UMC Utrecht

MASTER SERVICES AGREEMENT FOR PROVISION OF RESOURCES

The undersigned

1) University Medical Center Utrecht, whose registered office is at Heidelberglaan 100, 3584 CX Utrecht, legally represented by Mr. J.J. Gombert, Manager Finance of University Medical Center Utrecht's division Julius Center for primary care and health sciences and prof. dr. A.W. Hoes, Divisional Manager of the aforementioned Julius Center
VAT ID No.: NL00420531B01

(hereinafter referred to as "**UMC Utrecht**");

And

2) **St. Anne´s University Hospital Brno**
Pekařská 664/53, 656 91 Brno, Czech Republic
Represented by: MUDr. Martin Pavlík, Ph.D., DESA, EDIC, director
VAT ID No.: CZ00159816
Bank details: Czech National Bank
Account No.: 71138621/0710
IBAN: CZ97 0710 0000 0000 7113 8621
SWIFT: CNBACZPP

(hereinafter: **Resources Provider**);

hereinafter individually referred to as a "Party" and collectively referred to as the "Parties" in this Agreement.

Whereas

A) UMC Utrecht is a partner in multiple IMI Consortium COMBACTE (COMbatting BACTerial resistance in Europe) projects and has entered into multiple IMI COMBACTE Grant Agreements with the IMI JU (the IMI Joint Undertaking between the EU and EFPIA partners) for this purpose;

B) UMC Utrecht desires to engage Resources Provider to perform services in relation to clinical trials, including in the context of the COMBACTE research programs;

C) Resources Provider is engaged in the business of providing resources for (clinical testing) project management and services for academia, the pharmaceutical and/or medical device industry in the Czech Republic;

D) UMC Utrecht may agree on one or more Work Orders with Resources Provider in connection with certain clinical trials, which may include provisions for the coordination of projects and other services, to be mutually agreed upon by the Parties, all in accordance with and subject to the terms of this Agreement.

Now the Parties agree to the following terms and conditions:

1. Definitions

The following words and phrases have the following meanings:

1. "Agreement" means this Master Services Agreement comprising its clauses, schedules and any appendices attached to it;
2. "Auditor" means a person who is authorised to carry out a systematic review and independent examination of Clinical Trial related activities and documents to determine whether the evaluated Clinical Trial related activities were conducted, and the data were recorded, analysed and accurately reported according to the Protocol, UMC Utrecht's Standard Operating Procedures, ICH GCP and the applicable regulatory requirements;
3. "Change Order" means a written amendment to a Work Order, the form of which is attached hereto as Attachment 2;
4. "Clinical Trial" means an investigation to be conducted at a Trial Site in accordance with the relevant Protocol thereto for which trial a Work Order was signed;
5. "Clinical Trial Agreement" means an agreement between UMC Utrecht and an Institution concerning a Clinical Trial;
6. "Clinical Trial Subject" means a person recruited to participate in the Clinical Trial;
7. "Clinical Trial Authorisation" means a clinical trial authorised by the Competent Authority;
8. "Competent Authority" means the authority appointed to evaluate a Clinical Trial in accordance with law applicable to such Clinical Trial;
9. "Confidential Information" means any and all information, data and material of any nature belonging to UMC Utrecht or Resources Provider which a Party may receive or obtain in connection with this Agreement or other information the release of which is likely to prejudice the interests of UMC Utrecht or Resources Provider respectively, or which is a trade secret or Know How;
10. "Ethics Committee" means the accredited medical research ethics committee competent to review a Clinical Trial, and to which the relevant Protocol has been submitted for approval;
11. "Fees" mean the fees set out in the Payment Schedule in a respective Work Order;

12. "ICH GCP" means the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) together with such other good clinical practice requirements as are specified in Directives 2001/20/EC and 2005/28/EC of the European Parliament and the Council relating to medicinal products for human use and in guidance published by the European Commission pursuant to such Directives;
13. "Institution" means the institution that has signed a clinical trial agreement with UMC Utrecht to conduct a Clinical Trial at a Trial Site;
14. "Intellectual Property Rights" means patents, trademarks, trade names, service marks, domain names, copyrights, rights in and to databases (including rights to prevent the extraction or reutilisation of information from a database), design rights, topography rights, utility models, including applications for registration of any of them and all rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered and including applications for registration of any of them;
15. "Know How" means all technical and other information which is not in the public domain (other than as a result of a breach of confidence), including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, clinical data, manufacturing data and information contained in submissions to regulatory authorities, whether or not protected by Intellectual Property Rights or any applications for such rights;
16. "Party" means UMC Utrecht or Resources Provider and "Parties" shall mean both of them;
17. "Personal Data" means data as defined in the EU Data Protection Directive (Directive 95/46/EC) and any relevant successive legislation, such as the General Data Protection Regulation (EU 2016/679);
18. "Principal Investigator" means the responsible investigator at the Institution referred to;
19. "Project" means a Clinical Trial for which UMC Utrecht requires the provision of services by Resources Provider, such activities to be detailed in the relevant Work Order;
20. "Protocol" means the description of the Clinical Trial for which is specific Work Order is signed (a copy of which is attached to such Work Order) and all amendments thereto, for which Clinical Trial Authorization has been obtained;
21. "Research Staff" means the persons who will undertake the conduct of the Clinical Trial at the Trial Site on behalf of the Institution under the supervision of the Principal Investigator;
22. "Services" means the services as set out in the relevant Work Order;
23. "Trial Monitor" means one or more persons appointed by UMC Utrecht to monitor compliance of the Clinical Trial with ICH GCP and the Protocol and to conduct source data verification;

24. "Trial Site(s)" means any premises as agreed upon by UMC Utrecht and Institution in which a Clinical Trial will be conducted;
25. "Work Order" means a written order, the template form of which is attached hereto as Annex 1, detailing the services to be performed by Resources Provider for a particular Project (specifically the Parties' obligations related to the Project and related tasks and timelines) and the payment schedule corresponding to such services.

2. Obligations

2.1. Resources Provider will make available resources in order to provide the Services with specific expertise to secure implementation of the below mentioned activities, for the Projects allocated to it under the applicable Grant Agreement(s):

a) Support site selection activities;
b) Coordinate the participation of Trial Sites in projects;
c) Support Trial Sites with their participation in projects ;
d) ; and
e) Provide support for data collection activities.

2.2. Resources Provider shall deliver the Services to UMC Utrecht as set out in the Work Order(s) and will ensure that such Services are in accordance with this Agreement and all applicable laws and regulations.

2.3. Upon mutual agreement of the Parties, the template of the Work Order may be modified from time to time during the term of this Agreement or adapted on a project-specific basis to better meet the needs of particular project. Each Work Order shall contain the details of the requested Services and the Parties' obligations related thereto (e.g. Clinical Trial, Trial Sites involved, Services, fees, time line, payment schedule).

2.4. If during the performance of the Services Resources Provider finds a violation of regulatory or scientific standards of integrity (including but not be limited to, danger to health of employees and study subjects, adverse effects of the materials upon study subjects or continued performance of the Services will result in a breach of legislation or regulations), Resources Provider will immediately send written notice to UMC Utrecht to enable UMC Utrecht to find a remedy for such violation.

3. Change Orders

3.1. No addition to or modification of this Agreement or its appendices shall be effective unless made in writing and signed by both Parties, except with respect to the Protocol attached to a Work Order.

3.2. UMC Utrecht and the relevant Institution may agree to amend the Protocol attached to a Work Order at any time and the amended Protocol will immediately and *ipso facto*

form part of such Work Order. In case of amendments to the Protocol, UMC Utrecht will send the amended Protocol to Resources Provider and upon reasonable request of Resources Provider Parties will discuss whether such amendment justifies a change in the Services and Payment Schedule set out in the relevant Work Order and if so, Parties will execute a Change Order.

3.3. Parties will also execute a Change Order in case UMC Utrecht requires any other change in the Services which is not covered by the previous paragraph of this clause.

3.4. Each Change Order shall detail the requested changes to the applicable task, responsibility, duty, budget, time line or other matter. The Change Order will become effective upon the authorized signature of the Change Order by both Parties.

4. Fees and Charges, Costs and Expenses

4.1. In consideration for the Services performed by Resources Provider, UMC Utrecht agrees to pay Resources Provider the Fees as detailed in the applicable Work Order.

4.2. Fees include all costs and taxes unless set out otherwise in the and Payment Schedule of a Work Order. However, UMC Utrecht shall bear all costs relating to bank transfers of amounts payable to Resources Provider.

4.3. The IMI JU may, at any time during the implementation of the contract and up to five years after the end of the contract, arrange for financial audits to be carried out at the Institution, by external auditors, or by the IMI JU's services themselves including the European Anti-Fraud Office (OLAF) and Court of Auditors.

5. Invoicing

5.1. Resources Provider shall submit invoices to UMC Utrecht for the Services in EURO and based on the Payment Schedule set out in the relevant Work Order.

5.2. UMC Utrecht shall pay each invoice within thirty (30) days from the date of receipt of the final invoice.

5.3. If UMC Utrecht fails to pay the amount of the invoice to Resources Provider within the timeframe defined above then Resources Provider shall send a Late Payment Notice to UMC Utrecht with an additional thirty (30) day period to pay such invoice. If UMC Utrecht fails to pay the amount of the invoice within the additional sixty (60) day period, it shall result in UMC Utrecht obligation to pay the Resources Provider a late payment interest amounting to 0.01 % of the invoiced price per each initiated day of delay with payment.

6. Liabilities, Indemnifications and Insurance

6.1. Resources Provider shall indemnify UMC Utrecht against claims or proceedings from Clinical Trial Subjects, or any other third party in connection with damage that the Clinical Trial Subject has incurred and that has been caused by a breach of this Agreement or a wrongful act by Resources Provider.

6.2. In no event will either Party's liability towards the other Party include any indirect damages (indirect damages meaning: loss of profit, loss of revenue and loss of business opportunities).

6.3. The total liability of UMC Utrecht for all claims or proceedings under a Work Order together will be limited to amount payable by UMC Utrecht to Resources Provider under such Work Order or euro one million (whichever amount is the lowest).

6.4. Nothing in this clause shall operate so as to restrict or exclude the liability of any Party in relation to death or personal injury caused by the negligence of that Party or its servants or employees or to restrict or exclude any other liability of either Party which cannot be so restricted or excluded in law.

6.5. Each party will take out and maintain appropriate insurance cover satisfactory in respect of its potential liability rising out of this agreement. Parties shall produce to each other, on request, copies of insurance certificates, together with evidence that the policies to which they refer remain in full force and effect, or other evidence concerning the indemnity.

7. Confidentiality

7.1. UMC Utrecht and Resources Provider shall ensure that only those of its officers and employees directly concerned with the carrying out of this Agreement have access to the Confidential Information of the other Party. Each Party undertakes to treat as strictly confidential and not to disclose to any third party any Confidential Information of the other Party, except where disclosure is required by a regulatory authority or by law. The Party required to make the disclosure shall inform the other within a reasonable time prior to being required to make the disclosure, of the requirement to disclose and the information required to be disclosed. Each Party undertakes not to make use of any Confidential Information of the other Party, other than in accordance with this Agreement, without the prior written consent of the other Party. This obligation continues to be in force with a period of ten (10) years after the termination of this Agreement and any Work Order agreed between the Parties.

7.2. The obligations of confidentiality set out in the previous paragraph of this clause shall not apply to information which:

1. is or becomes part of the public domain by any other means than a wrongful act or breach of this Agreement by the Parties;

2. was or becomes in the Parties' lawful possession prior to the disclosure without restriction on disclosure;
3. is received from a third party having no obligation of confidentiality to the disclosing Party; or
4. has been developed independently by the receiving Party without recourse to the information.

7.3. Unless the disclosing Party provides prior written consent, any receiving Party may not use Confidential Information for any purpose other than that authorized in this Agreement, nor may the receiving Party disclose Confidential Information to any third party except as authorized in this Agreement or as required by law. Specifically authorized is the disclosure of Confidential Information:

1. under obligation of law or regulation, provided the information disclosed is necessary to comply with the legal requirements, and confidentiality is maintained to other third parties; or
2. to the Ethics Committee or Competent Authority.

7.4 Resources Provider abides by all applicable laws and regulations for protecting the personal data, including any transfer from the European Union to the United States. Resources Provider shall process any data about an identified or identifiable individual that are (a) within the scope of the EU Data Protection Directive (Directive 95/46/EC or the European General Data Protection Regulation as appropriate) and (b) transferred to Provider from the European Union in accordance with the U.S.-EU Privacy Shield. Provider's privacy policy sets out Provider's specific privacy practices with respect to personally identifiable information transferred from the European Union to the United States.

8. Intellectual Property

8.1. All Intellectual Property Rights and Know How owned by or licensed to any of the Parties prior to and after the date of this Agreement are and shall remain the property of that Party.

8.2. UMC Utrecht shall own the Intellectual Property Rights and Know How arising directly from the Clinical Trial.

8.3. Resources Provider will promptly inform UMC Utrecht of any invention or discovery (whether patentable or not), made or discovered in the course of performing the Services so that UMC Utrecht can meet its obligations toward the other participants in the IMI COMBACTE Grant Agreement and Resources Provider hereby now for then transfers all Intellectual Property Rights in such invention or discovery to UMC Utrecht and will and provide reasonable assistance to UMC Utrecht, including by executing all

relevant instruments, in filing or prosecuting Intellectual Property Rights, at the expense of UMC Utrecht.

8.4. No royalty or other payment will be due to Resources Provider from UMC Utrecht in respect of any such invention or discovery.

9. Quality Control

9.1. UMC Utrecht shall be entitled in its absolute discretion to monitor and audit the conduct by Resources Provider of any work relating to the Services performed under this Agreement. Such monitoring shall take such form as UMC Utrecht may reasonably think fit and shall include without prejudice to the foregoing generality the right to inspect any facility being used by Resources Provider in relation to the Services and to examine any procedures and records, both scientific and financial, relating to the Services, always provided that such inspections are not incompatible with local laws. No such monitoring by UMC Utrecht shall relieve Resources Provider of any of its obligations hereunder.

9.2. Resources Provider shall keep accurate books of account and records covering all transactions involving the Services provided by Resources Provider. UMC Utrecht, or its authorized representatives, shall have the right, during normal business hours, to examine such books and records to the extent necessary to determine Resources Provider's compliance with the supply of the Services under this Agreement. All such books and records shall be kept available until five (5) years after the termination of the Agreement and any Work Order.

9.3. Resources Provider shall permit the Trial Monitor and any Auditor access to all data concerning the relevant Clinical Trial for monitoring and source data verification. If such data is located at the premises of Resources Provider such access is to be arranged at mutually convenient times and on reasonable notice.

9.4. Resources Provider shall permit authorized representatives of the Ethics Committee and competent authorities to have access to, copy and verify information relating to the Clinical Trial, as required by applicable legislation or requested by UMC Utrecht.

9.5. In the event that the UMC Utrecht reasonably believes there has been any research misconduct in relation to the Clinical Trial, Resources Provider shall provide all reasonable assistance to any investigation into any alleged research misconduct undertaken by or on behalf of UMC Utrecht.

9.6. Resources Provider acknowledges that with respect to certain Projects, UMC Utrecht is subject to agreements with IMI JU, notably the IMI COMBACTE Grant Agreement. Therefore, Resources Provider also respects the obligations mentioned in Articles II.10, II.11, II.12 and II.21 of the IMI COMBACTE Grant Agreement included in Attachment 3 of this Agreement.

10. Term and Termination of the Agreement

10.1. This Agreement shall enter into force at the time of its signature by authorised representatives of both parties and effective from the date of publication in Register of Contracts under Czech Act no. 340/2015 Coll., on special conditions for the effectiveness of some contracts, the disclosure of these contracts and register of contracts and shall remain in full force and effect for a period of six (6) months with the option for renewal for a period of one (1) year, such renewal to be contingent upon a written agreement between the Parties. Resources provider shall notify UMC Utrecht of said effective date.

10.2. Either Party may terminate this Agreement for convenience by giving the other Party sixty (60) days prior written notice of termination. In the event UMC Utrecht terminates this Agreement for convenience, Resources Provider shall be entitled to the appropriate proportion of the Fees based on the work properly performed up to the termination date.

10.3. A Party may rescind the Agreement with immediate effect in other words without a notice of default being required if the other Party files for suspension of payment or bankruptcy, is declared bankrupt or is granted suspension of payment, no longer exists, is dissolved, has stopped business or commits a material breach, which, if capable of remedy, is not remedied within a reasonable default period after notice from the aggrieved Party demanding such remedy.

11. Termination of a Work Order

11.1. Work Orders shall terminate the earlier of:

a. completion of the Clinical Trial for which such Work Order was signed;
b. termination of the Clinical Trial Agreement for which such Work Order was signed;
c. successful completion of the activities to be performed by Resources Provider as detailed in the specific Work Order.

11.2. A Party may rescind a Work Order with immediate effect in other words without a notice of default being required if the other Party files for suspension of payment or bankruptcy, is declared bankrupt or is granted suspension of payment, no longer exists, is dissolved or has stopped business.

11.3. UMC Utrecht may rescind a Work Order with immediate effect in other words without a notice of default being required if:

1. a public authority or supervisory body has taken a decision as a result of which UMC Utrecht can no longer reasonably be required to continue such Work Order (in whole or in part); or

2. Resources Provider commits a material breach, which, if capable of remedy, is not remedied within ten (10) working days, unless a different default period is agreed in the Work Order, after written notice from the aggrieved Party demanding such remedy.

12. Termination: consequences

12.1. Upon the a Work Order terminating, Resources Provider will immediately take all necessary steps, if UMC Utrecht so requests in writing, to ensure a new supplier or UMC Utrecht can continue to perform what was to be performed pursuant to the Work Order without impediments. If the termination of the Work Order is the result of a breach caused by UMC Utrecht, the reasonable costs of such cooperation will fall to UMC Utrecht and in all other cases they will fall to Resources Provider.

12.2. Upon termination of this Agreement and/or a Work Order for any reason Resources Provider shall provide all documents, data and records relating to the relevant clinical study to UMC Utrecht without retaining a copy. No administrator, administrative receiver or other receiver or equivalent, nor Resources Provider itself, nor any of its creditors shall be entitled to any lien or other possessory remedy or security over the data which shall remain UMC Utrecht's property.

12.3. Termination of this Agreement and/or a Work Order shall not affect any right or obligations of the Parties which may have accrued prior to termination pursuant to the Agreement and/or such Work Order nor shall it affect the coming into or continuance in force of any provisions of this Agreement and/or such Work Order which are expressly or by implication intended to come into or continue in force after termination.

13. Publication

13.1. Under no circumstances may Resources Provider publish any articles or make any presentations relating to the Services provided to UMC Utrecht hereunder with respect to a Clinical Trial or referring to data, information or materials generated as part of the Services without the prior written consent of UMC Utrecht.

14. Data Protection

14.1. Resources Provider will only process personal data which is received from UMC Utrecht or the Institution in full compliance with all applicable data protection laws and regulations, the provisions of this Agreement and the instructions of UMC Utrecht and/or the Institution. Resources Provider will not process personal data received or generated as a result of performance of the Agreement for his own purposes.

14.2. The Parties agree to adhere to the principles of medical confidentiality in relation to Clinical Trial Subjects involved in the Clinical Trial. Personal data shall not be disclosed to UMC Utrecht by Resources Provider unless this is required to satisfy the requirements of the Protocol or for the purpose of monitoring or adverse event reporting, or in relation to a claim or proceeding brought by the Clinical Trial Subject in connection with the Clinical Trial. The Parties shall not disclose the identity of Clinical Trial Subjects to third parties without prior written consent of the Clinical Trial Subject, except in accordance with the provisions of the Personal Data Protection Act or as appropriated with respect to the handling of a claim or proceeding brought by the Clinical Trial Subject in connection with a Clinical Trial.

14.3. Each Party undertakes to implement all appropriate technical and organisational security measures to secure personal data processed under this Agreement or generated as a result of performance of this Agreement against unauthorised access, destruction, loss and unlawful processing. These measures must be also intended to warrant an appropriate level of security taking into account the risks the processing and the nature of the personal data. Upon first request of UMC Utrecht, Resources Provider will immediately take additional measures.

14.4. Parties will inform each other: (a) within four (4) hours of a security incident or a breach of one of the obligations stipulated in this clause, (b) as soon as possible of a complaint of an individuals whose personal data has been or is being processed and (c) a research by a supervisory body or other competent authority, to the extent this is permitted by applicable laws and regulations.

14.5. Resources Provider shall indemnify and hold harmless UMC Utrecht from any third party claims caused by Resources Provider's failure to comply with its obligations under this Agreement with respect to processing of personal data.

14.6. Immediately upon expiry or termination of this Agreement and/or a Work Order each Party undertakes to destroy or forward to the other Party without retaining a copy any personal data received from the other Party under the Agreement and/or such Work Order, as per request of the other Party.

15. Independent Contractors

15.1. The Parties are independent contractors, and this Agreement shall not be deemed to constitute either Party (or any of its employees) a partner, joint venturer, franchisee, servant, agent, or employee of the other. This Agreement does not give Resources Provider any right or entitlement to legally represent UMC Utrecht, to sign documents on behalf of UMC Utrecht or to file applications or documents with authorities on behalf of UMC Utrecht, unless with express, prior and written approval of UMC Utrecht.

16. Force Majeure

16.1. Neither Party shall be liable or deemed to be in default for any delays due to causes beyond the control of the Party, such as: war, civil disorders, acts of God, or governmental action; provided, that the affected Party promptly notifies the other of the cause and its effects on the Services to be performed hereunder, adequate precautionary measures are in place and the affected Parties does the utmost to mitigate the effects of such an event upon its performance.

17. Warranties

17.1. Resources Provider hereby warrants that the following statements are true and correct as of the signing date:

1. Resources Provider is an entity duly incorporated and validly existing under the applicable laws and is not subject to or threatened by any insolvency or bankruptcy or similar proceedings and no facts exist that would result in such event occurring.
2. Resources Provider is fully empowered to execute and perform this Agreement and to carry out the transactions contemplated hereby.
3. This Agreement is duly executed by Resources Provider and is the valid and binding obligation of Resources Provider, enforceable against Resources Provider in accordance with its terms.
4. The execution and performance of this Agreement by Resources Provider do not conflict with or result in a breach of its certificate of incorporation, articles of association by-laws or other similar organization documents or conflict with or violate any law or regulations or governmental orders applicable to Resources Provider.
5. Resources Provider is not subject to any pending claim, action, proceeding or investigation that may delay or prevent the consummation of, or which would be reasonably likely to adversely affect Resources Provider's ability to consummate, the Project contemplated by this Agreement.
6. Resources Provider has adequate resources to fulfil its obligations under this Agreement.

18. Assignment

18.1. Resources Provider may not assign, sell, transfer, delegate or otherwise dispose of this Agreement or any right, duty or obligation under this Agreement without UMC Utrecht's prior written consent. Resources Provider shall not be entitled to subcontract the Services.

18.2. All representations, convenants and warranties of this Agreement shall be binding upon and inure to the benefit of the Parties and their respective successor or permitted assigns. Nothing in this Agreement is intended or shall be construed to confer upon or give to any person or entity other than Resources Provider and UMC Utrecht any right, remedy or claim hereunder, except if agreed otherwise by the Parties.

18.3. Resources Provider shall have no rights vis-à-vis IMI JU under this Agreement.

19. Miscellaneous

19.1. Should there be any inconsistency between the Protocol and the terms of a Work Order or this Agreement, or any other document incorporated therein, including UMC Utrecht's Standard Operating Procedures, the terms of the Protocol shall prevail to the extent of such inconsistency.

19.2. If any provisions of this Agreement shall be declared invalid or unenforceable, the remainder of this Agreement shall not be affected thereby and shall remain in full force and effect.

20. Governing Law; Dispute Resolution

20.1. This Agreement shall be governed by, and construed in all respects in accordance with the laws of The Netherlands without regard to its conflicts of laws rules. Any claims, controversies or disputes arising out of or in connection with this Agreement which cannot be settled amicably between the Parties, shall be subject to the exclusive jurisdiction of the competent district court of Midden-Nederland, location Utrecht.

[This part of page is intentionally left blank; for signatures, see next page]

UMC Utrecht

IN WITNESS WHEREOF, this Agreement has been executed by the Parties hereto through their duly authorised representatives on the date(s) sets forth below.

Signed on behalf of **UMC Utrecht**

Signed on behalf of **UMC Utrecht**

Name: J.J. Gombert

Title: Division Manager Finance of Julius Center

Signature: [redacted]

Date: 1/10/18

Name: prof. dr. A.W. Hoes

Title: Division Manager Julius Center

Signature: [redacted]

Date October 1, 2018

Signed on behalf of **Resources Provider**

Name:

Title:

Signature: .....

Date: 11.10.2018 .....

UMC Utrecht

Attachment 1

SAMPLE OF WORK ORDER

{*}

between

UMCU Utrecht

(hereinafter: **UMC Utrecht**)

and

[NAME Resources Provider]

(hereinafter**: Resources Provider**)

This Work Order ("Work Order") is between UMC Utrecht and Resources Provider and relates to the Master Services Agreement dated .... (the "Master Agreement"), which is incorporated by reference herein. Pursuant to the Master Agreement, Resources Provider has agreed to perform certain services in accordance with written work orders, such as this one, entered into from time-to-time.

The parties hereby agree as follows:

1. Work Order. This document constitutes a Work Order under the Master Agreement and this Work Order and the services contemplated herein are subject to the terms and provisions of the Master Agreement.

2. Services and Payment of Fees and Expenses. The specific services contemplated by this Work Order and the related payment terms and obligations are set forth in Schedule 1 Payment Schedule, which is incorporated herein by reference. Resources Provider will ensure that such Services are in accordance with Schedule 2 Protocol, which is incorporated herein by reference.

3. Term. The term of this Work Order shall commence on the date of execution and shall continue until the services described in in Schedule 1 Payment Schedule are completed, unless this Work Order is terminated in accordance with the Master Agreement. If the Master Agreement is terminated or expires, but this Work Order is not terminated or

completed, then the terms of the Master Agreement shall continue to apply to this Work Order until the Work Order is either terminated or completed. The default period for Resources Provider to remedy a material breach shall be one month for this Work Order.

4. Change Orders. No modification, amendment, or waiver of this Work Order shall be effective unless in writing and duly executed and delivered by each party to the other.

Signed on behalf of **UMC Utrecht**

Name: J.J. Gombert

Title: Division Manager Finance of Julius Center

Name: prof. dr. A.W. Hoes

Title: Division Manager Julius Center

Signature: .....

Signature:.....

Date:.....

Date .....

Signed on behalf of **Resources Provider**

Name:

Title:

Signature: .....

Date: .....

UMC Utrecht

Work Order

Schedule 1 Payment Schedule

Work order agreed by both sides at the beginning of each month will serve as a template for invoicing.

Invoices will specify per scientific project the cost precisely allocated in working hours related to the activity under a particular contract and the other cost (such as travel costs that will be supported by an accounting record with clearly identifiable costs relevant to particular contract).

UMC Utrecht will compensate amount of 20 EUR per 1 working hour according to the table below.

Payment will be made upon receipt of invoices sent by {Resources provider}.

Work order No.:

	Project 1						Project 2					
2018	Coordinator 1			Coordinator 2			Coordinator 1			Coordinator 2		
	hrs	hr cost	total	hrs	hr cost	total	hrs	hr cost	total	hrs	hr cost	total
Month 1												
Month 2												
Month 3												
Month X												

Work Order

Schedule 2 Protocol

{Resource provider} will provide assistance to UMC Utrecht in clinical trial management and coordination, including site recruitment and coordination, monitoring activities and submissions. Trials may include projects within and outside of COMBACTE and may be investigator-initiated or commercially sponsored. Trials for which assistance will be provided will include ASPIRE-SSI, RESTORE-IMI and REMAP-CAP, and may include others.

Services in detail:

A. Support site selection activities e.g. assist in the identification and recruitment of local participating sites for clinical trials
B. Coordinate the participation of trial sites in clinical studies
C. Assist in national and local regulatory submissions for clinical trials
D. Assist in contracting procedures between trial sites and sponsor
E. Attend investigator meetings
F. Support trial sites with their participation in clinical studies
G. Provide support for recruitment and data collection activities

For the period of six months, these activities will be supported by {Resources provider} with 0.7 FTE project manager to a maximum amount of €10,000, and {Resources provider} will invoice UMC Utrecht based on the hours dedicated to the different trials, with a specification of dedicated hours to the different studies.

Supplementary work can only be accepted if pre-authorized in writing by UMC Utrecht.

Any clinical trials performed by Resources provider under this master services agreement in the territory of the Czech Republic shall meet the requirements of Czech legislation and shall be carried out only on the basis of separate written contracts.

UMC Utrecht

Attachment 2

SAMPLE OF CHANGE ORDER

{*}

between

UMCU Utrecht

(hereinafter: **UMC Utrecht**)

and

[NAME Resources Provider]

(hereinafter**: Resources Provider**)

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

IT IS NOW AGREED AS FOLLOWS:

1. The original Work Order N. {*}/2015 between the Parties, dated {*} {*} {*} shall be amended by the inclusion of additional Services to be performed by Resources Provider as described in Schedule 1 hereto.
2. UMC Utrecht agrees to pay a total of {*} € for the services detailed in Attachment 1 attached hereto.
3. Except as amended above, all terms of the foregoing Work Order shall remain and continue in full force and effect, and are hereby ratified and confirmed in all aspects.

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

Signed on behalf of **UMC Utrecht**

UMC Utrecht

Name: J.J. Gombert

Title: Division Manager Finance of Julius Center

Name: prof. dr. A.W. Hoes

Title: Division Manager Julius Center

Signature: .....

Signature:.....

Date:.....

Date .....

Signed on behalf of **Resources Provider**

Name:

Title:

Signature: .....

Date: .....

UMC Utrecht

Change Order
Schedule #1

BUDGET PROPOSAL FOR EXTRA ACTIVITIES -X_Study					
Task	Unit	# of Units	Unit Cost (€)	Total (€)	Comments
Direct Fees					
TOTAL STUDY				0,00	

Attachment 3: Relevant sections from the COMBACTE Grant Agreement

The following sections from the IMI COMBACTE grant agreement are relevant for subcontractors under the Clinical Trial Agreement, whereby IMU JU means the IMI Joint Undertaking between the EU and EFPIA, and the following words and phrases in these sections of the IMI COMBACTE grant agreement have the following meanings:

"*beneficiary*" means a *participant* eligible to receive *IMI JU* financial contribution in accordance with the *IMI JU* Statutes annexed to Council Regulation (EC) No 73/2008 on the establishment of the *IMI JU* of 20 December 2007;

"*dissemination*" means disclosure by any appropriate means other than that resulting from the formalities for protection, and including the publication in any medium;

"*EFPIA*" means European Federation of Pharmaceutical Industries and Associations;

"*EFPIA company*" means a *participant* which is a research based pharmaceutical company that is member of EFPIA; Where reference to work to be performed by an *EFPIA company* is made in Annex I, it shall be understood as referring to work to be performed by the *EFPIA company* or any of its *affiliated entities*, without these *affiliated entities* becoming *participants*;

"*foreground*" means the results, including data, know how and information, whether or not they can be protected, which are generated under the project and excluding *sideground*. Such results include rights related to copyright; design rights; patent rights; or similar forms of protection;

"*in kind contribution*" means contributions to the *project* by *EFPIA companies* and their *affiliated entities*, with resources such as personnel, equipment, consumables, declared in accordance with Articles II.4, II.13 and II.14;

"*participant*" means a legal entity being a party of the *consortium*, contributing to the *project* and having rights and obligations with regard to the *IMI JU* under the terms of the IMI COMBACTE grant agreement;

"*project*" means the research activities carried out by the *participants* as defined in Annex I of the IMI COMBACTE grant agreement;

"*research use*" means the use of *foreground* or *background* necessary to use *foreground* for all purposes other than for completing the *project* or for *direct exploitation*;

"*sideground*" means the results, including data, know how and information, whether or not they can be protected, which are generated by a *participant* under the *project* but outside of the *project objectives* and which are not needed for undertaking and completing the *project* or the *research use* of *foreground*;

II.10. Communication of data for evaluation, impact assessment and standardisation purposes

1. *Participants* shall provide, at the request of the *IMI JU*, the data necessary for:
- the review of the specific *IMI JU* programme and the Seventh Framework Programme;

- the evaluation and impact assessment of *IMI JU* activities, including the *research use* and *dissemination* of *foreground*.

Such data may be requested throughout the duration of the *project* and up to five years after the end of the *project*. The data collected may be used by the *IMI JU* in its own evaluations but will not be published other than on an anonymous basis.
2. Without prejudice to the provisions regarding protection of *foreground* and confidentiality, the *participants* shall, where appropriate, during the *project* and for two years following its end, inform the *IMI JU* and the European standardisation bodies about *foreground* which may contribute to the preparation of European or international standards.

II.11. Information and communication

1. The *participants* shall, throughout the duration of the *project*, use their reasonable efforts to engage with the public and the media about the *project* and to highlight the European Union (*IMI JU*) financial support and *EFPIA companies' in kind contribution*. Unless the *IMI JU* requests otherwise, any publicity, including at a conference or seminar or any type of information or promotional material (brochure, leaflet, poster, presentation etc), must specify that the *project* has received support from *EFPIA companies* and the European Union (*IMI JU*) and display the *IMI JU* and *EFPIA* logos and the European emblem. This obligation to use the *IMI JU* and *EFPIA* logos and the European emblem in respect of *projects* to which the European Union (*IMI JU*) and *EFPIA companies* contribute implies no right of exclusive use. It is subject to general third-party use restrictions which do not permit the appropriation of the *IMI JU* and *EFPIA* logos and the European emblem or the logo, or of any similar trademark or logo, whether by registration or by any other means. Under these conditions, *participants* are exempted from the obligation to obtain prior permission from the European Commission, *EFPIA* and the *IMI JU* to use the logos and the European emblem. Further detailed information on the EU emblem can be found on the Europa web page. Any publicity made by the *participants* in respect of the *project*, in whatever form and on or by whatever medium, must specify that it reflects only the author's views and that neither the *IMI JU* nor *EFPIA* nor the European Commission is liable for any use that may be made of the information contained therein.

2. The *IMI JU* and/or the European Commission and/or *EFPIA* shall be authorised to publish, in whatever form and on or by whatever medium, the following information:
- the name of the *participants*;

- contact addresses of *participants;*

- the general purpose of the *project* in the form of a non confidential summary provided by the *consortium*;

- the amount and rate of the *IMI JU* financial contribution granted to the *project*;

- the estimated amount and rate of the *IMI JU* financial contribution foreseen for each *beneficiary* in the table of the estimated breakdown of costs in Annex I; and after the final payment, the amount and rate of the *IMI JU* financial contribution accepted by the *IMI JU* for each *beneficiary*;

- the amount of the *EFPIA companies' in kind contribution* to the *project*, and *EFPIA companies'* contributions from outside Europe;

- the geographic location of the activities carried out;

- the list of *dissemination* activities and/or of patent (applications) relating to *foreground*;

- the details/references and the abstracts of scientific publications relating to *foreground* and the published version or the final manuscript accepted for publication;

- the publishable reports submitted to it;

- any picture or any audiovisual or web material provided to the *IMI JU* in the framework of the *project*.

The *consortium* shall ensure that all necessary authorisations for such publication have been obtained and that the publication of the information by the *IMI JU* and/or the European Commission and/or *EFPIA* does not infringe any rights of *third parties*.
Upon a duly substantiated request by a *participant*, the *IMI JU* and/or the European Commission and/or *EFPIA* may agree to forego such publicity if disclosure of the information indicated above would risk compromising the *participant's* security, academic or commercial interests.

II.12. Processing of personal data

1. All personal data contained in the *grant agreement* shall be processed in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data by the *Community* institutions and bodies and on the free movement of such data. Such data shall be processed by the *IMI JU* solely in connection with the implementation and follow-up of the *grant agreement* and

the evaluation and impact assessment of European Union and *IMI JU's* activities, including the *research use* and *dissemination* of *foreground*, without prejudice to the possibility of passing the data to the bodies in charge of a monitoring or inspection task in accordance with European Community and European Union legislation and this *grant agreement*.
2. *Participants* may, on written request, gain access to their personal data and correct any information that is inaccurate or incomplete. They should address any questions regarding the processing of their personal data to the *IMI JU*. *Participants* may lodge a complaint against the processing of their personal data with the European Data Protection Supervisor at any time.
3. For the purposes of this *grant agreement*, the Controller identified in Article 8.4 shall be the contact person for the *IMI JU*.

II.21. Financial audits and controls

1. The *IMI JU* may, at any time during the implementation of the *project* and up to five years after the end of the *project*, arrange for financial audits to be carried out, by external auditors, or by the *IMI JU*'s services themselves. The audit procedure shall be deemed to be initiated on the date of receipt of the relevant letter sent by the *IMI JU*. Such audits may cover financial, systemic and other aspects (such as accounting and management principles) relating to the proper execution of the *grant agreement*. They shall be carried out on a confidential basis.
2. The *participants* shall make available directly to the *IMI JU* all detailed information and data that may be requested by the *IMI JU* or any representative authorised by it, with a view to verifying that the *grant agreement* is properly managed and performed in accordance with its provisions and that costs have been charged in compliance with it. This information and data must be precise, complete and effective.
3. The *participants* shall keep the originals or, in exceptional cases, duly authenticated copies – including electronic copies - of all documents relating to the *grant agreement* for up to five years from the end of the *project*. These shall be made available to the *IMI JU* where requested during any audit under the *grant agreement*.
4. In order to carry out these audits, the *participants* shall ensure that the *IMI JU*'s services and any external body(ies) authorised by the *IMI JU* have on-the-spot access at all reasonable times, notably to the *participants* offices, to their computer data, to their accounting data and to all the information needed to carry out those audits, including information on individual salaries of persons involved in the *project*. They shall ensure that the information is readily available on the spot at the moment of the audit and, if so requested, that data be handed over in an appropriate form.
5. On the basis of the findings made during the financial audit, a provisional report shall be drawn up. It shall be sent by the *IMI JU* or its authorised representative to the *participant* concerned, which may make observations thereon within one month of receiving it. The *IMI JU* may decide not to take into account observations conveyed or documents sent after that deadline. The final report shall be sent to the *participants* concerned within two months of expiry of the aforesaid deadline.

6. On the basis of the conclusions of the audit, the *IMI JU* shall take all appropriate measures which it considers necessary, including the issuing of recovery orders regarding all or part of the payments made to the *beneficiaries* by the *IMI JU* and the application of any applicable sanction.
7. The European Commission including OLAF3 and the Court of Auditors shall have the same rights as the *IMI JU* among the *beneficiaries* and the agent responsible for allocating it, including right of access, for the purpose of on-the-spots-checks.