

# COOPERATION AGREEMENT

The following Parties

Smlouva odběr/dodav. č. 1110/0046/18  
Č. zakázky 8545  
Č. činnosti 2110  
Č. FÚ 0001  
Datum 21. 3. 2018. Podpis [redacted]

## Masaryk University

### Faculty of Medicine

Registered office: Kamenice 5, 625 00 Brno

IČ (company identification number): 00216224

Authorised representative: prof. MUDr. Martin Bareš, Ph.D., the Dean

As the Contracting Authority

and

## Clinical Research Center Salzburg GmbH

Place of Business at Strubergasse 21, 5020 Salzburg, Austria As the Provider

hereby enter 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	EMPIRE
Registry	European MultiPartner IPF Registry

(hereinafter referred to as the "Registry")

- 1.2. The Provider is owned by Gemeinnützige Salzburger Landeskliniken Betriebsgesellschaft mbH (SALK) and Paracelsus Medizinische Privatuniversität Salzburg – Privatstiftung (PMU) in equal shares. By its statutes the objective of the Provider is to coordinate and administer clinical and other studies initiated by industry and other sponsors.
- 1.3. Whereas, the data to the Registry under this Agreement will be collected, among other sites, at Universitätsklinik für Pneumologie der PMU, Landeskrankenhaus Salzburg – Universitätsklinikum der PMU, located at Müllner Hauptstraße 48, 5020 Salzburg, Austria (hereinafter the "Site") with Gemeinnützige Salzburger Landeskliniken Betriebsgesellschaft mbH as its legal entity. Site is authorised to search for and work with all data collected in the registry specified in the previous clause hereof.
- 1.4. Whereas, the data collection to the Registry will be conducted at the Site under the direction of Dr. Stefan Zembacher (hereafter the "Investigator") as an employee of the Site.
- 1.5. Whereas, the parties agree that the only parties to this Agreement are the parties named above, the Contracting Authority and the Provider. The Investigator as an employee of the Site shall sign this Agreement to indicate his consent and to indicate that he has duly noted the content but not as a contracting party. Insofar as duties, acts or omissions of the Investigator 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 Investigator.

- 1.6. [REDACTED] director of Universitätsklinik für Pneumologie der PMU is the Investigator of the registry hereof and signs this Agreement as a sign of his consent to the performance of the Project at the Site. However, he does not sign as a contracting party.
- 1.7. The Provider hereby agrees and ensures the Site 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.
- 1.8. 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 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 Investigator has sufficient education and expertise to be able to properly fulfil his/her obligations arising herefrom. 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, unless provided otherwise by law or scientific, medical or ethical standards. 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. The Provider performs activities, to which it agreed herein, in person or through a third party authorised by the Provider, for whose actions, however, the Provider is responsible to the same extent



as if it had performed them itself. 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, provided only pseudonymised or anonymised Subject's data are entered into the Registry and submitted to the Contracting Authority. 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.

### 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 written consent of 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. 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. Notwithstanding the foregoing the Provider, the Investigator and the Site are irrevocably authorized to use all Project Data generated by the Site of the Project for non-commercial purposes, teaching, research and patient care without payment. A non-exclusive, free, non-transferable and non-sublicensable license shall be granted for this purpose.

3.8. The Provider shall demonstrably notify the Contracting Authority of any changes in the details specified herein, including its e-mail address, 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 following e-mail address 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.

Provider's Contact details:

[REDACTED]

#### 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), except the authorized use of Project Data for non commercial purposes, teaching, research and patient care, 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. Furthermore, the Parties undertake to observe the valid provisions according to Austrian data protection legislation also with regard to collecting and transferring data, in particular with regard to the Austrian Data Protection Law including the provisions of General data protection regulation as of . The Parties declare that they will adopt the required measures to protect the captured personal data and will indemnify and hold the other party harmless for claims arising out of its failure to do so.
- 4.5. The obligations under this Article shall survive the termination hereof for an indefinite period.

#### **V. Liability**

- 5.1. The liability of the Provider is limited to incidents of gross negligence or willful misconduct by the Provider and/or Site in the performance of the Project according to the Protocol, applicable law and this Agreement. There is no liability for the achievement of a certain result or that results can be used for a certain purpose. The Provider is liable for gross negligence and intent in accordance with the laws of Austria. The liability for slight negligence is excluded.

The Contracting Authority shall be liable for and shall indemnify and hold harmless the Provider, Site and Investigator against any damage and claim resulting from the conduct of the Project in accordance with the Agreement, the Protocol and applicable law.

- 5.2. The liability of the parties for consequential damage, indirect damage and/or lost earnings is excluded.

#### **VI. Remuneration of the Provider**

- 6.1 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, Site or the Principal Investigator.

Due to Anti-Corruption laws payments directly to the Investigator or the Project Personnel are not allowed.

- 6.2 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.

- 6.3 The Contracting Authority shall pay the agreed remuneration into the Provider's account specified above based on a tax receipt issued by the Provider on the last day of the period for which the remuneration under the preceding paragraph is payable.
- 6.4 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.
- 6.5 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.

#### **VII.**

##### **Term of the Agreement**

- 7.1. 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.
- 7.2. 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.

#### **VIII.**

##### **Final Provisions**

- 8.1 This Agreement shall be governed by the laws of Austria with the exclusion of international law.
- 8.2 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 Salzburg, Austria.
- 8.3 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]. 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 above. All annexes form an integral part hereof.
- 8.4 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.
- 8.5 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.



8.6 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.

8.7 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.

8.8 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, ~~21-08-2018~~ 2018



Masaryk University  
Institute of Biostatistics and Analyses  
prof. MUDr. Martin Bareš, Ph.D., the  
Dean Contracting Authority



Priv.Dož. Dr. Florian Jagler



Mag. Johannes Adlgasser  
Provider



ANNEX N. 1: TAX QUESTIONNAIRE  
ANNEX N. 2: BUDGET OF THE PROJECT  
ANNEX N. 3: TECHNICAL SPECIFICATION DOCUMENT IN ENGLISH