

COOPERATION AGREEMENT

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

Concluded between

Masaryk University

Registered seat at: Žerotínovo náměstí 617/9, postal code 602 00, Brno, Czech Republic
ID No.: 00216224
VAT No.: CZ00216224

Faculty of Medicine

On address: Kamenice 5, postal code 625 00, Brno, Czech Republic
Represented by: prof. MUDr. Martin Repko, Ph.D.

Bank:

Account No.:

SWIFT code:

IBAN:

(Hereinafter as „FM MU”)

and

Boehringer Ingelheim İlaç Ticaret a.ş.

Registered seat at: Esentepe Mah. Harman 1 Sok. Nidakule Levent

No:7-9 Kat:15-16 34394 Şişli/İstanbul

VAT No.: 1790002474

Represented by: Dr. Belgin Özdilsiz

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

WHEREAS

- A. FM MU is a part of the public university oriented, among other things, to research in Health Sciences;
- B. Boehringer is a pharmaceutical company which supports research and development activities and make investments in this regard 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 a continuation of the cooperation between the Parties.
- 1.2 Under the provisions of this Agreement, the FM MU undertakes to continue to administer the EMPIRE - European MultiPartner IPF REgistry (hereinafter referred to as "Project") which is an investigator-initiated study and Boehringer undertakes to provide FM MU with agreed remuneration to financially support the Project without being a Sponsor as understood in clinical trials regulations under the conditions set forth below in this Agreement. **For the avoidance of doubt, the Contracting Parties state that the Project in this contract means only that part of the EMPIRE registry carried out in Turkey.**
- 1.3 Parties agree that this contribution to the Project is limited to financial contribution only. Parties agree that FM MU 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 implemented in Turkey under the leadership of the coordinating physician and the project manager of the Project. FM MU is solely responsible for selecting Turkey as an additional centre to the Project and covering the conduct of the Project with the participating physicians 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, FM MU shall continue to provide professional services as specified and defined in Appendix No 1-*The Protocol* and within a time frame set forth therein.
- 2.2 Boehringer undertakes to provide FM MU according to its best knowledge with the 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 FM MU undertakes to provide services according to the Protocol with due care, in compliance with applicable regulatory provisions, ethical and professional standards required for the provision of such services by law and/or agreed between the Parties.
- 3.2 Boehringer undertakes to provide necessary cooperation to FM MU in order to fulfil the subject of this Agreement.
- 3.3 Neither Party grants to the other Party any licenses or ether rights under intellectual property rights which such Party controls as of the effective date of this 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 Boehringer undertakes to pay remuneration in accordance with the provisions of Appendix no. 2 of this Agreement - *The Budget and payment conditions* according to the provisions of this article. Remuneration shall be exclusive of value-added tax (VAT) which shall be added thereon and invoiced by the FM MU according to the regulations in force on the date of taxable supply if applicable.
- 4.2 **Due date.** Boehringer undertakes to make all payments under this agreement within thirty (30) days of receipt of the FM MU's tax document to a bank account designated by the FM MU.
- 4.3 **Transfer Costs.** The amount invoiced by the FM MU is exclusive of any transfer costs and expenses incurred in connection with processing the invoiced payment. Boehringer shall bear all such transfer costs.
- 4.4 **Late Payment.** Interest after due date will be charged at a rate of 0.25% above the London Interbank Offered Rate (LIBOR) in the event of a delay in payment. The date of the payment will be taken to be the day when the payment is credited to the bank account of the FM MU.
- 4.5 **Operating costs** for the first year will be invoiced after the publication of this agreement in the Registry of contracts. The date of the taxable supply is the date of the publication in the Registry of contracts. Eventual operating costs for years following the first year of duration of the contract will be invoiced on the date of anniversary of the effectiveness of the contract. The date of the taxable supply will be the date of anniversary of the effectiveness of the contract.
- 4.5 **Variable costs** (described in Appendix No. 2) will be invoiced based on actual costs incurred by FM MU and invoiced separately every quarter after the presentation of appropriate supporting invoice documentation. The date of the taxable supply will be the last day of the quarter. Any additional costs for the project are to be agreed between Boehringer Turkey and the FM MU.

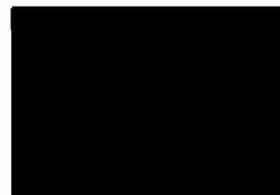
5. CONFIDENTIALITY OBLIGATIONS

- 5.1 Both Parties can be the "Disclosing Party" or "Receiving Party" in the context of this article.
- 5.2 For the purpose of this article the "Confidential Information" shall mean all information, know-how and techniques (in whatever form held) that is proprietary to or possessed by a Party and generally unknown to the public or that has not yet been revealed, whether in tangible or intangible form, whenever and however disclosed, including, but not limited to:
- a) any scientific or technical information, protocol, invention, design, process, procedure, formula, improvement, technology or method, concepts, samples, reports, data, know-how, works-in-progress, designs, drawings, photographs, development tools, specifications, software programs, source code, object code, flow charts, and databases;
 - b) any operational, management, administrative, financial or other affairs of either Party (including any business plans or forecasts, trade secrets, information relating to the Party's past, present or future business activities, or those of its affiliates or subsidiaries);
 - c) any other information that should reasonably be recognized as Confidential Information by the Parties
- 5.3 The Receiving Party undertakes and agrees:

- a) to hold the Confidential Information in confidence and not to disclose it or permit it to be made available to any other person, firm or company except to its Representatives provided that:
 - (i) the Receiving Party advises such Representatives of the Receiving Party's obligations under this Agreement;
 - (ii) such Representatives are subject to contractual obligations of confidentiality to the Receiving Party that cover the Disclosing Party's Confidential Information that is no less stringent than the obligations of the Receiving Party set forth in this Agreement; and
 - (iii) the Receiving Party shall be responsible for all use and disclosures of the Confidential Information by its Representatives.
- a) only to use such Confidential Information for the agreed-upon Purposes and not to exploit the Confidential Information in any way;
- b) on the written request of the Disclosing Party, to promptly return to the Disclosing Party all the Confidential Information and any copies of it or, at the Disclosing Party's request to confirm that it has been saved as required by law or regulation, or that it has been destroyed. The Receiving Party shall not be required to return reports, notes or other material prepared by it or its Representatives which incorporate Confidential Information provided that this information is kept confidential as per the terms of this Agreement.

6. PUBLICATION

- 6.1 **Publication by FM MU.** The Parties agree that pursuant to this article that FM MU shall be entitled to publish or present the Results of the Project for non-commercial purposes.
- 6.2 **Submission of Manuscripts.** Prior to any written, oral or audio-visual publications of the Results of the Project, FM MU shall first submit to Boehringer 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. Unless Boehringer informs LFMU 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, FM MU shall be free to proceed with the proposed publication without restriction. In the event that a delay of the proposed publication is required, FM MU 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. If Boehringer submits during the sixty (60) day period any modification proposals to FM MU, 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.
- 6.3 **Good Scientific Practice.** Both FM MU and Boehringer 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.
- 6.4 **Co-authorship.** For any original publication co-authorship of persons employed by FM MU or Boehringer should reflect scientific participation in the Project and will be discussed and agreed upon unanimously between FM MU and Boehringer.



7. DURATION OF THE AGREEMENT

- 7.1 Parties acknowledge that the FM MU is an obligated subject under Act no. 340/2015 Coll. of the Czech Republic, on special conditions for the effectiveness of some contracts, the disclosure of these contracts and the Registry of contracts (Act on the Registry of contracts). Parties declare that they agree that the Agreement and all its amendments will be published by the FM MU in the Register of contracts under the conditions of the Act on the Register of contracts.
- 7.2 Parties declare that the confidential parts of the Agreement and its amendments will not be published in the Register of contracts. If Parties will not disclose the Agreement or its parts in the Register of contracts under the Act on the Register of contracts they are pursuing the mutual protection of legitimate interests.
- 7.3 This Agreement becomes valid by the signature of both parties and affective by its publication in the Registry of contracts.
- 7.4 This agreement is concluded until the end of the Project, which is scheduled for 30 September 2022.

8. WAIVER OF RIGHTS

- 8.1 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.

9. CHANGES TO THE AGREEMENT

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

10. ANNOUNCEMENTS AND COMMUNICATIONS

- 10.1 All announcements and communications between Parties shall take place in writing.
- 10.2 The contact persons are

On the side of **FM MU**



On the side of **Boehringer Ingelheim İlaç Ticaret:**



11. INTERPRETATION OF THE AGREEMENT.

- 11.1 In the event of any conflict between the expressions in the body of this Agreement and in the tables and appendices mentions hereof, the expressions used in the primary part of this Agreement shall prevail.

12. GOVERNING LAW AND JURISDICTION

12.1 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.

13. ENTIRETY OF THE AGREEMENT AND SEVERABILITY OF ITS INDIVIDUAL PARTS

13.1 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.

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

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

13.4 This Agreement replaces all overcoming previous arrangements in the same matter, in particular the contract concluded between the parties on 31st October 2016.

14. PHARMACOVIGILANCE

14.1 Boehringer and FM 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.

In Brno, 21 -09- 2021

on behalf of **Faculty of Medicine, Masaryk University**
prof. MUDr. Martin Repko, Ph.D., dean of the Faculty

In Istanbul, 26.08.2021

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Dr. Belgin Özdilsiz

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LIST OF APPENDICES:

Appendix No 1- Protocol

Appendix No 2- The Budget and payment conditions

Appendix No 3- Pharmacovigilance Agreement

Appendix no. 2 of the COOPERATION AGREEMENT

Concluded between

Masaryk University

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

Company ID: 00216224

VAT No: CZ00216224

Faculty of Medicine

On address: Kamenice 753/5 (University Campus Bohunice), 625 00, Brno, Czech Republic

Represented by: prof. MUDr. Martin Repko, Ph.D., Dean of the Faculty of Medicine MU

and

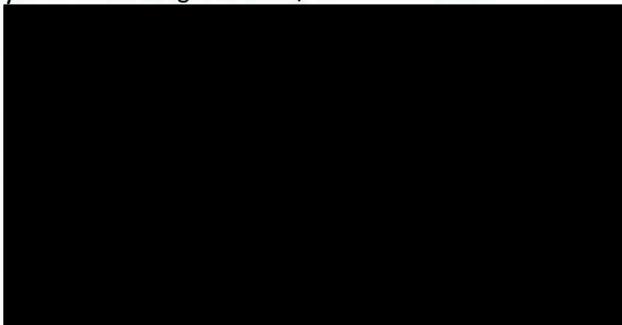
Boehringer Ingelheim İlaç Ticaret A.Ş

Company Vat: 1790002474

Registered seat at: Esentepe Mah. Harman 1 Sok. Nidakule Levent

No:7-9 Kat:15-16 34394 Şişli/İstanbul

Represented by: Dr. Belgin Özdilsiz, Medical Director



[Handwritten signature]

EXPECTED COSTS

1. OPERATING COST

1.1. Administrative and other costs connected to the project – per year

TOTAL per year	65,180 €

* Applicable for the period Q4/2021–Q3/2022

2. VARIABLE COSTS

2.1. Data entry*

TOTAL per year	34.500,- €

* The item does not include reimbursement for data entry from 2019 and 2020 (211 baseline forms and 1,457 follow-up forms)

**Estimate only. The amount will be calculated based on the real number of valid records

2.2. Steering committee

TOTAL per year	1.900,- €

* Travelling costs and accommodation for SC member if being held face-to-face



3. TOTAL COST – SUMMARY

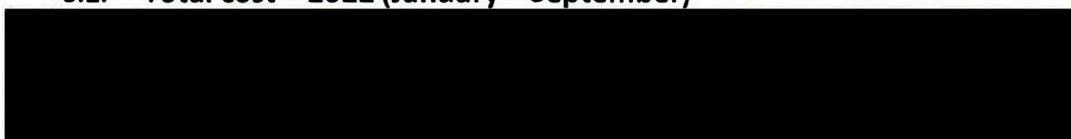
3.1. Total cost – 2021



TOTAL in 2021 – operating costs	92,630 ,- €
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* Estimate only; final cost will be invoiced based on the real number of valid records in 2021 and number of forms from 2019–2020 (211 baseline forms and 1,457 follow-up forms)

3.2. Total cost – 2022 (January – September)



TOTAL in 2022	34,060,- €
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* Estimate only; final cost will be invoiced based on the real number of valid records.
Calculated as ca. 10% increment in number of records in comparison to the previous year

