

COOPERATION AGREEMENT

The following Parties

Smlouva odběr/dodav. č. 119/004/19
Č. zakázky 8545/66
Č. činnosti 8220
Č. FÚ 0061
Datum 22.3.2019 Podpis [redacted]

Masaryk University

with its registered seat at Žerotínovo nám. 9, 601 77 Brno, Czech Republic

Faculty of Medicine

located at Kamenice 5, 625 00 Brno, Czech Republic

Email address for invoicing: [redacted]@med.muni.cz

represented by prof. MUDr. Martin Bareš, Ph.D., Dean of the Faculty

Registration number: 00216224

VAT number: CZ00216224

Bank name: [redacted]

Bank address: [redacted]

Account number: [redacted]

SWIFT CODE: [redacted]

Masaryk University is a public university pursuant to the provisions of act number 111/1998 Sb., on tertiary education, as amended, that is not entered in the Commercial Register

As the **Contracting Authority**

and

Company name: Carmel Medical Center

Address: 7 Michal St, Haifa

Country: Israel

ID no.: 589906114

VAT no.: the same as ID no

Represented by: Financial department.

Bank name: [redacted]

Bank Branch, [redacted]

Bank address: [redacted]

Account number: [redacted]

IBAN: [redacted]

SWIFT CODE: [redacted]

Account holder Name: [redacted]

Account owner Address: [redacted]

Contact person: [redacted]

E-mail: [redacted]

Phone: [redacted]

As the **Provider**

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 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 No.: IBA0866 | EMPIRE |
| Registry | European MultiPartner IPF Registry |

The Provider is a healthcare facility. As such, the Provider is entitled to retrieve and work with all data collected for use in the Project mentioned in the art. 1.1. (hereinafter the "Project"). The data used for the Project are collected, stored and processed by the Contracting authority in a database, that will be, for the purpose of the project, referred to as the Registry (hereinafter as the "Registry").

- 1.2. Pursuant to this contract, the Provider undertakes to enter pseudonymised or anonymised patient data into the Registry in an agreed-upon manner and extent under the conditions stipulated by this contract. The contracting Authority becomes the controller of the data after they are entered into the registry. The Contracting Authority undertakes to reimburse the Provider for the aforementioned activity in accordance with this clause. The amount of the reimbursement is specified below in the section 5. of this Agreement.
- 1.3. Whereas, the transfer of the data to the Registry will be conducted at the workplace of the Provider under the direction of the **Datamanager** as an employee of the Provider.
- 1.4. Whereas, the parties agree that the only parties to this Agreement are the parties named above, namely the Contracting Authority and the Provider. Insofar as duties, acts or omissions of the Datamanager are addressed within this Agreement this represents the obligation of the Provider to ensure, that these duties, acts or omissions are carried out by the Datamanager. The costs connected with the work of Datamanager are covered by the Provider. The Contracting Authority then remunerates the Provider for the data entered into the Registry as specified below in the section 5. of this Agreement.
- 1.5. 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, 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 performance of the Project by the Parties and in this regard also the regulation of the obligation of confidentiality and protection of confidential information, mainly for the purposes of protecting Subject's Data Privacy and the Contracting Authority and its interests.

II.

Conditions of Performance by the Provider

- 2.1. The Provider declares that the Datamanager has sufficient education and expertise to be able to properly fulfil his/her obligations arising from this Agreement. The Provider shall, at its expense and liability, obtain all permits and authorisations that are necessary to perform its 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 its 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 its 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 the Provider's activities. The Provider is responsible for the correctness and completeness of the data entered into the electronic data collection system.
- 2.7. Before entering the patient's data into the Registry, the Provider must receive the patient's written informed consent to this entry. The Provider shall keep the informed consent signed by the patient in the patient's medical records for the duration of the project and for at least five years after the end of the project. The consent will not be provided to the Contracting authority, unless such consent is explicitly requested by a regulatory or supervisory authority.
- 2.8. The Provider may use the template informed Content contained in the Annex no. 3 of this agreement, the Provider may however use its own informed consent to match legal requirements of his country. In any case, the informed consent must contain following information:
- Information about the Project
 - Information that the data regarding patient's treatment will be anonymized or pseudonymized by provider and entered into the Registry and explicit consent of such operation
 - Explicit consent of the Patient that will enable Contracting authority to process data entered into the registry for the purpose of the Project and eventual secondary use of data for research purposes in the field of Idiopathic pulmonary fibrosis.
 - Contact information of the Contracting authority so that the patient can request further information regarding the data processing and guarantees/safeguards of his personal data protection
 - An option to grant permission or deny further processing of the collected data for secondary use in research in field of Idiopathic pulmonary fibrosis.
 - An explicit consent of the patient that the independent third party may access his medical record in order to verify the correctness and validity of the data entered into the Registry.
- 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 laws applicable in the country of Provider's residence.
- 2.10. The Contracting authority reserves the right to authorize independent third party to audit, inspect and verify the correctness of the data by the Provider. The Provider and Datamanger must enable such inspections and provide the necessary cooperation to the independent auditor.
- 2.11. The Provider shall report any personal data breach to the Contracting authority without undue delay after becoming aware of a personal data breach. The content and structure of the notification should correspond to the requirements set forth by Art. 33 section 3 of GDPR.

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 the Provider 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 notice to the Contracting Authority.
- 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 and in compliance with the rules of professional guarantee which are included in the Annex No.2 of this Cooperation Agreement. 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, if the individual processing operations do not interfere with the principles of privacy and personal data.
- 3.7. The Provider shall demonstrably notify the Contracting Authority of any changes in the details specified herein, including its 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 (7 days). 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 it learns or could learn in the exercising of its 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 itself 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 the Provider 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. The Project is conducted in the interest of medical, scientific research and therefore also in the patient's interest. It is neither expressly nor implicitly bound or related to further conditions which serve non-project related procurement. This Agreement does not have any influence on the product application, the pricing and the turnover volume of the products used by the Provider or the Datamanager.
- 5.2. Contracting authority undertakes to pay for the proper operation of the Provider under this contract an agreed remuneration. Total amount of the remuneration depends on the number of validly filled out forms. The amount of the reward for 1 piece of form (hereinafter referred to as "remuneration per unit") depends on the type of completed form with regard to the type of visit (examination) of the patient at the Provider. The remuneration per unit, excluding VAT, is:

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| for each form relating to the patient's initial visit | 40 EUR |
| for each form relating to the patient's control (follow-up) visit | 30 EUR |

The Provider commits to pay adequate amount of the remuneration to the Datamanager and so at least 70 % from the total remuneration paid for the Datamanagers' validly filled out forms.

- 5.3. The total amount of the remuneration will correspond with the sum of all remuneration per unit for all validly filled out forms by the Provider in the given period. VAT will be claimed as set out in the Annex to this Agreement in accordance with the VAT Act.
- 5.4. The remuneration will be paid quarterly by one-off payments for each quarter of a calendar year (hereinafter quarter). The basis for the total amount of remuneration for the given quarter shall be the the total numbers of validly filled out forms from the project database approved by the Contracting Authority in the given quarter.
- 5.5. Due to Anti-Corruption laws payments directly to the Datamanager or the Project Personnel are not allowed.
- 5.6. The remuneration is payable based on an invoice - tax document delivered to the Contracting Authority not later than the 10 days after the end of the quarter mentioned in paragraph 5.4. The invoices shall be sent electronically to the email address [REDACTED]@med.muni.cz. The date of taxable transactions for the relevant period is the last day of the relevant period mentioned in paragraph 5.4. The maturity is settled within 30 days from the date of receipt of the error-free tax document by the Contracting Authority. The basis for determining the total amount of remuneration for the period agreed by the Contracting Authority in accordance with point 5.4 will be attached to the tax document. The remuneration will be credited to the account of the Provider listed in the header of this agreement. Transaction charges will be charged according to the SHA condition (the sender pays only the bank charges for the outgoing payment and the payee pays its fees).
- 5.7. If any tax (accounting) receipt is not issued properly, the Contracting Authority shall be entitled to return the receipt to the Provider and the Contracting Authority shall not be in default in payment of the remuneration until the delivery of a correct tax (accounting) receipt. The remuneration is then payable within 14 days after the date of delivery of a correct tax (accounting) receipt.
- 5.8. The remuneration will be paid in respect of the applicable legislation on income tax and value added tax on the basis of data provided by the Provider listed in Annex 1 to this Agreement - Tax Questionnaire. For the avoidance of doubt, the Parties agree that amounts mentioned in paragraph 5.2 are amounts including potential income tax, if the Contracting Authority is legally obligated to deduct the tax at source.

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 31 December 2019, depending on which occurs first.
- 6.2. The Contracting Authority is entitled to terminate this Agreement if the Provider does not fulfil its 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 Acts.
- 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 [REDACTED]@iba.muni.cz. 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.
- 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 its rights hereunder or part thereof to a third party without the prior written consent of the Contracting Authority or to assign its 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 its claims from the Contracting Authority against its debts owed to the Contracting Authority without the prior written consent of the Contracting Authority.
- 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.

Annex No.1: Tax questionnaire

Annex No.2: Protocol of the Project

Annex No.3.: Template Informed Consent in English

Brno, 21-03-2019

Masaryk University
prof. MUDr. Martin Bareš, Ph.D.

[REDACTED]

25/2/19

Provider

