Warsaw, 07.03.2023

LETTER OF INTENT

on the co-execution of a study visit within the framework of the Project

"Academy of Clinical Research - development of competencies of research teams in medical entities providing hospital services and doctors employed in primary health care institutions".

as part of the Operational Programme Knowledge Education Development 2014-2020 Priority axis V Support for the health area Measure 5.2 Pro-quality measures and organisational solutions in the health care system facilitating access to affordable, sustainable, and high-quality health services.

concluded on the date of the last Party's signature between:

Medical Research Agency with its registered office in Warsaw, at Stanisława Moniuszki street 1 A, 00-014 Warsaw, REGON: 382836515, NIP: 525 278 39 49, acting pursuant to the Act of 21 February 2019 on the Medical Research Agency (Journal of Laws of 2022, item 451), hereinafter referred to as the "Agency",

represented by:

Radosław Sierpiński, MD, PhD, President of the Medical Research Agency,

and

Istituto di Ricerche Farmacologiche Mario Negri IRCCS, with its registered office in Milano, Italy, Via Mario Negri 2, VAT registration number IT03254210150. hereinafter referred to as “IRFMN”

represented by: Giuseppe Remuzzi, Director

hereinafter jointly referred to as the "Parties" and separately as the "Party".

Bearing in mind that:

- The Medical Research Agency is implementing a Project whose main objective is to improve the competence of members of research teams, and the study visit associated with its implementation is an

opportunity for participants to acquire knowledge that can be used in daily practice in clinical research at their research centres;

- IRFMN as national and international leader in the development and conduction of clinical research, has trained staff and carries out highly complex projects. Cooperation with outstanding specialists, access to state-of-the-art technologies and the application of specific standards to ensure the safety of the research participant, the efficiency of the work and the high quality of the data obtained confirm the unit's character as a leader on the map of national international clinical trial centres;

- The realisation of a study visit to a renowned unit provides a unique opportunity for participants to learn about the mechanisms of planning, organising, and conducting clinical trials at the highest world level. Direct contact with specialists cooperating with IRFMN will enable the acquisition of professional, up-to-date knowledge and familiarisation with the practical aspects of the work, and consequently contribute to raising national standards of conducting clinical trials;

- The Agency intends to select through a tender procedure, in accordance with the Public Procurement Law, a contractor (hereinafter the "Contractor") for a 3-day study visit for a group of 15 - 17 people from 13 to 15 June 2023, the programme of which will include site visits for participants, and the Contractor will be required to incorporate IRFMN recommendations in the study visit it organises. The Contractor will be responsible for organizing the visit in terms of logistics, i.e. providing transport, accommodation and meals.

The Parties declare their willingness to cooperate in the implementation of the study visit within the framework of the Project and agree on a framework of cooperation defined as follows.

Article 1

In connection with the planned implementation of a study visit to the IRFNM:

1. Agency undertakes to take into account in its contract with the Contractor for the study visit the arrangements of this Letter of intent setting out the basic conditions for the organisation of the visit to the IRFNM and to commit the Contractor to apply them.
2. In the tender procedure, the Agency will select a Contractor who will sign a contract with IRFMN.
3. The Parties agree that the cost of the visits will be 5 000,00 euros + tax. In the offer submitted by the Contractor the cost of 5 000,00 + tax euro must be included.
4. Agency undertakes to cooperate with IRFMN and will be responsible for:
    a. choosing the Contractor in tender procedure.
    b. recruitment of participants.
    c. financing of study visit.
    d. Including in tender procedure all requirements regarding the organization of the study visit received from IRFMN.

5. IRFMN undertakes to cooperate with the Contractor selected by the Agency. Within the framework of IRFMN cooperation:
    a. IRFMN will allow the participants, Agency members, translator and study visit supervisor access to the IRFMN for the study visit.
    b. IRFMN will organise and conduct site visits to the IRFMN in the following or other thematic areas:
        i. the general organisation of the work of the IRFMN;
        ii. practical aspects on clinical research management system at IRFMN;
        iii. exchange of experience related to study conduction, inspections and audits of research projects;
    c. IRFMN will participate in establishing the schedule and course of the study visit at stage of the tender preparation.
6. After selecting the Contractor, Agency, IFRMN and Contractor will finally confirm the schedule of the visit.

Article 2

1. The Agency declares that it will appoint a person to coordinate the trilateral cooperation between the IRFMN, the Contractor and the Agency.

    Contact details of the person appointed by the Agency to coordinate the trilateral cooperation between the IRFMN, the Contractor and the Agency:

    a. Lukasz Pronicki (+48 889-449-820; lukasz.pronicki@abm.gov.pl)

    Contact details of the person appointed by the IRFMN to coordinate the trilateral cooperation between the Agency, the Contractor, and the Agency:

    a. Eliana Rulli (telephone number +39 0239014645; eliana.rulli@marionegri.it)

2. Each Party acknowledges that the other Party will process personal data of its employees, to the extent necessary for the purpose of performing the Letter of intent, any processing of personal date in the course of performing the Letter of intent will be made in accordance with the applicable laws in this regard, in particular with all the requirements set out in GDPR.
3. With regard to all personal data of members of Agency personnel made available to the IRFNM, the IRFNM will perform on behalf of the Agency the obligation referred to in Clause 14 of the GDPR towards all data subjects, as applicable. The information clause is available at https://abm.gov.pl/privacy-policy.

Signed by /
Podpisano przez:

Radosław
Sierpiński

Date / Data:
2023-03-10 10:22

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Medical Research Agency

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Firmato digitalmente da: REMUZZI GIUSEPPE
Data: 09/03/2023 16:43:43

Istituto di Ricerche
Farmacologiche Mario Negri
IRCCS