompanying the tasks may be deleted. If the task involves more cost items, new lines may be added to the respective task. For the costs provided, provide: Name of cost Cost category 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 Information on how the cost is distributed across the particular years of project execution –	Informative, non-editable text.

combined cost of the task 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 measures/tasks under the Project. 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. If "Purchase of medical equipment" is identified as the cost and "Kit" is selected as the unit of measurement, the description of the calculation should list the items comprising the kit. A maximum of ten tasks and maximum 100 cost items (combined for all tasks) may be added.	

Calculation of the cost of tasks under the Project	Name of section
Budget of task	Name of subsection. Fields repeatable for each task
Task no. [task number]: [Task name]	Non-editable field, value entered automatically.
+	Subsection for each cost item in the task. Possibility of adding a new cost item using "+"
No.	Item number automatically completed with the subsequent whole number, beginning from 1.
Name of cost	Text field, mandatory, max. 100 characters

Cost group	Dropdown list as per the cost dictionary • cost of research infrastructure - max. up to 30% of Project value; • cost of procedure of development and production od CAR/CAR-T Therapy - max. up to 65% of Project value; • cost of insurance of clinical trial - max. 2% of Project value; • cost of Project administration and management - max. 5% of Project value; • other - this group should include costs not assigned to any of the above-mentioned groups - max. 10% of Project value

Cost category	Mandatory, single-choice field. Values to choose from: 1. Remuneration (Labour-Code employment contract) 2. Remuneration (engagement letter) 3. Costs of remuneration (contract for a specific task) 4. Costs of remuneration (addition do remuneration) 5. Medical service 6. Drug 7. Other 8. Third-party service other than medical 9. Cost of insurance 10. Cost of stamp duty 11. CRO engagement 12. Purchase of medical equipment 13. Medical device 14. Research infrastructure 15. Research reagents and intermediate products for production 16. Upgrade / adaptation of facilities 17. Systems and software Mandatory field. Selectable values depend on the identified cost category. If the respective category has only one unit of measurement available, it is entered automatically to the field.

Institution to which the cost item is attached (Leader/Partner)	Single-choice field. The list contains the name of the applicant and names of the Leader/Partner defined in the application. Mandatory field.
Rate/unit price	Field for entering the price (decimal number) Mandatory field.

Unit of measurement	Available units of measurement by cost category Remuneration (Labour-Code employment contract) – unit of measurement: month Remuneration (engagement letter) – unit of measurement: hour Costs of remuneration (contract for a specific task) – unit of measurement: task Costs of remuneration (contract for a specific task) – unit of measurement: hour Costs of remuneration (addition do remuneration) – unit of measurement: month Medical service – unit of measurement: examination Drug – unit of measurement: package Drug – unit of measurement: dose Drug – unit of measurement: other Third-party service other than medical – unit of measurement: service Cost of insurance – unit of measurement: policy Cost of stamp duty – unit of measurement: other Cost of stamp duty – unit of measurement: number of fees CRO engagement – unit of measurement: service Purchase of medical equipment – unit of measurement: piece Purchase of medical equipment – unit of measurement: kit Medical device – unit of measurement: piece

	Research infrastructure – unit of measurement: piece Research infrastructure – unit of measurement: kit Research reagents and intermediate products for production – unit of measurement: piece Research reagents and intermediate products for production – unit of measurement: package Research reagents and intermediate products for production – unit of measurement: other Upgrade / adaptation of facilities – unit of measurement: service Systems and software – unit of measurement: piece Systems and software – unit of measurement: service Systems and software – unit of measurement: licence Systems and software – unit of measurement: other (no default value, text field, mandatory, max. 20 characters)

Number	Field for entering decimal number. Mandatory field.
Description of cost calculation	Text field, mandatory, max. 500 characters.
Total cost of item (PLN)	Field completed automatically, non-editable. Outcome of activity [Unit cost] * [Number]
Cost, by year	Name of subsection.
Please provide the total cost of item, by year	Permanent, non-editable text.

[Time range]	Name of field: Rate/unit price. Completed automatically based on information on the rate / unit price mentioned above for particular years (in accordance with the information provided under II.C. Project – execution schedule) Name of field: Number – editable field, sum of costs in particular years must be equal to the value in the "Number" field The sum of values entered to the fields of particular time ranges must be equal to the value in field "Total cost of item (PLN)". Sum of costs in particular years must be equal to the value in the "Total cost of item (PLN)" field Please provide the total cost of item, by year Rate/unit price. Number Total cost Rate/unit price Number Total cost Rate/unit price Number Total cost Rate/unit price Number Total cost Rate/unit price Number Total cost Rate/unit price Number Total cost Rate/unit price Number Total cost Rate/unit price Number Total cost Example distribution of fields:

	Total cost of item (PLN)	Non-editable field completed based on the values entered in the part "Detailed budget of the Project". Sum of costs in particular years must be equal to the value in the "Total cost of item (PLN)" field

Total budget of the Project, by task	Name of section. The section contains the table presented below.

Task (as per the tasks from the detailed budget of the Project)	Applicant (PLN)	Partner (PLN)	Total (PLN)
Task (as per the tasks from the detailed budget of the Project) Non-editable field	[sum of costs assigned to the Leader for the respective cost category from all tasks]	[sum of costs assigned to all Partners for the specified cost category from all tasks]	[sum of values from the "Leader" and "Partner" columns of the respective line]
Task 1	as above	as above	as above
Task 2	as above	as above	as above
		Sum total (PLN):	[Sum of values from the columns above]

Total budget of the Project, by cost group	Name of section. The section contains the table presented below.

Category (as per cost categories from the detailed budget of the project)	Group - cost of research infrastructure	Cost of the procedure of development and production of CAR/CAR-T Therapy	Cost of medical procedures related to the conduct of clinical trials	Cost of insurance of the clinical trial	Project administration and management costs	Other
Category (as per cost categories from the detailed budget of the project) Non-editable field	[sum of costs assigned to the cost group: cost of research infrastructure for the respective cost category]	[sum of costs assigned to the cost group: cost of the procedure of development and production of CAR/CAR-T Therapy for the respective cost category]	[sum of costs assigned to the cost group: cost of medical procedures related to the conduct of clinical trials]	[sum of costs assigned to the cost group: cost of insurance of clinical trial]	[sum of costs assigned to the cost group: cost of research infrastructure for the respective cost category]	[sum of costs assigned to the cost group: other for the respective cost category]
Remuneration (Labour-Code employment contract)						

Remuneration (engagement letter)						
….						
Upgrade / adaptation of facilities						
Systems and software						
Sum total (PLN):						

Total cost of the Project (PLN)

Subsection

Total cost of the Project (PLN)

Funding support level

Subsection

Funding support applied for (PLN)

IV. Appendices

Mandatory appendices – to be appended as pdf files:

1. Document proving the authorisation to make binding decisions
2. Consortium agreement signed by qualified electronic signature by the Leader and all Partners.
3. CV of the Principal Investigator
4. CV of the Project Administration Manager

Non-mandatory appendices – to be appended as pdf files (max. 15)

1. Draft Agreement for the conduct of clinical trial (Sponsor, Investigator, Centre)
2. Other appendices
   (Non-mandatory field. Permitted files in PDF format, max. file size 2 MB. Appendices can be added. The following information appears under the field: "Permitted appendix format is .pdf; maximum appendix size 2 MB".

Tab: VI. Statements"

1. I hereby represent that the Leader and Consortium Members do not fund and do not apply for funding of the tasks covered by this application from public funds from other sources.
2. I hereby represent that a Consortium Agreement has been entered into, whose content complies with the guidance in the Minimum scope of regulation of consortium agreements for this Competition, attached as Appendix 5 to these Regulations.
3. I hereby represent that the information contained in this Funding Application is true to facts.
4. I hereby represent that this Funding Application does not violate any third-party rights and there are no legal obstacles to submit the Application and carry out the Project as per the Funding Application, in particular, I hereby represent that no other arrangements or agreements have been entered into, in addition to the Consortium Agreement, to preclude or restrict the involvement of the Leader and Consortium in the Project addressed by the Funding Support.
5. I hereby represent that the Leader and Consortium Members are not in arrears with the payment of taxes or contributions to social and health security, Labour Fund, National Disabled People Rehabilitation Fund, or other mandatory charges required by specific regulations.
6. I represent that I am authorised to represent the Applicant in the scope covered by this Funding Application and submit this Application for and on behalf of the Leader as well as all Consortium Members.
7. I represent that the Leader and Consortium Members are not excluded from applying for funding support, including the exclusion mentioned in Article 207(4) of the Act of 27 August 2009 on Public Finance (Journal of Laws no. 157, item 1240, as amended).

8. I hereby represent that no judicial, administrative, enforcement, tax or criminal tax procedures are pending whose outcome could affect the performance of the tasks defined in this Funding Application.
9. I represent that the Project complies with the applicable regulations of EU and national law, including those governing public procurement and public aid.
10. I am aware that the content of this Funding Application with appendices may be made available to other institutions and experts who conduct assessments, evaluations and inspections, and I commit myself to taking part in evaluation measures to assess the Programme.
11. I am aware of criminal liability for provide false information or making false statements.
12. I represent that the trial is non-commercial and its results will not be used for the purpose of obtaining marketing authorisation of a medicinal product, amending an existing authorisation or for marketing purposes.
13. I represent that the Leader and Consortium Members have read these Regulations and accept its terms in whole, including they accept in whole the content of the funding support agreement attached as Appendix 2 to the Regulations.
14. I represent that the Leader and Consortium Members have read the information clause ("Information clause for Applicant") and commit myself, on behalf of the Data Controller (President of the Medical Research Agency) to meet the information obligation towards the individuals whose details are provided in the Funding Application ("Information clause for individuals identified by the Applicant in the application").
15. I represent that the Leader and Partners do not conduct business activity in the scope funded by the Agency.
16. If they do conduct business activity in the scope funded by the Agency, the leader and Partners agree, if and as required by regulations on public aid, to enter into an additional agreement with the Agency that will govern the terms and conditions of the provided funding.

Information Clause for Applicant

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 L 119/1 of 4/05/2016), we hereby inform you that:

1) The Data Controller of your personal data is the President of the Medical Research Agency, at ul. Moniuszki 1A, 00-014 Warszawa.
2) The Controller has appointed a Data Protection Officer whom you can contact on 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 delivery and performance of a contract for the execution and funding support for the Project under Article 6(1)(b) GDPR,
b) evaluation of an application submitted in the competition for the development of a Polish (CAR/CAR-T) adoptive therapy using genetically modified immunocompetent cells, and if funding support is granted, evaluation, inspection, audit, of the project, assessment of information and promotional measures, its acceptance, assessment and financial accounting, based on Article 6(1)(e) GDPR – the processing is necessary to carry out a task delivered in public interest or exercise of official authority vested in the Controller, and Article 6(1)(c) GDPR, and Act of 21 February 2019 on the Medical Research Agency (Journal of Laws 2019 item 447),
c) protection of legitimate interest of the Controller, or potential determination, investigation or defence against claims, under Article 6(1)(f) GDPR and Article 9(2)(f) GDPR.

4) Your personal data may be provided to public authorities and government offices or other legally authorised entities or those performing tasks carried out in the public interest or in the exercise of official authority. Your personal data may be disclosed by us to to entities which handle the Controller's information and communications systems, and those providing information and communications tools, providing messenger services, and to institutions and experts carrying out evaluation and assessments.
5) We do not process your personal data in an automated way, including in the form of profiling.
6) Your personal data will be processed for the duration of the assessment of your application – during the performance of the contract, oversight of the implementation of the project, its acceptance, assessment and financial accounting, evaluation of the project, inspection, audit, assessment of information and promotional measures, as per archiving regulations, and until the lapse of statutory time limits for bringing potential claims.
7) 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 transfer data.
8) You also have the right to object.
9) You have the right to lodge a complaint with the relevant supervisory authority, i.e. the President of the Personal Data Protection Office.
10) The provision of your personal data is voluntary, but if you do not provide them, this will result in our inability to assess and select your project application, to enter into the project performance and funding agreement, or to supervise, evaluate, inspect, audit project performance, assess information and promotional measures, conduct financial evaluation and accounting.
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 identified by the Applicant in the application

Under Regulation (EU) No 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 2016 No 119), you are informed that:

1) The Data Controller of personal data of the natural persons identified by the Applicant is the President of the Medical Research Agency, at ul. Moniuszki 1A, 00-014 Warszawa.
2) If the Controller has not received personal data directly from those mentioned in Paragraph 1, we inform that the personal data have been received from our Applicant.
3) The Controller has appointed a Data Protection Officer whom you can contact on iod@abm.gov.pl
4) Personal data of those mentioned in Paragraph 1 will be processed by the Controller based on:

   a) Article 6(1)(b) GDPR, take all steps prior to entering into a contract, to process the delivery and performance of the Contract,
   b) 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,
   c) Article 6(1)(e) GDPR, necessity to comply with a legal obligation and under the Act of 21 February 2019 on the Medical Research Agency (Journal of Laws item 447 and of 2020, item 567),
   d) Article 6(1)(f) GDPR, only for the purpose of and to the extent necessary for performing the Controller's tasks related to the performance of the Contract, a legitimate interest pursued by the Controller is to enable communication related to the assessment of the application and the conclusion and performance of the subject matter of the Contract, accept and transfer statements of intent of the parties to the Contract, submit potential claims, and, upon termination or expiry of the Contract, and as necessary to determine, pursue or defend against potential 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, science degrees, professional experience.
6) The personal data mentioned in Paragraph 1 may be provided to public authorities and government offices or other legally authorised entities or for the performance of tasks carried out in the public interest or in the exercise of official authority. The personal data may be disclosed by us to entities which handle the Controller's information and communications systems, and

those providing information and communications tools, providing messenger services, and to institutions and experts carrying out evaluation and assessments.

7) Based on the personal data of the people mentioned in Paragraph 1, the Controller will not take any automated decisions about you based on your personal data, including decisions resulting from profiling within the meaning of GDPR.
8) Personal data of those mentioned in Paragraph 1 will be processed for the duration of the assessment of the application and, if funding support is received – during the performance of the contract, oversight of the implementation of the project, its acceptance, assessment and financial accounting, evaluation of the project, inspection, audit, assessment of information and promotional measures, unless a longer processing period is necessary, e.g. due to archiving obligations, statutory limits on claims.
9) Those mentioned in Paragraph 1 have the right to request the Controller to access, rectify, delete or restrict the processing of their personal data, and the right to transfer data.
10) Those mentioned in Paragraph 1 shall also have the right to object.
11) Those mentioned in Paragraph 1 have the right to lodge a complaint with the supervision authority, i.e. President of the Personal Data Protection Office.
12) The provision of personal data mentioned in Paragraph 1 is required for the assessment of the application. Decline to provide personal data will make it impossible to assess the application.
13) Data of those mentioned in Paragraph 1 will not be provided to a third country/ international organisation, unless the Controller is required to do so by law.

Public aid and de minimis aid

17. Does the enterprise apply for public aid?
    NO YES

18. Does the enterprise apply for more intensive public aid?
    NO YES

19. Public aid and de minimis aid – description:

Titles of required tasks

Task 1. Develop and optimise the use and improve the safety of CAR/CAR-T cell therapy in the treatment of blood cancers in Poland by developing the infrastructure and a team capable of producing and administering CAR/CAR-T cells

Task 2. Obtain appropriate permits and certificates for the production of CAR/CAR-T cells and their use in the treatment of patients (development of the production method and marketing authorisation);

Task 3. Prepare the trial protocol and register the trial

Task 4. Perform a clinical trial, including create an electronic medical database to measure the clinical effect and safety of the therapy in clinical practice.

Task 5. Conduct research activity targeted at enabling the use of CAR/CAR-T therapy for other indications (e.g. solid tumours, infectious diseases, autoimmune or degenerative diseases) and innovation in CAR technology

Task 6. Develop and implement a programme for training of healthcare professionals involved in treatment of patients with the use of CAR/CAR-T cells;

Task 7. Establish a Polish network of healthcare facilities able to manage the CAR/CAR-T technology;

Task 8. Manage and administer the Project

Task 9. Other – possibility for the applicant to add only 2 tasks on its own (the maximum number of sentences is 10)

Dictionary of entity categories:

1. Healthcare provider responsible for the production in Poland of CAR/CAR-T cell products (and possibly administration thereof to patients), whereas the provider may participate in research activity under the project (at least one)

2. Healthcare provider with documented experience in the administration of hematopoietic cells which will perform procedures related to the administration of CAR/CAR-T cells, exercising comprehensive care of patients in which a therapy based on CAR technology has been applied. These entities may participate in research activity under the project (at least three)

3. Other entity or entities mentioned in Article 17 of the Act on the Medical Research Agency, with documented experience in immunology, oncology, molecular biology, pre-clinical trials

- each of the above-mentioned being a public sector entity or a research institute as defined in the Act of 30 April 2010 on research institutes.