

1510/36/17

COOPERATION AGREEMENT
(NATURAL PERSON - EMPLOYEE OF THE HEALTHCARE FACILITY)

The following Parties

Masaryk University

Institute of Biostatistics and Analyses

Registered office: Kamenice 3, 625 00 Brno

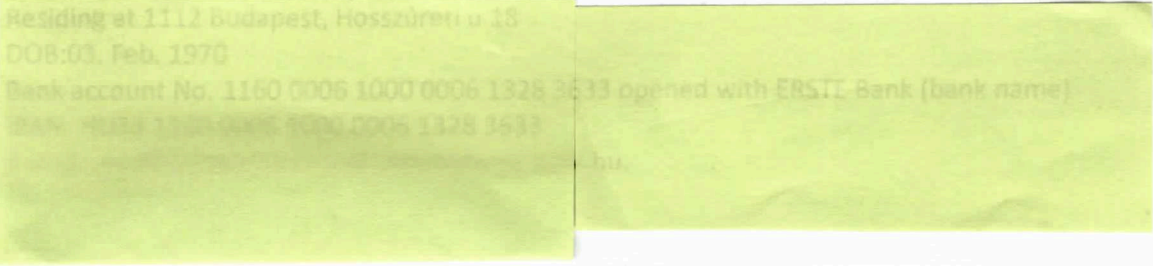
IČ (company identification number): 00216224

Authorised representative: RNDr. Ladislav Dušek, Ph.D., Director

As the **Contracting Authority**

and

First Name, Surname Veronika Müller, MD, PhD, DSc



hereby enter in accordance with Section 1746 (2) of Act No. 89/2012 Coll., the Civil Code, as amended (hereinafter referred to as the "**Civil Code**") into this Cooperation Agreement:

I.

Subject-Matter of the Agreement

1.1. The Contracting Authority is a legal entity - entrepreneur that is professionally engaged in the collection of statistical data on patient treatment, their aggregation and, among other things, the creation of fully anonymous medical registers of a statistical nature. This activity also includes a project in which the Contracting Authority provides the data collection for the registry specified in this section hereof.

Project	EMPIRE
Registry	European MultiPartner IPF Registry

1.2. The Provider is a natural person, a healthcare facility employee, authorised to search for and work with all data collected in the registry specified in the previous clause hereof (hereinafter referred to as the "**Registry**").

1.3. The Provider hereby agrees to enter patient data in the agreed extent, in the agreed manner and under the conditions agreed herein. The Contracting Authority agrees to pay the remuneration specified below to the Provider for the activity under this clause hereof.

1.4. As part of the obligation established hereunder, the Provider will obtain or may obtain access to the data, information, documents or various other information carriers that contain, among other things, confidential information about the project specified in clause 1.1 hereof (hereinafter referred to as the "**Project**") and the manner of its functioning, and as such form the trade secret and know-how of the Contracting Authority. The Parties hereby expressly declare that, with respect to the type and nature of the performance to be provided by the Provider to the Contracting Authority hereunder, the subject-matter hereof is the regulation of the obligation of confidentiality and protection of confidential information, mainly for the purposes of protecting the Contracting Authority and its interests.

II.

Conditions of Performance by the Provider

- 2.1. The Provider declares that he/she has sufficient education and expertise to be able to properly fulfil his/her obligations arising herefrom. The Provider shall, at his/her expense and liability, obtain all permits and authorisations that are necessary to perform his/her obligations hereunder, especially the authorisation to search, insert and any other operations that must be executed with the data collected in the registry.
- 2.2. The Provider shall be responsible for the proper and timely entry of data in the Registry in the agreed sequence, by the agreed deadlines and to the agreed extent.
- 2.3. When performing the activities and providing the services hereunder, the Provider is bound by all orders, instructions and requests (hereinafter referred to as the "*instruction*") of the Contractual Authority. The Provider shall, however, as an expert, always notify the Contracting Authority of any inappropriate nature of such an order and the unsuitability or incompleteness of the information provided by the Contracting Authority, and explain his/her opinion. If the Contracting Authority insists on the execution of the order, the Provider shall comply therewith. The Contracting Authority is also entitled to control the activities of the Provider hereunder.
- 2.4. The Provider hereby agrees to act in accordance with the relevant legislation as well as with all ethical rules when fulfilling his/her obligations hereunder.
- 2.5. The Provider hereby agrees to comply and proceed in accordance with the valid project protocol and in accordance with the user manual (training manual) to enter the clinical data in the electronic data collection system.
- 2.6. The Provider shall proceed with his/her activities with professional care and complete the tasks described herein for the Contracting Authority properly and timely so that the Contracting Authority does not suffer any damage during the course of his/her activities. The Provider is responsible for the correctness and completeness of the data entered into the electronic data collection system.
- 2.7. The Provider performs activities, to which he/she agreed herein, in person or through a third party authorised by the Provider, for whose actions, however, he/she is responsible to the same extent as if he/she had performed them himself/herself. The Provider shall subject such a person to the obligation of confidentiality and respecting the Contracting Authority's rights at least to the same extent to which the Provider is bound under this Agreement and applicable legislation.
- 2.8. The Provider hereby agrees, before entering the patient in the study (or his/her entry in the project), to arrange the signing of the patient's informed consent to this entry (inclusion) and the processing of confidential or specific personal data of the patient. The Provider shall keep the informed consent signed by the patient in the patient's medical records.
- 2.9. In relation to all data entered by the Provider in the Registry within the meaning hereof as well as the actual process of entering and maintaining data in the Registry and their handling, the Provider shall have the written informed consent of the relevant patient granted in advance in the form and in the wording specified by the Contracting Authority.
- 2.10. The Provider, who is in a basic employment relationship, is also required to meet all related duties towards the employer before the commencement of fulfilment of the obligations hereunder and comply with these obligations even while fulfilling the obligations hereunder. If the activity of the Provider hereunder is identical to the subject of activity of the Provider's employer or is in conflict with the Provider's confidentiality obligation, or it would potentially conflict with the interests of his/her employer or obligations assumed by the Provider, the Provider shall obtain the consent of his/her employer to the activities hereunder in advance.

III.

Other Rights and Obligations of the Parties

- 3.1. The Parties agree to provide mutual cooperation in performing the activities hereunder.
- 3.2. The Provider agrees to protect all interests of the Contracting Authority that are or must be known to him/her regarding the subject-matter hereof and to timely notify the Contracting Authority of all facts that may be of substantial importance for the subject-matter hereof and the activities of the Contracting Authority.
- 3.3. The Parties expressly confirm that the implementation hereof is not perceived or intended by the Parties as a means to convince or motivate to use, prescribe or otherwise support any medication or otherwise influence the provision of healthcare services to individual patients, or to directly or indirectly influence any expert decisions. At the same time, the Parties expressly acknowledge that no other duties and obligations except for the obligations expressly specified herein arise by virtue hereof to the Contracting Authority.
- 3.4. Similarly, for the avoidance of doubt, the Parties agree that their cooperation hereunder does not establish the co-authorship of the Provider within the meaning of copyright law in relation to the databases created within the project. In the event that, in the future, however, the nature of the mutual cooperation is questioned, the Parties have decided, for cautionary purposes, that the Provider hereby waives any property rights that may arise to the Provider under applicable legislation due to co-authorship.
- 3.5. The results of the Provider's activities hereunder or any part thereof or any information associated therewith must not be disclosed by the Provider (whether in the form of a journal article, lecture or otherwise) or provided to a third party for publication without the prior written consent of the principal investigator.
- 3.6. The Contracting Authority is entitled to handle information, details and data disclosed by the Provider and use the results of the Provider's activities hereunder without limitation. The Contracting Authority is, in particular, entitled to process, edit, copy, disclose to third parties and publish such results of those activities in whole or in part.
- 3.7. The Provider shall demonstrably notify the Contracting Authority of any changes in the details specified herein, including the e-mail address stated in the header hereof, usually in advance but no later than 7 days from the date of change; any consequences of non-compliance with this obligation shall be borne by the Provider. The Contracting Authority is entitled to communicate with the Provider in matters regarding the performance hereof or associated herewith also electronically using the e-mail address stated in the header hereof or notified to the Contracting Authority no later than as specified in the previous sentence. The Provider shall respond to an e-mail message sent by the Contracting Authority within 1 month of its receipt.

IV.

Confidentiality of Information, Confidentiality Obligation

- 4.1. In the performance of activities under and in connection with this Agreement for the Contracting Authority, the Provider agrees to comply with the principle of confidentiality, privacy and internal-use-only nature of all transmitted information and data, as well as the information and data of which he/she learns or could learn in the exercising of his/her rights and obligations arising from and in connection with this Agreement. This information and data are referred to as "**confidential information**" while mainly the following facts shall be considered as being such for the purposes hereof:
 - Facts forming a trade secret of the Contracting Authority, i.e. all significant (in terms of competition), identifiable, measurable facts and facts not commonly available in the respective business circles related to the plant, whose owner (here referred to as the Contracting Authority) adequately ensures their confidentiality in an appropriate manner;
 - Facts belonging to the know-how of the Contracting Authority;
 - The content of this Agreement, as well as any agreement, contract and arrangement that are based on this Agreement;

- All facts which the Provider learns or of which the Provider becomes aware in connection with the fulfilment of his/her obligations or while exercising the rights hereunder, in particular the facts, knowledge, skills and information regarding the project, register and the manner of their functioning.

The Parties further expressly agree that only that information which was expressly marked as such or which is public or will be publicly disclosed with no fault of the Provider shall not be considered confidential.

- 4.2. The Provider hereby expressly agrees to maintain the confidentiality of confidential information. For the purposes of this Agreement, confidentiality means, in particular, the obligation of non-disclosure, non-publication and non-use of confidential information, whether for himself/herself or for a third party, in any form (both directly and indirectly), and also the obligation to secure confidential information so as to prevent its disclosure to third parties. In connection with the confidentiality obligation, the Provider shall, among other things, maintain vigilance when communicating with third parties and avoid situations in which he/she could violate the confidentiality obligation.
- 4.3. The Provider agrees, except in cases arising from the law or the final decision of a court or another public authority, not to disclose any confidential information to a third party, unless this obligation is specifically waived by the Contracting Authority in relation to a specific person.
- 4.4. The obligations under this Article shall survive the termination hereof for an indefinite period.

V.

Remuneration of the Provider

- 5.1. For the proper activities of the Provider hereunder, the Contracting Authority agrees to pay the agreed remuneration to the Provider depending on the number of validly completed forms, where the remuneration per 1 form (hereinafter referred to as "**partial remuneration**") depends on the visit (examination) of the relevant patient to the Provider, for which the form is completed. Specifically, the partial remuneration is:
- EUR 40.00 per form relating to a patient's initial forms
 - EUR 30.00 per form relating to a patient's follow-up form

All prices are exclusive of value added tax (VAT), which will be charged according to applicable legal regulations.

The total remuneration shall be paid to the Provider by the Contracting Authority and the specific amount shall correspond to the sum of all amounts of partial remuneration to which the Provider became entitled in the relevant period for all validly completed forms.

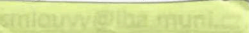
- 5.2. The remuneration shall be paid to the Provider within 60 days after the end of the period for which the remuneration is payable under clause 5.1 of this Article, provided that the Provider submits all information and documents hereunder, especially those that are necessary to determine the amount of the remuneration, for the relevant period to the Contracting Authority in a timely manner.

VI.


Term of the Agreement

- 6.1. This Agreement is concluded for a definite period, specifically until the end date of the term of the project, but not later than until 30 September 2017, depending on which occurs first.
- 6.2. The Contracting Authority is entitled to terminate this Agreement if the Provider does not fulfil his/her obligations arising herefrom in a proper or timely manner. The termination notice must be made in writing and delivered to the Provider. The notice period is one week from the date of delivery of the notice to the Provider.

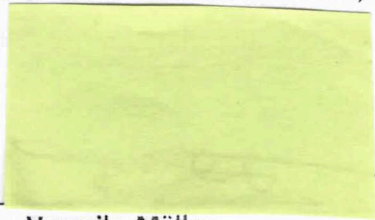
VII.
Final Provisions

- 7.1. This Agreement shall be governed by the laws of the Czech Republic with the exclusion of international law. Matters not specifically regulated by this Agreement shall be governed by the relevant law.
- 7.2. The Parties agree that any disputes arising between them out of legal relationships established by or in connection with this Agreement shall be resolved by the general courts of the Czech Republic.
- 7.3. This Agreement is drawn up in the English language and concluded as follows: the Provider will sign a written copy of the Agreement, scan it in legible form and send it electronically to the Contracting Authority's e-mail address at . If the Contracting Authority agrees with the Agreement, it will sign the printed version of the scanned copy of the Agreement, then again legibly scan it and send it electronically to the Provider's e-mail address specified in the header hereof. All annexes form an integral part hereof.
- 7.4. Any invalidity of any provision hereof shall not affect the validity of the remaining provisions. In this case, the Parties shall cooperate as necessary to agree on an amendment hereto where the invalid part of the Agreement will be replaced by a new agreement within one month after the need arises.
- 7.5. The Parties agree that any reply to an offer with an amendment or deviation within the meaning of Section 1740 (3) of the Civil Code shall be always considered a counterproposal.
- 7.6. This Agreement may not be amended or modified other than by written amendments signed by authorised representatives of both Parties, which thenceforth become an integral part hereof. Amendments to this Agreement may be concluded also using the steps described in clause 7.3 of this Article hereof.
- 7.7. The Parties hereby declare that they are bound only by the practices on which have they expressly agreed. The Parties also do not wish to have any rights and obligations beyond the express provisions hereof derived from existing or future practices established between the Parties.
- 7.8. The Provider is not entitled to request the Contracting Authority and/or a court ordered resumption of negotiations on this Agreement due to a substantial change in circumstances resulting in a gross imbalance in the rights and obligations of the Parties.
- 7.9. The Provider shall not be entitled to transfer his/her rights hereunder or part thereof to a third party without the prior written consent of the Contracting Authority or to assign his/her claims towards the Contracting Authority or part thereof to a third party without the prior written consent of the Contracting Authority. The Provider is not entitled to unilaterally offset his/her claims from the Contracting Authority against his/her debts owed to the Contracting Authority without the prior written consent of the Contracting Authority. If the Provider violates his/her obligations hereunder, he/she agrees to compensate the Contracting Authority for any non-material damage incurred.
- 7.10. The Parties declare that this Agreement has been concluded in accordance with their true and free will and that neither Party has concluded the Agreement in distress or under otherwise obviously disadvantageous conditions, as evidenced by their signatures.

Brno, 2 January 2017



Masaryk University
Institute of Biostatistics and Analyses
doc. RNDr. Ladislav Dušek, Ph.D., Director
Contracting Authority



Veronika Müller
First Name, Last Name
Provider