

## EU RESPONSE - DisCoVeRy

### FIRST AMENDMENT TO AGREEMENT BETWEEN Masaryk University and ECRIN-ERIC

This first amendment (the "First Amendment") to the AGREEMENT FOR THE PERFORMANCE OF THE TRIAL (the "Agreement") is made by and between:

**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 is at Zerotinovo nam. 617/9, Brno 601 77, Czech Republic, ID number 00216224, represented by Prof. MU Dr. Martin Bareš Ph.D., Rector.

Hereinafter referred to as "ECRIN PARTNER"

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

### WHEREAS,

ECRIN PARTNER and ECRIN entered into an Agreement (*EU-RESPONSE DISCOVERY CTU Agreement\_Masaryk University\_V01\_04-05-2021*) (the "Agreement") as of May 4<sup>th</sup>, 2021 (Effective Date) for the performance of the Clinical Trial entitled "**Multi-centre, adaptive, randomized trial of the safety and efficacy of treatments of COVID-19 in hospitalized adults**".

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**;

### THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

#### 1. PURPOSE

The purpose of this amendment is especially:

- To add the support for site agreement negotiation (the "Support"), the monitoring of clinical sites and the local project management in the activities delegated by the Sponsor to ECRIN (hereinafter referred to as "Tasks list").
- To modify the financial dispositions.

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### 2. MODIFICATION OF ARTICLE 2.2: OBLIGATIONS OF ECRIN PARTNER

The following sentences shall be added:

*“ECRIN PARTNER shall be responsible for carrying out its Tasks as described in the Tasks list (see Appendix 1). In particular, ECRIN PARTNER shall:*

- *Be responsible to inform the national competent authorities and ethical committees that the research has started in the Czech Republic.*
  - *Be responsible to send information letters for investigators, hospital directors and laboratories that the research has been authorized and could be initiated in the site (if required).*
  - *Be responsible in close collaboration with the Sponsor for supporting the negotiation and signature of the site agreement, in the Czech Republic. For the Purpose of this Amendment, supporting the site agreement negotiation and signature (the Support”) shall mean facilitate the exchange of information and the communication between the contractual parties involved in site agreement negotiation. For the avoidance of any doubt, such support will not be given in relation to any legal matter. Consequently, the Support does not and shall not constitute in any manner a legal advice/ a legal service.*
  - *Be responsible for monitoring of the Clinical Trial in the trial sites in the Czech Republic according to the Monitoring Manual written and validated by the Sponsor.*
  - *Be responsible for the notification the end of the study to investigators, other study partners, national competent authorities and ethical committees in the Czech Republic.*
- Is responsible for ensuring that the tasks related to the Monitoring as described in the Protocol current version and Monitoring Manual are fulfilled strictly in accordance with the terms of this Agreement, and all applicable international and national laws, regulations and guidelines, including without limitation, the Declaration of the Helsinki (latest updated version), "ICH Harmonised Tripartite Guideline, Guideline for Good Clinical Practice", the Directive on Clinical Trials (2001/20/EC) of the European Parliament and of the Council of 4 April 2001 and the EU GCP Directive 2005/28/EC.”*

### 3. MODIFICATION OF ARTICLE 3: COST AND PAYMENTS

There are changes in the financial dispositions. Therefore, following details shall be added in the article:

*“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 91.170,- EUR (including 25% overhead).*

### 4. GENERAL DISPOSITIONS

All other terms and conditions of the Agreement shall remain in effect and unchanged.

Amendment 1 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).

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### 5. APPENDICES

Appendix 1 of the Agreement shall be replaced by the current Appendix 1 of the present Amendment due to the addition of the support for the site agreement. Appendices 2 and 3 shall be replaced by the current Appendices 2 and 3 of the present Amendment.

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

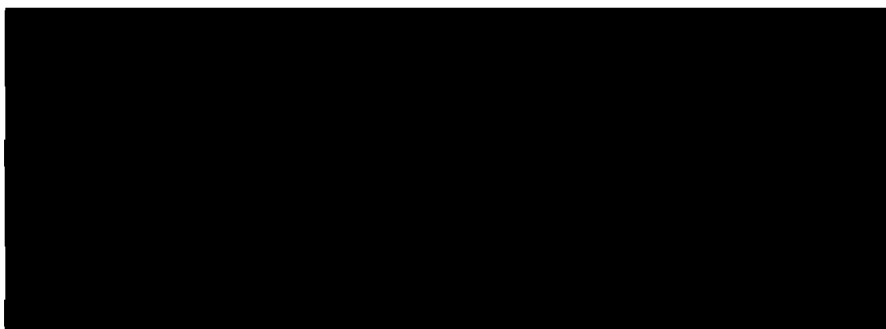
- Appendix 1: Tasks list (Version n° 2, 29/09/2021)
- Appendix 2: Financial annex (Version n° 2, 02/12/2021)
- Appendix 3: Protocol (Version n°15, 21/09/2021)

**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 PARTNER**  
**Masaryk University, Faculty of Medicine**  
**Žerotínovo nám. 617/9**  
**601 77 Brno, Czech Republic**

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

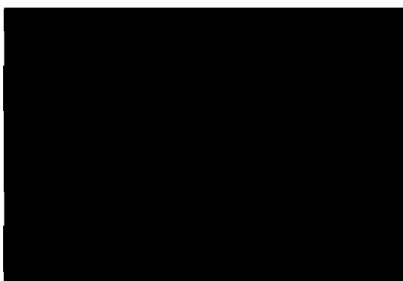
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**2. For and on behalf of ECRIN-ERIC:**  
**European Clinical Research Infrastructure Network**  
**BioPark, 5-7 rue Watt**  
**75013 Paris, France**

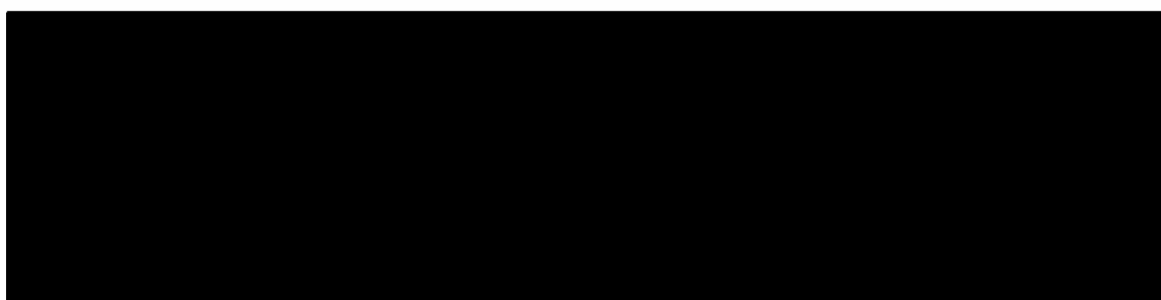
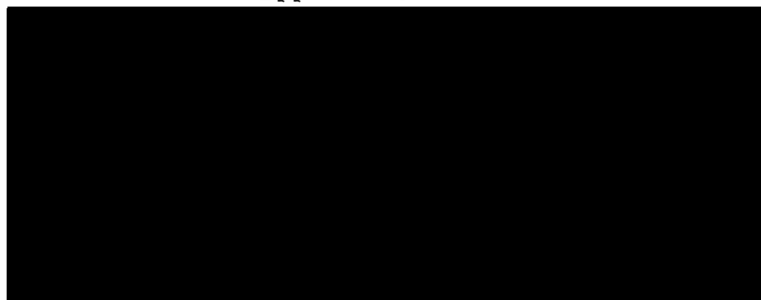
LEGAL REPRESENTATIVE:  
Prof. Dr. Jacques Demotes  
Director General of ECRIN-ERIC

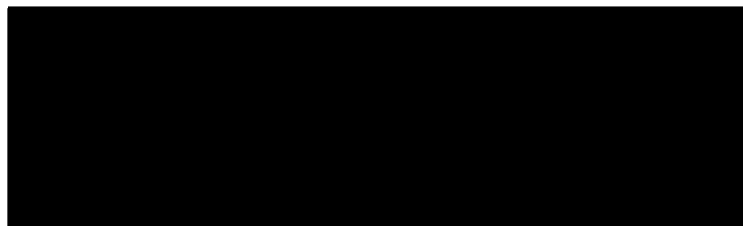
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## **EU RESPONSE - DisCoVeRy**

### **Appendix 1:**



**EU RESPONSE - DisCoVeRy****Appendix 2:**

ECRIN PARTNER is linked third party of ECRIN and a total of **91 170 Euros** (including 25% overheads) is budgeted under ECRIN for the tasks to be carried out by ECRIN PARTNER.

For all required tasks, an overall budget was calculated and agreed between ECRIN and the ECRIN partner as follows:

|             | PM          | Personnel Costs | Other Direct Costs |              | Indirect costs (25 %) | Total costs (EUR) | EC contribution |
|-------------|-------------|-----------------|--------------------|--------------|-----------------------|-------------------|-----------------|
|             |             |                 | Consumables        | Travel       |                       |                   |                 |
| <b>WP 1</b> | <b>20,6</b> | <b>55 616</b>   | <b>9 400</b>       | <b>7 920</b> | <b>18 234</b>         | <b>91 170</b>     |                 |

According to the Grant Agreement **10105736** action is divided into the following ‘reporting periods’:

- 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

The overall agreed budget will be paid on installments following the reporting periods of the Grant Agreement.

Interim and final payments will be transferred to ECRIN PARTNER without unjustified delay after approval of each periodic and final report by the European Commission.

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### **Appendix 3:**

