AGREEMENT FOR THE PERFORMANCE OF THE TRIAL

EU RESPONSE - DisCoVeRy

Project ID: EudraCT-2020-000936-23

INVOLVING

European Clinical Research Infrastructure Network (ECRIN-ERIC)

www.ecrin.org

Hereinafter referred to as "ECRIN"

and

Masaryk University

Hereinafter referred to as "ECRIN PARTNER"

[redacted]

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THIS AGREEMENT IS MADE BY AND BETWEEN (hereinafter referred to as the **"Agreement"**):

European Clinical Research Infrastructure Network (ECRIN-ERIC), registered under SIRET n°801 933 235 00021, established in 5-7 rue Watt, 75013 Paris, France, represented by Prof. Dr. Jacques Demotes, Director General of ECRIN-ERIC

Hereinafter referred to as **"ECRIN"**

AND

Masaryk University, whose registered office at Zerotinovo nam. 617/9, Brno 601 77, Czech Republic, ID number 00216224, represented by Prof. MUDr. Martin Bareš Ph.D., Rector

Hereinafter referred to as **"ECRIN PARTNER"**

Hereinafter individually or collectively referred to as the "Party" or the "Parties".

WHEREAS

A clinical trial entitled **Multi-centre, adaptive, randomized trial of the safety and efficacy of treatments of COVID-19 in hospitalized adults** (hereinafter referred to as the "Clinical Trial") is to be conducted in different European countries pursuant to the protocol current version (hereinafter referred to as the "Protocol").

The Clinical Trial is the core part of the **EU-RESPONSE** of a European Consortium Agreement which receives funding from the European Union Horizon 2020 program under Grant Agreement no. **10105736.**

Inserm is the Sponsor of the Clinical Trial in the European Union (EU).

Inserm, as Sponsor of the "Discovery" Clinical Trial, requested ECRIN to initiate as soon as possible the activities in the participating countries. In order to meet the desired timetable it was necessary for ECRIN to perform start-up activities of the project. Thus, the Parties reached a previous agreement through a Letter of Intent (Appendix A) fully signed on 27/10/2020. In the event of a conflict, discrepancy or inconsistency between the terms of the Letter of intent and this Agreement, this Agreement shall prevail.

The purpose of this agreement is especially:

- To state the Tasks delegated by the Sponsor to ECRIN (hereinafter referred to as "Tasks list").
- To set forth the terms and conditions for the provision of this tasks.

ECRIN will perform the tasks delegated by the Sponsor in the different EU countries through its Partners which are considered as either subcontractors, linked third parties or beneficiaries as stated in the above-mentioned Grant Agreement.

Masaryk University (hereinafter referred to as ECRIN PARTNER), hereby agrees to undertake the tasks specified for ECRIN PARTNER in the Tasks list, lines 1 – 38, (see Appendix 1) in the Czech Republic according to the Protocol current version (see Appendix 3) subject to the terms and conditions of this Agreement.

For the avoidance of doubt, ECRIN Partner is considered as a **linked third party** under the aforementioned H2020 Grant Agreement.

The purpose of this Agreement (hereinafter referred to as the "Agreement") is:

- To state the tasks (hereinafter referred to as the Tasks) subcontracted by ECRIN to ECRIN PARTNER;
- in particular, to set forth the terms and conditions governing the performance of the Tasks in the **Czech Republic**.

HEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

1. PERFORMANCE OF THE CLINICAL TRIAL RELATED TASKS

The Clinical Trial-related tasks shall be conducted by the participating Parties:

1.1 In all respects in accordance with their respective roles and responsibilities as described in the present agreement and Tasks list, Lines 1-38, regarding Initial Regulatory Submission (see Appendix 1).

1.2 In accordance with the protocol (see Appendix 3).

1.3 In accordance with the requirements laid down by laws and regulations applicable in the participating countries.

1.4 Each Party has a duty to inform the other Party as soon as possible of any difficulties encountered in carrying out the Tasks assigned to it and which may compromise the objectives of the Clinical Trial.

2. DUTIES

2.1. Obligations of ECRIN

2.1.1. ECRIN shall be responsible for the coordination of the Clinical Trial in the following countries: Portugal, Slovakia, Czech Republic, Ireland, Poland, Turkey, Spain, Norway, Greece and Hungary.

2.1.2. ECRIN shall centralize and transmit some Clinical Trial-related documents and information from following countries Portugal, Slovakia, Czech Republic, Ireland, Poland, Turkey, Spain, Greece, Norway and Hungary to the Sponsor or to any person authorized by the Sponsor for the completion of the Clinical Trial as described in the aforementioned Tasks list.

2.1.3. ECRIN shall transfer to ECRIN PARTNER the monitoring manual and all documents necessary to perform the Tasks.

2.1.4. For the avoidance of doubt, ECRIN has no obligation to transfer to ECRIN PARTNER any data or information other than data and information strictly needed by ECRIN PARTNER for the performance of the Tasks assigned to ECRIN PARTNER.

2.2. Obligations of ECRIN PARTNER

ECRIN PARTNER shall be responsible for carrying out its Tasks as described in the Tasks list Lines 1-38, regarding Initial Regulatory Submission (see Appendix 1). In particular, ECRIN PARTNER shall:

2.2.1. Be responsible for applications to National Competent authorities, Ethics Committees and any relevant Authorities, in the Czech Republic.

2.2.2. For all work involving databases of personal data, electronic or otherwise, including but not limited to medical information and genetic information the ECRIN PARTNER shall fully comply with prevailing data protection provisions, in particular the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) and any related law and regulations applicable in the participating countries.

2.2.3. In particular, ECRIN PARTNER agrees and warrants:

2.2.3.1. That it will only process the data on the Sponsor's written instructions and for the purposes stated in this Agreement.

2.2.3.2. That if it cannot provide such compliance for whatever reasons, it agrees to inform promptly the Sponsor and ECRIN of its inability to comply.

2.2.3.3. That it will implement appropriate technical, organizational and security measures in such a manner that the personal data processing will meet the requirements of the GDPR.

2.2.3.4. That it will ensure that all employees, agents, officers and contractors involved in the handling of personal data: (i) are aware of the confidential nature of the personal data and are contractually bound to keep these data confidential; (ii) have received appropriate training on their responsibilities with regard to the processing of personal data.

2.2.3.5. That it will inform the Sponsor and ECRIN as soon as possible if the Sponsor's instructions violates the GDPR or other data privacy provisions within the EU or its Member States.

2.2.3.6. That it will inform ECRIN and the Sponsor as soon as possible if Sponsor's instructions violates any provision of this Agreement.

2.2.3.7. That it will promptly notify the Sponsor and ECRIN about:

2.2.3.7.1. Any legally binding request for disclosure of the personal data by a law enforcement authority.

2.2.3.7.2. Any accidental or unauthorized access.

2.2.3.8. That upon request of the Sponsor, and/or ECRIN, and/or of the supervisory authority, it will submit its data processing facilities for an audit of the measures referred to in paragraph 2.2.3.3.

2.2.4. Shall fulfill its obligations under this Agreement and during the term of this Agreement and will not enter into any agreement which would in any way prevent it from performing its Tasks under this Agreement.

2.2.5. Has disclosed any existing relationship, which may adversely impact the execution of the Tasks.

[redacted]

2.2.6. Has, and shall continue to have at its own expense for the duration of this Agreement, all of the authorizations required under any applicable laws and regulations to perform the work involved in performing the Tasks at its facilities.

3. COST AND PAYMENTS

ECRIN PARTNER as a linked third party of ECRIN shall follow the H2020 funding principles and rules regarding the eligibility of costs declared, reporting principles and payments of third parties, as set out in Grant Agreement no. 10105736, as further fully described in this article, and described in Appendix 1 and 2.

According to the Grant Agreement 10105736 action is divided into the 'reporting periods' as follow:

- RP1: 01/07/2020 – 31/12/2021
- RP2: 01/01/2022 – 30/06/2023
- RP3: 01/07/2023 – 31/12/2024
- RP4: 01/01/2025 – 30/06/2025

Consequently, the payment of ECRIN PARTNER for the performance of Tasks will be performed following reporting periods as outlined in the aforementioned Grant Agreement, and described in Appendix 2, for a total maximum amount of 18 510 EUR (including 25% overhead).

The payments for the work performed will be done after each reporting period following the general rules of the H2020 and approval of each periodic report by the European Commission. After each reporting period, ECRIN PARTNER shall submit to ECRIN within 30 days a periodic financial report which shall include detailed eligible costs and an explanation of the use of resources. If a financial statement is not submitted for a reporting period, it may be included in the next periodic financial report as an adjustment to the previous period. The final financial report shall be submitted within 30 days after the end of the project.

Interim and final payments will be transferred to the ECRIN PARTNER without unjustified delay after approval of each periodic and final report by the European Commission.
ECRIN PARTNER submitting to ECRIN a financial report shall certify that, according to the H2020 rules:

- The information provided is full, reliable and true;
- the costs declared are eligible;
- the costs can be substantiated by adequate records and supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations.

The agreed costs for the performance of the Tasks under this Agreement (see Appendix 2) are valid for the entire Agreement period and shall not be subject to any adjustment.

In the event that amendments to the Protocol (including but not limited to change in the number of Clinical Trial participants per trial site, addition of a Clinical Trial site) require changes to the Clinical Trial financing arrangements, such changes to the Clinical Trial financing arrangements shall take into consideration the funding principles and the budget set out in Grant Agreement no. 10105736. This agreement shall be amended accordingly.

ECRIN shall not be responsible or liable in case such a financing re-arrangement is not possible within the H2020 project.

4. CLINICAL TRIAL DATA AND RESULTS

4.1. The ownership and the dissemination of results of the Clinical Trial shall comply with the terms set forth in the Consortium Agreement and the specific Grant Agreement 101015736 as further fully described in this article.

4.2. For the avoidance of any doubt, "DisCoVeRy Results" shall mean Results obtained from the performance of DisCoVeRy, of any kind and in any form whatsoever, whether or not protected or protectable by an intellectual property right, and in particular all discoveries and/or inventions arising from the total or partial performance of DisCoVeRy, whether or not protected or protectable by an intellectual property right and/or instrument, as well as all accessory tangible and intangible items, in particular files, analyses or interpretations. DisCoVeRy Results exclude DisCoVeRy Data.

4.3. According to the current version of the Consortium Agreement as of March 2021 which is still under negotiation by the time of the signature of the present Agreement, "DISCOVERY Results" are owned by the Party that generates them. However, the Consortium Agreement states that immediately following generation or collection of DisCoVeRy Data, DisCoVeRy Results and any Database gathering them, including the DisCoVeRy Database, the Party having generated them automatically and in full transfers to the Sponsor, without consideration, any of its ownership rights, title and interest in the respective DisCoVeRy Data, DisCoVeRy Results and Database, which will be own Results of Inserm.

4.4. For the avoidance of doubt, based on the activities performed by ECRIN PARTNER under the present Agreement, the Parties do not expect any IP Results to be generated by ECRIN PARTNER in connection with or as a result of its activities under the Agreement. Consequently, ECRIN PARTNER acknowledges and agrees not to make claims to possible IP from Data and Results and not to pursue IP protection that would prevent or block access to or use of any data, conclusions drawn directly from those Data and Results.

4.5. Once the negotiations of the Consortium Agreement have been finalized and the Consortium Agreement has been signed by the concerned Beneficiaries, the present Agreement should be amended, as necessary, to be aligned with the last version of the Consortium Agreement.

5. CONFIDENTIALITY

For the purpose of this Agreement, Confidential Information should include but not limited to any and all information related to the Clinical Trial which is disclosed by ECRIN to ECRIN PARTNER as a result of this Agreement. (Hereinafter referred to as the "Confidential Information")

5.1. Confidentiality of provided information

5.1.1. ECRIN PARTNER hereby agrees that at all times during the term of this Agreement, ECRIN PARTNER with its professional staff, affiliates, independent consultants and any other cooperating partners, will hold and maintain in confidence all proprietary and Confidential Information related to the Clinical Trial, written or oral, provided by ECRIN.

5.1.2. ECRIN PARTNER undertakes to use such Confidential Information only in relation to the execution of the Tasks unless otherwise agreed with the disclosing Party.

5.1.3. ECRIN PARTNER agrees that it will not permit Confidential Information in its possession to be reproduced, disseminated or otherwise disclosed to any third party or used for any purpose

not previously authorized in writing by ECRIN other than those contemplated by this Agreement.

5.1.4. In the event ECRIN PARTNER becomes legally compelled to disclose any Confidential Information, it shall immediately provide ECRIN with notice thereof prior to any disclosure, shall use its best efforts to minimize the disclosure of any CONFIDENTIAL INFORMATION, and shall cooperate with ECRIN.

5.1.5. The obligations set forth in this Article shall not apply to information for which the Party it is able to prove that:

- The Confidential Information becomes publicly available by means other than a breach of confidentiality obligations;
- The disclosing Party subsequently informs the recipient that the Confidential Information is no longer confidential;
- The Confidential Information is subsequently communicated to the recipient without any obligation of confidence by a third party who is in lawful possession thereof and under no obligation of confidentiality;
- That the disclosure or communication of the Confidential Information is foreseen by law or by other provisions of this grant agreement or the supplementary agreement;
- That the disclosure or communication of Confidential Information is required by the Laws and Regulations.

5.2. Confidentiality of results

5.2.1. ECRIN PARTNER including its professional staff, agrees not to disclose or transfer or publish or commit to any third party the data, in whole or in part, and the results of the Clinical Trial which are Confidential Information.

5.2.2. In the event ECRIN PARTNER's independent consultants or any other cooperating partners (hereinafter "PARTNERS") shall be involved, ECRIN PARTNER will undertake that such PARTNERS are obliged to respect the commitment specified in this Agreement to the same extent.

5.2.3. In any case, all Confidential Information containing personal data shall be handled in accordance with all applicable laws, including, but not limited to the European Data Protection Directive EC/95/46 and the locally applicable laws and regulations on Data Protection.

5.2.4. The terms and conditions of these obligations of confidentiality and restricted use contained herein are applicable during the term of the Agreement and shall survive its date of termination, whether by expiration or by earlier termination.

6. SUBCONTRACTING

6.1. ECRIN PARTNER represents and warrants to ECRIN that shall not sub-contract part of its Tasks to a third party in the framework of this Agreement without notifying ECRIN through a written notice and having received ECRIN's written consent and, if necessary, the authorization of the Sponsor. The prior information shall be notified to ECRIN at least thirty (30) days before the date of signature of any subcontracting agreement.

6.2. Notwithstanding such ECRIN consent, ECRIN PARTNER shall ensure that:

- Its agreement with the subcontractor(s) is made on terms that reflect the requirements of this Agreement.
- The subcontractor shall not claim any intellectual property right or right of use of Data and Results pertaining to Clinical Trial.

6.3. In any event, ECRIN PARTNER shall remain fully liable for the completion of the share of the Tasks that it entrusts to said third party subcontractor as well as for the acts and omissions of any such permitted third party.

7. LIABILITY AND INDEMNITY

7.1 ECRIN PARTNER is exclusively and fully liable for its assigned Tasks related to the Clinical Trial and for the implementation of all technical, organizational, human, material, legal operations, and safety rules required by the performance of its tasks.

7.2 ECRIN PARTNER shall take out appropriate insurance cover in respect of its potential liability and shall produce to ECRIN, on request, a copy of the insurance certificate as evidence to confirm that it has such coverage. Failure to maintain adequate insurance coverage does not relieve or reduce ECRIN PARTNER liability under this Agreement.

7.3 ECRIN PARTNER undertakes to carry out its assigned Tasks with outmost care, observing approved and recognized scientific standards.

7.4 ECRIN PARTNER shall indemnify and hold ECRIN harmless from any and all claims, demands, damages, liabilities and costs incurred by ECRIN which directly or indirectly result from, or arise in connection with, any negligent act or omission of ECRIN PARTNER, its agents, or employees, pertaining to its activities and obligations under this Agreement.

8. INSPECTION AND AUDIT

8.1 Should ECRIN PARTNER become aware of an upcoming inspection or audit related to the Clinical Trial, ECRIN PARTNER should inform ECRIN and the Sponsor in writing within 72 hours.

8.2 ECRIN PARTNER hereby allows any Regulatory Authorities may inspect the facilities and all related documents being used by ECRIN PARTNER for the performance of the Tasks.

8.3 ECRIN PARTNER agrees that, during an audit or an inspection by a Regulatory Authority it will not disclose information and materials that are not required to be disclosed to such Regulatory Authority without the prior written consent of ECRIN.

8.4 ECRIN PARTNER shall provide ECRIN with a copy of all correspondence related to such audit or inspection and a summary of the audit findings or the inspection report.

8.5 If any inspection, audit or examination by a Regulatory Authority results in a finding that ECRIN PARTNER has failed to comply with the terms of this Agreement, ECRIN PARTNER promptly take such measures at its own cost and expense as are necessary to correct such default identified in any such inspection, audit or examination.

9. MODIFICATION

9.1 This Agreement, including the attached Annexes, constitutes the entire and only Agreement between the parties relating to the Clinical Trial.

9.2 Any agreement to change the terms of this Agreement and its Appendices in any way shall only be valid if the change is made in writing and approved by mutual agreement of authorized representatives of all the Parties. Such amendments shall be assigned by all the Parties and annexed to this Agreement.

10. INTUITU PERSONAE

The Agreement is executed *intuitu personae*. Consequently, ECRIN PARTNER is not authorized to transfer all or part of the rights and obligations hereunder to a third party without the prior and written agreement of ECRIN and of the Sponsor.

11. TERM AND TERMINATION OF THE AGREEMENT

11.1 Parties acknowledge that the ECRIN PARTNER is an obligated subject under the 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 ECRIN PARTNER in the Registry of contracts under the conditions of the Act on the Registry of contracts.

11.2 This Agreement shall become valid as from the date of signature of the last Party to sign and enter into force by its publication in the Registry of contracts according to the Act no. 340/2015 Coll. of the Czech Republic (effective date) and shall remain in effect up to 04/03/2024. The agreement may be extended by amendment. Any and all extension shall be subject to the drafting of an amendment to be signed by an authorized representative of each Party.

11.3 This Agreement can, only after discussing between the Parties, be terminated by written notice in case of

- Early termination of the Study
- Any technical, administrative cause (e.g. Study not authorized, suspended or prohibited by the Authorities) or methodological impossibility to pursue the Study
- Termination for Breach

11.4 In the event of a breach by any Party of any of its obligations under this Agreement, the other Party may provide written notice to the breaching Party, such notice specifying the breach and requiring that the default be remedied within thirty (30) days. If the breach has not been remedied by the breaching Party to the satisfaction of the other Parties within thirty (30) days of receipt by the breaching Party of the notice identifying the breach and requiring its remedy, the Parties may terminate automatically, totally or partially, this Agreement with respect to the Defaulting Party with immediate effect. Such termination shall become effective with respect to such Defaulting Party as of the date of the notice of termination. Fees in relation with Tasks carried out up to this termination remain payable.

11.5 The defaulting Party concerned by the termination undertakes to communicate to the other Party or subrogated third parties, free of charge and immediately, all the files and information required to allow them to continue the implementation of the Study.

11.6 Exercising this cancellation right does not exonerate the defaulting Party from fulfilling its contracted obligations until the effective date of the termination and shall not, in any case be interpreted as a waiving, by the Party or Parties requesting the termination, of damages and interest in any way whatsoever.

12. FORCE MAJEURE

For the avoidance of doubt, Force Majeure means any unforeseeable and exceptional event affecting performance of the Agreement, which is outside the control of the Parties, and which cannot be avoided in spite of the efforts which the Parties may reasonably make.

No Party shall be considered to be in breach of this Agreement if such breach is cause by Force Majeure. Each Party shall notify the other Party of any Force Majeure as soon as possible. If impossibility or delay in fulfillment due to a case of Force Majeure continues for longer than three (3) months, the latter Party may automatically terminate the Agreement at any time by written notification sent to the other Party.

13. SURVIVAL

Upon termination of expiration of the Agreement for any reason, the provisions relating to the Clinical Trial Data and Results, Confidentiality, Liability, Indemnity and Litigation shall survive termination of this Agreement.

14. WAIVER

No failure, delay, relaxation or indulgence by any Party in exercising any right conferred on such Party by this Agreement shall operate as a waiver of such right, nor shall any single or partial exercise of any such right nor any single failure to do so, preclude any other or future exercise of it, or the exercise of any other right under this Agreement.

15. NOTICES

All notices or other communications required or permitted to be made or given hereunder shall be deemed so made or given when hand-delivered or sent in writing by registered or certified mail, postage prepaid and return-receipt requested, or by a recognized courier service, charges prepaid and properly addressed to the representatives of the Parties at their addresses mentioned herein:

ECRIN-ERIC	ECRIN PARTNER
European Clinical Research Infrastructure Network (ECRIN-ERIC) **BioPark, 5-7 rue Watt** **75013 Paris, France**	**Masaryk University** **Faculty of Medicine** **Kamenice 5** **62500 Brno-Bohunice Czech Republic**

16. LITIGATION

In the event of any dispute arising between the Parties in relation to the terms of this Agreement, the parties shall use their best endeavors to resolve the matter on an amicable basis.

To initiate conciliation, a Party must give notice in writing to the other Party, requesting conciliation in accordance with this clause. Within thirty (30) days after this notification, the Parties shall try to appoint a single conciliator, but in the absence of agreement, each Party shall appoint one conciliator. The mission assigned to the Conciliator(s) by the Parties is to suggest a solution in order to resolve amicably such dispute within sixty (60) days after the notification.

In the event the Parties are unable to resolve the dispute informally within a reasonable time, any action brought by either party to this Agreement shall be heard by the defendant court of competent jurisdiction.

17. GOVERNING LAW

This Agreement and all disputes arising hereunder will be governed by and interpreted in accordance with the laws of France without giving effect to the principles of conflict of laws. The parties hereby consent to and agree that the competent courts, where the ERIC has its statutory seat, shall have the sole and exclusive jurisdiction to resolve all such disputes.

18. GENERAL PROVISION

The invalidity of one or more provisions of this agreement does not affect the validity of the others. The invalid provision is to be replaced by a provision, which, in compliance with the legal prescriptions, suits the purpose best. The modification shall be made in writing and approved by mutual agreement of authorized representatives of all the Parties as specified in article 8.

19. APPENDICES

The following documents are appended to the Agreement and form an integral part hereof:

- Appendix A: Letter of Intent (Version n° 1, 27/10/2020)
- Appendix 1: Tasks list (Version n° 2, 01/04/2021)
- Appendix 2: Financial annex (version n° 1, 07/04/2021)
- Appendix 3: Protocol (Version n° 12, 09/03/2021)

20. SIGNATURE

This Agreement is executed in two counterparts, depending on the number of the parties, each of which shall be considered an original hereof but which together shall constitute one agreement.

IN WITNESS WHEREOF, the parties, acting through their duly authorized representatives, have executed two (2) copies of this Agreement

1. For and on behalf of ECRIN

European Clinical Research Infrastructure Network (ECRIN-ERIC)
BioPark, 5-7 rue Watt
75013 Paris, France

LEGAL REPRESENTATIVE:
Prof. Dr. Jacques Demotes
Director General of ECRIN-ERIC

DATE: 4-5-21 SIGNATURE:

[redacted]

2. For and on behalf of the ECRIN PARTNER

Masaryk University
Žerotínovo nám. 617/9, 601 77 Brno, Czech Republic

LEGAL REPRESENTATIVE:
Prof. MUDr. Martin Bareš, Ph.D.
Rector of Masaryk University

DATE: 10 -06- 2021 SIGNATURE:

[redacted]

[redacted]