



## **COOPERATION AGREEMENT**

Concluded under provision § 1746 (2) of Act no 89/2012 Sb., Civil Code  
(Hereinafter as "Agreement")

Concluded between

### **Masarykova univerzita**

Registered seat at: Žerotínovo náměstí 617/9 Postal Code 602 00, Brno, Czech Republic

Company ID: 00216224

VAT No: CZ00216224

Department: Institut biostatistiky a analýz (IBA)

Kamenice 126/3 (University Campus Bohunice), 625 00, Brno, Czech Republic

Represented by: doc. RNDr. Ladislav Dušek, Ph.D.



(Hereinafter as „IBA“)

and

### **Boehringer Ingelheim İlaç Ticaret A.Ş**

Company Vat : 1790002474

Registered seat at Maslak Mah. Buyukdere Cad. USO Center No:245 Kat:13 34398 Sarıyer İstanbul

Represented by: Erdal Yalcın / Medical Director

(Hereinafter as "Boehringer Turkey", whereas IBA and Boehringer Turkey may each be referred to from the time to time hereafter as a "Party", and jointly as the "Parties".)

### **WHEREAS**

- A. IBA is a research institute oriented to the solution of scientific projects and providing related services, especially in the field of biological and clinical data analysis, organization and management of clinical trials, software development and ICT application. IBA activities are primarily focused on organizational and expert services for large scientific projects and clinical research projects;
- B. Boehringer is a pharmaceutical company which supports research and development activities and make investments in this regard in order to contribute developments in health.

NOW THEREFORE, the Parties agreed as follows:

## **1 SUBJECT MATTER OF AGREEMENT**

- 1.1 The purpose of this Agreement is to set out the conditions of the cooperation between the Parties.
- 1.2 Under the provisions of the Agreement, the IBA undertakes to administer the Project which is a investigator initiated study and Boehringer Turkey undertakes to provide IBA with agreed remuneration in order to financially support the said study without being a sponsor as understood in clinical trials regulations under the conditions set forth below in this Agreement.
- 1.3 Parties agree that this contribution to the Project is limited to financial contribution only. Parties agree that IBA bears the sole responsibility for and shall procure that the conduct of all work to be carried out pursuant to the Project shall comply with all relevant legal provisions as amended from time to time, including but not limited to local regulations and recommendations of the issued by the respective competent authorities.
- 1.4 The Project will also be conducted in Turkey under the lead of the coordinating physician and the project manager of the Project. IBA is solely responsible for selecting Turkey as an additional center to the Project and covering the conduct of the Project with the participating physicians, including physician Prof Dr Nesrin Mogulkoc from hospital Ege University Hospital in Turkey engaged for the performance of the Project in accordance with the Protocol, the provisions of the Agreement and all applicable laws, regulations, codes, guidelines and official publications

## **2 PROTOCOL**

- 2.1 In order to administer the Project, IBA shall provide professional services as specified and defined in Appendix No 1 – The Protocol and within a time frame set forth therein.
- 2.2 Boehringer Turkey undertakes to provide IBA according to its best knowledge with complete information necessary to lay down the extent and amount of professional services which shall be provided in order to administer the Project. The Parties agree to amend the Protocol to reflect any information, conditions and circumstances that may affect the character, extent and amount of professional services as well as time necessary to administer the Project.

## **3 RIGHTS AND OBLIGATIONS OF THE PARTIES**

- 3.1 IBA undertakes to provide services according to the Protocol with due care, in compliance with applicable regulatory provisions, ethical and professional standards required for provision of such services by law and/or agreed between the Parties.
- 3.2 Boehringer Turkey undertakes to provide necessary cooperation to IBA in order to fulfil the subject of this Agreement.
- 3.3 Neither Party grants to the other Party any licenses or other rights under intellectual property rights which such Party controls as of the effective date of the Agreement, except as necessary to perform such other Party's obligations under this Agreement or otherwise expressly set forth in

this Agreement.

#### **4 PAYMENT CONDITIONS**

- 4.1 **Total Remuneration.** Boehringer Turkey undertakes to pay remuneration in accordance with the provisions of Appendix 2 – The Budget and payment conditions according to the provisions of this Section 4. Remuneration shall be exclusive of value added tax (VAT) which shall be added thereon and invoiced by IBA, if applicable.
- 4.2 **Installment Schedule.** The sum referred to in Section 4.1 above shall become duly payable in accordance with Installment Schedule set forth in the Appendix 2. In case there is no installment schedule agreed, IBA shall invoice for professional service performed on monthly basis / within 90 days after the service was provided.
- 4.3 **Transfer Costs.** The amount invoiced by IBA is exclusive of any transfer costs and expenses incurred in connection with processing the invoiced payment. Boehringer Turkey shall bear all such transfer costs.
- 4.4 **Due Date.** Boehringer Turkey undertakes to make all payments due hereunder within thirty (30) days of receipt of an invoice by IBA to a bank account designated by IBA.
- 4.5 **Late Payment.** In the event of a delay in payment, interest after due date will be charged at a rate of 0.25% above the London Interbank Offered Rate (LIBOR). The date of the payment will be taken to be the day when the payment is credited to the bank account of IBA.
- 4.6 **Starting costs,** that include fees for user account management, reporting and revision of recipients, and also project administration, data analysis will be invoiced by the start of the project in 2016, after signing the contract (5180,- euro in total).
- 4.7 **Variable costs** (described in Appendix No- 2) will be paid based on actual costs incurred by IBA and invoiced separately every quarter after presentation of appropriate supporting invoice documentation as determined in the cost proposal. Any additional costs for the project are to be agreed between BI TR and IBA.

#### **5 PUBLICATION**

- 5.1 **Publication by IBA MU.** The Parties agree that pursuant to this Section 11. IBA MU shall be entitled to publish or present the Results of the Project for non-commercial purposes.
- 5.2 **Submission of Manuscripts.** Prior to any written, oral or audio-visual publications of the Results of the Project, IBA shall first submit to Boehringer Turkey a manuscript of the proposed publication at least sixty (60) days in advance (or unless otherwise agreed in individual cases) of such proposed date of submission for publication for review by Boehringer Turkey. Unless Boehringer Turkey informs IBA and in writing during this sixty (60) day period that the proposed publication must be delayed in order to protect a patentable invention or changed (i) to avoid disclosure of Confidential Information, trade secrets or know-how, (ii) to ensure the accuracy of the publication, or (iii) to enable scientifically relevant supplementary information to be

provided, IBA shall be free to proceed with the proposed publication without restriction. In the event that a delay of the proposed publication is required, IBA shall withhold such submission for publication for an additional period agreed upon in good faith by the Parties, however no longer than eighteen (18) months after submission of a respective patent application by Boehringer Turkey. If Boehringer Turkey submits during the sixty (60) day period any modification proposals to IBA, these proposals shall be considered, unless the modification proposals prejudice the scientific character of the publication, in particular the obligation to be truthful and objective. In case of disputes the Parties shall use their best efforts to reach an amicable settlement.

5.3 Good Scientific Practice. Both IBA and Boehringer Turkey undertake with regard to publications of the Results of the Project to adhere to the rules of Good Scientific Practice and the guidelines for publications of Project data as outlined e.g. by editors of the major medical journals as well as all ethical standards concerning publications and authorship.

5.4 Co-authorship. For any original publication co-authorship of persons employed by IBA or Boehringer Turkey should reflect scientific participation in the Project and will be discussed and agreed upon unanimously between IBA and Boehringer Turkey.

## **6 DURATION OF THE AGREEMENT**

6.1 The agreement will be in force until the Project is terminated and either Party may terminate this Agreement by serving notice of 90 days on the other Party. Obligation of Boehringer Turkey to remuneration for the Services provided prior to the delivery of such notice shall not be affected.

## **7 WAIVER OF RIGHTS**

7.1 Except in the cases expressly stated in this Agreement, the waiver of any rights by any Party hereto or the non-exercise of any rights resulting from the breach of any provision of this Agreement shall not result in the waiver of any rights related to the breach and shall in no way alter the effect of the relevant provision.

## **8 CHANGES TO THE AGREEMENT**

8.1 This Agreement may be modified or amended solely by means of written amendments to be signed by both Parties.

## **9 ANNOUNCEMENTS AND COMMUNICATIONS**

9.1 All announcements and communications to be made under this Agreement shall take place in writing, and if addressed to the Sponsor, shall be sent to the latest address announced to the IBA. If addressed to the IBA, such items shall be sent to the above-specified address or to any other address announced by the IBA to the Sponsor.

## **10 INTERPRETATION OF THE AGREEMENT**

10.1 This Agreement makes use of certain words and phrases which have a specific meaning for the sake of simplifying the Agreement. These words and phrases and other interpretation aids are defined in Capitalized terms. The headings in this Agreement are strictly for orientation purposes and shall not influence the interpretation of this Agreement. In the event of any conflict between the expressions in the body of this Agreement and in the tables and appendices hereof, the expressions used in the primary part of this Agreement shall prevail.

## **11 GOVERNING LAW AND JURISDICTION**

11.1 This Agreement is governed by the laws of the Czech Republic and the parties irrevocably agree that it shall fall within the exclusive jurisdiction of the courts of the Czech Republic, unless the Parties agree otherwise.

## **12 ENTIRETY OF THE AGREEMENT AND SEVERABILITY OF ITS INDIVIDUAL PARTS**

12.1 If any provision of this Agreement proves to be unenforceable, the parties shall replace it with an enforceable provision with the same or the closest similar meaning, and this Agreement shall remain unaffected as a whole.

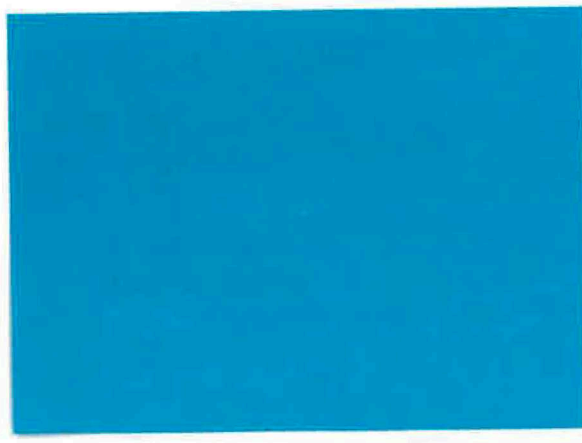
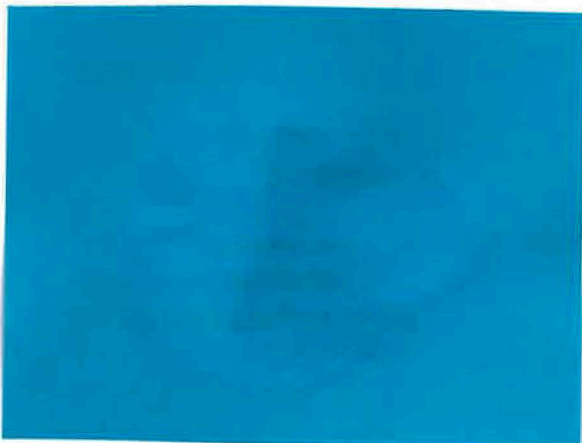
12.2 This Agreement is executed in two counterparts of which shall each Party receive one.

12.3 The stamp tax to be arisen out of the execution of this Agreement will be paid by Boehringer Turkey.

## **13 PHARMACOVIGILANCE**

13.1 BI and IBA MU shall fully comply with all provisions regarding drug safety information exchange, AE reporting, monitoring and inspections and requests of governmental or other regulatory authorities as set forth in the applicable laws and regulations, this Agreement, the Protocol and the Pharmacovigilance Agreement attached hereto as Appendix 3.

**IN WITNESS WHEREOF**, the parties have caused this Agreement to be duly executed by their authorized representatives.



**LIST OF APPENDICES:**

**Appendix No 1 – Protocol**

**Appendix No 2 – Budget**

**Appendix No 3 – Pharmacovigilance Agreement**