***Załącznik nr 9 do SWZ***

**Próbka tekstu nr 2**

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The financing economy of the Medical Research Agency is based on financing from the state budget. The draft budget bill for 2021 submitted to the Polish Parliament adopted by the Council of Ministers on 28 September 2020 contains the following draft financial plan for 2021 for the Medical Research Agency:

**The revenues and costs of the Medical Research Agency planned for 2021 amount to:
PLN xxx with the intended use of financial resources for the following:**

1. **The operating costs have been planned at PLN xxx:**
2. Costs of depreciation of fixed assets and intangibles: PLN xxx.
3. Materials and energy: PLN xxx; this item includes planned financial resources
for the costs of consumption of electricity, water, fuel and materials related to the Agency’s activity, i.e. office and household goods, equipment.
4. Third-party services: PLN xxx; this item includes planned financial resources to cover the costs of:
* lease of MRA headquarters along with operating costs (3 floors are planned to be rented since 2021, 2 floors have been rented since June 2020);
* transport services and costs related to car servicing (rental and parking):
* IT services (maintenance of the financial, HR and accounting system and the IT system referred to in Article 21 of the ABM Act);
* cell phone and Internet services;
* publishing services (publication of a report on clinical studies and a magazine);
* film and printing services;
* photocopying and maintenance services;
* postal and courier services;
* renovation of rooms;
* legal advisory services;
* organization of conferences, seminars, social campaigns;
* purchase of licences and software;
* translation services;
* services concerning the creation of document templates for conducting non-commercial clinical research studies (protocol, ICF, etc.);
* catering services;
* remuneration for experts evaluating applications for funding on the basis of signed contracts under business activity;
* electronic access to information services, e.g., Lex, Gofin;
* costs related to the financial statement audit for 2020;
* office space insurance;
* other services (car wash, stamps, electronic signatures, etc.);
* POWER project services.
1. Remuneration PLN xxx, of which:

- personal remuneration: PLN xxx; personal remuneration financed from a subjective subsidy;

- non-personal remuneration: PLN xxx; remuneration of MRA Board members, remuneration of experts evaluating applications for co-financing, performing: substantive assessment of periodic and final reports, substantive assessment
of project implementation control, substantive assessment of international projects, substantive assessment of applications in connection with filing protests.

(including: non-personal remunerations of the POWER project: PLN xxx)

1. Benefits for natural persons: PLN xxx.
2. Social insurance and Labour Fund contributions, contributions to employee capital plans: PLN xxx; the item is a result of planned remuneration costs of obligatory social insurance and Labour Fund contributions, as well as contributions to employee capital plans since 2021.
3. Other operating costs: PLN xxx; the item includes financial resources planned to cover the costs of the following:
* domestic and foreign business trips, including study visits of Agency employees to international institutions with similar tasks, participation in international conferences, short-term inspections of projects;
* allocation to the Company Social Benefits Fund;
* training of the Agency’s employees and raising qualifications;
* costs of occupational medicine and other benefits for employees;
* travel and accommodation costs of MRA Board members;
* other POWER project costs.
1. **Costs of task implementation, including funds transferred to other entities have been planned in the amount of PLN xxx**, and will be used to co-finance the tasks referred to in Art. 15 Section 1 and 2 of the Act on Medical Research Agency of 21 February 2019. (Journal of Laws of 2019, item 447, as amended).

Moreover, the Medical Research Agency has planned the **Funds for property expenses in the amount of PLN xxx** in its financial plan, which will be dedicated to new modules for the OPI IT system and for the clinical study search engine.

Notwithstanding the above, referring to the request for an opinion on amendments in the annual financial plan of the Medical Research Agency for 2020 of November 17, 2020 I would like to inform you that due to the information provided by the Ministry of Health regarding changes in the financial plan for 2020 - there is no need to transfer from the cost item under the purposeful subsidy The costs of the implementation of tasks, including funds transferred to other entities of financial resources to the item Funds for capital expenditure in the amount of PLN xxx thousand.

The Agency will be entitled to finance property expenses, i.e. equipping the conference room and modernizing the ICT system referred to in art. 21 of the Act of February 21, 2019 on the Medical Research Agency without the need to make the indicated transfer.

Currently, the change of the financial plan for 2020 will concern only the transfer between the operating costs of funds from the item Other operating costs to the item Depreciation of the amount of PLN xxx thousand.

# One of the competitions organized by the Agency concerns adoptive therapies (CAR/CAR-T).

# Grounds for the competition

Adoptive therapies (CAR/CAR-T) using the potential of genetically modified immunocompetent cells (T-cells, NK cells, and others) represent an extremely promising therapeutic tool for cancer patients. So far, oncology has achieved significant successes in the fight against cancer thanks to the use of chemotherapy and radiotherapy, however, in many cases the therapeutic effect is unsatisfactory or temporary. In recent years, adoptive therapy using modified immunocompetent cells (CAR-T) has become an extremely attractive alternative, showing high efficiency in the treatment of patients in the terminal stage of haematological malignancies. This type of therapy seems to be one of the biggest breakthroughs in oncology since the introduction of chemotherapy. At the same time, the potential of adoptive therapies is not limited to blood cancers. Currently, there is an intensive growth of research aimed at using the potential of CAR-T in the treatment of solid tumours, autoimmune diseases and even infectious diseases. Some of the benefits of adoptive CAR/CAR-T therapies include:

* an additional therapeutic option for patients for whom the current standard therapeutic procedures do not bring the expected results,
* the possibility of treating neoplasms that do not respond to chemotherapy, even in palliative patients,
* the possibility of complete recovery of patient from neoplastic disease - lifelong remission,
* the possibility of restoring the patient’s efficient functioning in society following one-time treatment,
* faster recovery of patients.

In Poland, the existing potential in the area of therapeutic application of adoptive therapies is not fully utilized and Polish patients do not have access to the currently most promising adoptive therapy. The main reasons for this phenomenon are the very high cost of this type of treatment, but also stringent requirements for medical entities offering this type of therapy.

# Principles of Good Clinical Practice

Clinical trials funded by the Medical Research Agency must be carried out in compliance with the principles of Good Clinical Practice (GCP), i.e.:

1. Clinical trials should be conducted on the basis of ethical principles based on the Declaration of Helsinki and in line with GCP (Good Clinical Practice) recommendations and applicable law;
2. Before commencing a clinical trial, potential risks and inconveniences in relation to expected benefits for a trial participant and society should be considered;
3. It should be borne in mind that the rights, safety and well-being of trial participants are an  overriding value and are more important than the interests of science and society;
4. The results of non-clinical studies and data obtained from previous clinical trials with the investigational product should sufficiently justify the proposed clinical trial;
5. Clinical trials should be justified from the scientific viewpoint and described in a detailed and clear protocol;
6. A clinical trial should be carried out as per the protocol accepted beforehand by an Bioethics Committee;
7. Medical care should be provided and all medical decisions concerning clinical trial participants should be always taken by a qualified physician,
8. Each of the persons conducting a clinical trial should have relevant qualifications: educational background, training and experience matching the tasks to be performed by this person in the trial;
9. Informed and free consent to participate in a clinical trial should be obtained from each person subjecting to a clinical trial prior to enrolment;
10. All information on a clinical trial should be registered, processed and stored in the manner that enables proper reporting, interpretation and verification;
11. Confidentiality of the data enabling the identification of persons participating in should be protected and respected in accordance with the applicable provisions on the protection of personal data;
12. The investigational medicinal product should be manufactured, transported and stored as per GMP (Good Manufacturing Practice) requirements. Product use should be consistent with the approved clinical trial protocol;
13. Trials should be conducted with the use systems and procedures that constitute the warranty of quality in every aspect of the trial.

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