

# AMENDMENT No. 1

to the

# **Clinical Trial Agreement**

between

**University Medical Center Utrecht**, principal place of business at Heidelberglaan 100, 3584 CX, Utrecht, Netherland, duly represented by **Example 100**, Director Business Operations (hereinafter: **Sponsor**)

and

University Hospital Motol, registered office at V Úvalu 84, 150 06, Praha 5, duly represented by acting on the power of attorney (Hereafter: Institution)

Each separately referred to as the "Party", each collectively referred to as the "Parties".

# Whereas

- the Parties entered into a Clinical Trial Agreement (CTA) V1.0 on 23-Nov-2020;

- the Parties have agreed to the end of the enrolment date of 1-May-2022 for this Clinical Study;

- the Parties now wish to amend the CTA to the new circumstances, which includes amending the Annex B titled "HONEST PREPS Financial addendum to the Clinical Trial Agreement" of the CTA to "Updated HONEST PREPS Financial addendum to the Clinical Trial Agreement"

# IT IS NOW AGREED AS FOLLOWS

1. The first sentence of section 5.1 of the CTA shall be amended to state the following:

The Site Parties shall use reasonable endeavours to recruit 100 Clinical Study Subjects which fulfil in- and exclusion criteria for the Clinical Study within the timelines specified in the Protocol.

2. Annex B titled " HONEST PREPS Financial addendum to the Clinical Trial Agreement" of the CTA shall be replaced with an updated budget see Annex B "Updated HONEST



PREPS Financial addendum to the Clinical Trial Agreement" as attached as Schedule 1 hereto.

- 3. If the Institution does not complete all tasks, a reconciliation will be performed based on actual completed tasks.
- 4. Except as amended above, all terms of the CTA shall remain and continue in full force and effect, and are hereby ratified and confirmed in all aspects.



IN WITNESS WHEREOF, the Parties have hereto requested their duly authorized representatives to execute this Agreement, as of the date written above.

Signed on behalf of the **Sponsor** 

Signature:

Name:

Title: Director Business Operations

Date:

Signed on behalf of the **Study Site** 

Signature: \_\_\_\_\_

Name:

Title: acting on power of attorney

Date:

Signed by the Site Investigator

Signature:

Name:

Title:

Date:



## ANNEX B

## Updated HONEST PREPS Financial addendum to the Clinical Trial Agreement

#### Payment for study coordinator/research nurse

Sites can invoice Euro:

- after approval to start inclusion based on a minimum expected recruitment target of 100 subjects by 1-May-2022.

## Payment for included study subjects:

- Euro per per correctly included and fully evaluable subject enrolled in the study before 1-May-2022 without an upper limit.

## Payment for Pass through costs:

- Reimbursement of ethical/regulatory submissions or other pass through costs will be done based on actual costs upon prior approval.

Payment schedule						
	Subjects	Payment	amount		occurrence	prerequisite
1.		In Advance	€	Ex VAT, Inc Overhead	once	-if approval to start inclusion; -after 1 <sup>st</sup> subject inclusion
2.	Per subject	Retrospective	€	Ex VAT, Inc Overhead	Per included subject,	- Last Patient First Visit (LPFV) 30-Apr-2022 inclusive.

Invoices may be sent on a monthly basis until inclusion is stopped on 1-May-2022 or when the contract is ended.

In addition to article 12 of the Agreement, the following shall apply:

This Payment schedule is applicable after approval to start inclusion until the end of patient recruitment on 1-May-2022 (LPFV 30-Apr-2022) and the applicable study activities thereafter (eCRF completion, subject follow-ups, data cleaning, queries and site close out procedures).

Depending on available funding, protocol development of ECRAID POS-ICU-VAP program and the performance of the Study Site, the Sponsor decides to:

- Transfer to the ECRAID POS-ICU VAP platform study after 1-May-2022, or
- Stop the HONEST project and terminate the Agreement.



In case of transfer to the ECRAID POS-ICU-VAP platform, final study activities for HONEST-PREPS shall be completed within reasonable timeframe.