8510/21/15

Cooperation Agreement

The Cooperation Agreement (the "**Agreement**") has been concluded pursuant to Section 1746(2) of the Act no. 89/2012 Coll., the Civil Code between:

Masaryk University
Žerotínovo nám.9, 601 77 Brno
IČ : 00216224
DIČ : CZ00216224

Institute of Biostatistics and Analyses
Represented by **doc. RNDr. Ladislav Dušek, Dr.**

SWIFT CODE:
IBAN:

(hereinafter referred to as the "**Institute**")

and

Małgorzata Sobiecka, MD

(hereinafter referred to as the "**Investigator**")

(together referred to as the "**Parties**")

I. Purpose of the Agreement

The Agreement is concluded to define mutual rights and obligations between the Parties in relation to the Investigator´s performance for the Institute considering the conditions given in the Agreement.

II. Subject of the Agreement

1) Investigator commits to the Institute to enter the data concerning the patients with idiopathic pulmonary fibrosis [redacted] into database [redacted] (hereinafter referred to as the "Registry").

2) Registry shall serve solely observational, non-interventional purposes and will serve the collection of anonymous data and treatment of patients in standard clinical practice. No additional diagnostic or monitoring procedures shall be applied to patients beyond standard clinical practice in connection with the Registry.

3) Investigator hereby declares that he/she has the adequate skills, knowledge and qualification to perform appropriately according to the Agreement. The Investigator is obliged to obtain all the relevant permissions and comply with applicable legislation to be able to perform according to the Agreement.

4) The Investigator who is under an employment relationship is obliged to meet all the commitments connected to the employment before as well as during performing the obligations arising from the Agreement. If the Investigator´s activity arising from the Agreement may be in conflict with his/her employer´s activity or with the confidentiality rule, the Investigator is obliged to take out his/her employer´s prior consent to perform his/her duties as stated in the Agreement.

5) The Investigator is obliged to make sure that no trade secret or no other confidential information concerning the Investigator, the Institute or a third party is violated or infringed while performing the obligations set in the Agreement.

III. Term and Termination

The Agreement is concluded for a definite period of time - from 1st May 2015 to 31st December 2016 unless agreed otherways by the Parties.

IV. Compensation and Payment conditions

1) The Institute shall pay for Investigator´s performance a financial remuneration, amounting to: 40 EUR per baseline visit (valid form Enrolment + Treatment) and 30 EUR per valid form Follow-up (max 4 Follow-ups will be paid, means one Follow-up per quarter). The given remuneration is final and covers any and all Investigator's expenses in connection with Investigator's performance may they arise.

2) Remuneration will be transferred to Investigator´s bank account set forth above in the Agreement. The bank transfer fees are shared.

3) The financial remuneration will be paid in quarterly installments.

V. Obligations of the Investigator

1) Investigator undertakes to carry out his/her duties in accordance with the Agreement in time, in accordance with his/her best knowledge and belief and in accordance with the Protocol which constitutes an integral part of the Agreement and in accordance with the legitimate interests of the Institute.

2) The Investigator hereby agrees that through the inclusion of patients into the non-intervention study he/she will monitor the treatment of patients according to standard clinical practice. The Investigator commits to enter patients data via electronic data entry sheets (hereinafter referred to as "electronic CRFs"). The Investigator also commits not to enter any data on electronic data sheets allowing any identification of patients.

3) Before entering the data the Investigator must give the patient a complete and understandable information about the project and verify that the patient agrees with the entry of anonymous data about the treatment into the database. Inclusion of patients into the project will be possible only with their consent. Request of a patient ´s permission must be in conformity with ethical principles. Signature of the document "Informed Consent Form" is required even though it is a non-interventional trial and the patient is not exposed to diagnostic or therapeutic procedures beyond standard clinical practice.

4) The Investigator declares that he/she will enter all the data into the electronic sheets truthfully to the best of his/her knowledge. The Investigator agrees to comply with all the legislation and standards concerning the protection of personal data. The data into electronic sheets, forms, records of undesirable effects and other documents sent by the Investigator will be recorded strictly pseudonymous, ie. that they might not be the basis for patient´s identification. Only treating physician will be able to identify the patient based on information in the eCRF records

5) Any adverse event and serious adverse event (unfavorable and unintended sign or symptom, complications, accidents, a significant change in laboratory parameters or ECG, etc.) that occur during the treatment must be documented in the form called "Adverse Event Form " and all questions relating to this event must be completely filled in and a completed questionnaire concerning each adverse event must be sent according to the conditions specified in the Protocol.

6) Investigator undertakes to meet the obligations arising from the Agreement in accordance with relevant laws, legislation and rules (including internal rules and guidelines set by his/her employer, as well as all the ethical rules concerning the service in the medical field.

7) Neither the results of Investigator´s performance according to the Agreement nor their parts nor the information connecting to them can be published by the Investigator (e.g. as a journal article, lecture or in any other ways) or be provided to a third party without a prior written consent by the Institute. However, the consent shall not be denied without good reason.

VI. Confidentiality

1) The Agreement is considered to be strictly confidential and is the subject of Institute´s trade secret. Investigator undertakes not to publish, not to disclose to a third person, not to use for its own benefit either the content of the Agreement or any information related to the subject of the Agreement without a prior consent by the Institute (except for the obligations stated by mandatory statuory provisions of relevant laws). The same applies when dealing with other information and/or documents obtained from the Institute in relation with the Agreement. Notwithstanding anything in the Agreement to the contrary, this Confidentiality obligation shall survive termination of the Agreement for five (5) years.

VII. License

Institute is authorized to use the information provided by the Investigator and the results of Investigator´s work according to the Agreement without any limitation. Above all the results of Investigator´s work can be processed, modified, multiplied, provided to a third party or published either in parts or as a whole.

VIII. Termination

1) The Agreement can be terminated by a written notice by either of the Parties for any reason or even without any reason. The notice period is 30 days and it starts the day following a notice delivery to another party. The notice must be delivered in person (receipt of delivery is needed) or as a registered letter.
2) If Investigator does not meet all his/her obligations arising from the Agreement appropriately and in time, the Institute can withdraw from a Agreement immediately. The withdrawal is effective on a day following a delivery of a written notification on withdrawal to the Investigator. The notice can be delivered either in person (receipt of delivery is needed) or as a registered letter.

IX. Final provisions

1) The Agreement is valid and effective on the day of its signature by the last Party.
2) An integral part of the Agreement is Annex 1 – Tax questionnarie.
3) The Agreement shall be governed by and construed in accordance with the laws of the Czech Republic.
4) In the case of any controversy or claims arising out of or relating to the Agreement or interpretation, breach, termination or invalidity thereof the Parties shall make reasonable efforts to resolve it amicably. If amicable settlement of any such dispute is not achieved within the period of twenty (20) Business Days following notice of any Party to the other Party or Parties in dispute, all disputes arising from the Agreement and/or in connection with it shall be finally decided by the Czech court having subject-matter jurisdiction.

5) Each Party shall bear its own costs and expenses in connection with the preparation, execution and consummation of the Agreement, including, without limitation, any and all professional fees and charges of its advisors.

6) Any changes or any amendments to the Agreement shall be made in written form and shall be signed by both Parties.

7) The Agreement is executed in two counterparts, each Party shall receive one copy.

IN WITNESS WHEREOF the Parties have duly executed the Agreement

In Warszawa on 23.JUN 2015,

Doc. RNDr. Ladislav Dušek, Dr.

Małgorzata Sobiecka, MD