EX-10.4 7 d94468dex104.htm EX-10.4

Exhibit 10.4

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) CUSTOMARILY AND ACTUALLY TREATED BY THE REGISTRANT AS PRIVATE OR CONFIDENTIAL.

ANNEX A: TERMS AND CONDITIONS - SCHEDULE A



Funding Agreement

(CEPI Identification: Valneva 0001)

Agreement Summary

AWARDEE INFORMATION

Name: Valneva SE

Mailing Address: 6 rue Alain Bombard, 44800 Saint-Herblain, France

Project Lead: [***]
Management Contact: [***]
Bank Account Details: [***]

CEPI INFORMATION

Mailing Address: Marcus Thranesgate 2, PO Box 123 Torshov, N-0412 Oslo, Norway

Project Lead: [***]
Management Contact: [***]

AGREEMENT INFORMATION

incorporates by reference:

Project Name VLA1553, a Lyophilized, Single-Dose, Live-Attenuated Chikungunya Virus Vaccine

CEPI Program Name CEPI CfP3i Chikungunya Vaccines

Effective Date 1 April 2019

This Agreement includes and The agreement (referred to as the "Agreement") means this Agreement Summary together with the following:

• Terms and Conditions ("T&Cs") (Annex A)

• Glossary of Defined Terms for the T&Cs (Schedule A)

• Effects of Termination for the T&Cs (Schedule B)

• CEPI Policies and Procedures as of Effective Date (Schedule C)

Team Charter (Annex B)

• Integrated Product Development Plan ("IPDP") (Annex C)

• IPDP Reporting Templates (Annex D)

• Project Budget (Annex E)

• Payment Request Form and Financial Report Templates (Annex F)

THIS AGREEMENT is between Valneva SE ("Awardee" or "You") and the Coalition for Epidemic Preparedness Innovations ("CEPI") and is effective as of the Effective Date. Each party to this Agreement may be referred to individually as a "Party" and together as the "Parties." This Agreement sets out the

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terms and conditions governing the performance of the Project, funding of the Project and how the results of the Project will be used to further CEPI's mission. As a condition of this funding award, the Parties enter into this Agreement by having their authorized representatives sign below.

Signed for and on behalf of COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS by:

Signature: [***]

Name: [***]

Title: [***]

Date: 7/24/2019

Signed for and on behalf of Valneva SE by:

Signature: [***]

Name: [***]

Title: [***]

Date: 7/24/2019

Signature: [***]

Name: [***]

Title: [***]

Date: 7/24/2019

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CfP3i Award Terms and Conditions

1. These Terms and Conditions

- 1.1 These "Terms and Conditions" (or "T&Cs") describe the contractual relationship between CEPI and Awardee for a particular Project under CEPI's CfP3i Programme. They describe each Party's rights and obligations, and provide instructions on the conduct of funded activities and the intended use of the results from funded activities. The Parties commit to participate in the Project with good intent and in good faith.
- 1.2 A glossary of defined terms used in these T&Cs is set out in Schedule A. A table setting out the effects of termination may be found in Schedule B to the T&Cs.
- 2. Project Organization and Management
- 2.1 **Start Date.** Awardee and CEPI commenced work on certain of the Project activities as described in the IPDP on 1 April 2019. The provisions of this Agreement will apply with effect from such date unless provided otherwise.
- 2.2 **IPDP**. The Awardee's Project activities, which are intended to further develop a Chikungunya Vaccine are set out in the Integrated Product Development Plan (IPDP), which may be found in Annex C. The IPDP also sets out the associated Project deliverables, milestones and timelines. [***].
- 2.3 **Project Organization**. The Project will be organized and managed as described in the Team Charter in Annex B. The Project management shall be Awardee's sole responsibility provided that Awardee shall consult with CEPI concerning the management of the Project to the extent required by the Team Charter and/or this Agreement and will consider CEPI's comments in good faith. Awardee will be expected to provide monthly and quarterly reporting of its activities under the Project (referred to as "IPDP Reports"), templates for these reports may be found in Annex D. The Project Budget is described in Annex E. The Payment Request Form and a template for quarterly Financial Reports may be found in Annex F.
- 2.4 Joint Monitoring and Advisory Group. The Team Charter establishes a Joint Monitoring and Advisory Group (or "JMAG") to facilitate communications and interactions between the Parties, as well as review Project activities in terms of timelines and budget. [***].
- 2.5 The Awardee will:
 - a. undertake the activities and comply with the obligations described in the Team Charter;

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- b. participate in the designated activities and meetings of the JMAG;
- c. keep accurate, complete and reliable records of activities performed and results arising as a result of the activities set out in the IPDP ("IPDP Records");
- d. maintain the IPDP Records for [***] after the termination or expiry of the Project, or for any longer period as required by law, the CEPI Clinical Trials Policy or Awardee's own policies;
- e. monitor progress of the Project and make IPDP Reports to the JMAG as described in the IPDP;
- f. propose amendments to the IPDP and Project Budget to the JMAG, as may be required; however, such amendments may require CEPI approval beyond the JMAG level; and
- g. notify CEPI if the Project Lead designated in the IPDP becomes unavailable and designate a replacement reasonably satisfactory to CEPI within [***].
- 3. Sub-Awardee Participation in the Project
- 3.1 Sub-Awardees. Awardee's activities under the Project may be undertaken by Affiliates and contracted third parties (collectively, "Sub-Awardees") designated in the IPDP and Project Budget. Awardee will be responsible for the acts and omissions of its Sub-Awardees.
- 3.2 **CEPI Approval of Additional Sub-Awardees**. Any proposed Sub-Awardee not expressly referred to in the IPDP or Project Budget must be approved by CEPI in writing before a sub-award has been made. Such approval not to be unreasonably withheld, conditioned or delayed by CEPI.
- 3.3 **Sub-Awardee Obligations**. A Sub-Awardee must agree to comply with all of the relevant obligations applicable to Awardee, whether explicitly identified as such or as is reasonable from the nature of the obligation. Each sub-agreement with a Sub-Awardee must:
 - a. be consistent with the Work Package Stream structure as well as the associated milestones and budgets;
 - b. require the same record keeping obligations and provide CEPI the same access (either directly or indirectly through Awardee) to IPDP and Financial Records (as are applicable to Awardee);
 - c. require compliance with the same laws, policies and procedures as are applicable under these T&Cs;
 - d. be consistent with Awardee's obligation in this Agreement, including in the sections related to Dissemination and Publication of Project Data (Clause 11); Dissemination of Project

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Materials (Clause 12); Intellectual Property (Clause 13); Equitable Access (Clause 14); Sharing of Commercial Benefits (Clause 15); Preparation for Outbreaks (Clause 16); the Public Health License (Clause 17); and Term and Termination (Clause 20); and

e. prohibit the Sub-Awardee from subcontracting its obligations without CEPI's consent. Such consent not to be unreasonably withheld, conditioned or delayed.

3.4 The Awardee will:

- a. sign an agreement with each Sub-Awardee, prior to their conducting any activities under the Project or amend any relevant agreement signed with a Sub-Awardee prior to the Effective Date of this Agreement, to be consistent with Awardee's relevant obligations to CEPI under the IPDP:
- b. in addition to, and without in any way diminishing or otherwise altering, Awardee's obligations under this Agreement (including Clause 14.3) and under the IPDP with respect to use of Sub-Awardees in LMICs, cooperate with CEPI in good faith and to the extent reasonably possible to preferentially use Sub-Awardees operating in LMICs where Outbreaks are likely to occur in order to build infrastructure and develop experienced personnel in the relevant territory; and
- c. promptly provide a copy of each Sub-Awardee agreement or amendment thereto to CEPI, provided that Awardee shall have the right to redact any confidential information contained therein that is not necessary for CEPI to determine compliance with Clause 3.3.

4. Project Funding and Work Package Streams

- 4.1 **Work Package Streams**. The IPDP will be organized into discrete phases, corresponding with the Project Budget. The associated activities, budgets, deliverables and timelines for each phase are set out in Work Package streams in the IPDP (each a "Work Package Stream").
- 4.2 **Project Payments**. Payments for the Project will be made in US dollars (\$) to Awardee's bank account identified on the Agreement Summary. CEPI will make payments in advance covering the planned activities for the subsequent six (6) month period, and beginning on the Effective Date of this Agreement.
- 4.3 **Subsequent Tranches**. CEPI will pay the initial 6-month tranche of funding after receipt of a payment request by Awardee following signature of this Agreement. All subsequent 6-month tranches will be paid by CEPI within [***] after receipt of all of the following: (i) a payment request by Awardee; and (ii) the required IPDP Report (Annex D) and Financial Reports (Annex F), adjusted appropriately for any underspend from any previous payments.

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- 4.4 **Payment when there is a Breach**. CEPI is not obliged to pay any tranches of funding for the Project for so long as Awardee is in breach of a material obligation under this Agreement.
- 4.5 **Delayed Payments.** CEPI may delay or condition a payment if:
 - a. Awardee has not achieved a milestone by the agreed time, unless such delay has been approved by the JMAG;
 - b. CEPI has been notified that Awardee or any of its Sub-awardees are no longer in compliance with the Warranties under Clause 18 at the time the tranche is requested; or
 - c. Awardee has not completed the payment request form or submitted satisfactory IPDP Reports and/or Financial Reports.
- 4.6 **No Obligation to Fund Additional Work Packages**. CEPI may decide not to proceed with any additional or sequential Work Package if it is not in the best interest of CEPI's mission. For clarity, reference to additional or sequential Work Packages means any Work Package other than the Work Package consisting of the Work Package Streams set out in the IPDP.
- 4.7 **Retained Payment**. CEPI will retain [***] of the final payment tranche until Awardee submits the final IPDP Report and Financial Report.
- 4.8 **Withholding tax**: Payments under this Agreement are to be made without withholding for or on account of any tax unless required by law, in which case, any such tax withheld shall be treated as having been paid by the paying Party to the other Party for all purposes under this Agreement, and the paying Party shall duly account for such tax withheld to the relevant tax authority and provide reasonable evidence of this to the other Party. The paying Party will notify yhe other Party in writing as soon as reasonably practicable once it becomes aware it has an obligation to so withhold and the Parties will cooperate with respect to reasonable requests by that other Party to secure a reduction in the rate of applicable withholding tax or to permit that other Party to obtain a repayment of, or credit for, tax withheld.
- 4.9 The Awardee will:
 - a. use award payments only in accordance with the IPDP, agreed Work Package Streams and Project Budget;

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- b. provide a Financial Report to CEPI regarding its expenditures pursuant to the Project Budget, using the template provided in Annex F; and
- c. reimburse CEPI for any funding underspend.

5. Financial Management and Oversight

- 5.1 **Financial Practices**. Awardee's financial management of the Project will be governed by controls, good management practices, procedures and standards at least as rigorous as its local Generally Accepted Accounting Principles (GAAP), or International Financial Reporting Standards (IFRS) if adopted by the Awardee, as confirmed in Awardee's annual audited financial statement.
- 5.2 **Financial Oversight**. Subject to the confidentiality provisions contained in Clause 22.4, CEPI, or its designee, will have on-site access to Awardee's Financial Records [***], at such times as CEPI may request, provided CEPI has given not less than [***] notice, in order that CEPI may monitor Awardee's expenditure of Project funds. CEPI or its designee will have such on-site access to Awardee's Financial Records more than [***] in the following circumstances:
 - i. where CEPI has reasonable grounds indicating that the Awardee is in material breach of this Agreement or has misapplied CEPI Funding; and
 - ii. where required in the context of an audit of CEPI by one or more of its funders.

5.3 The Awardee will:

- a. keep accurate, complete and reliable records of revenues and expenditures under the Project Budget ("Financial Records") against an individual project code;
- b. retain all Financial Records for [***] after termination or expiry of the Project or for any longer period as required by law or Awardee's own policies and allow CEPI access to such records as set out in Clause 5.2 for such retention period;
- c. provide [***] written notice to CEPI before destroying Financial Records;
- d. provide up-to-date audited financial statements, as requested by CEPI, and relevant extracts from the auditors' report for such financial statement as well as the management letter to the auditors;

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- e. if requested by CEPI, Awardee will procure Awardee's external auditors to conduct a Project audit (on and off site) and provide CEPI with audited statements regarding the Project Budget (in accordance with ISA800) at CEPI's reasonable cost and expense;
- f. procure a Project audit as identified above from Sub-Awardees at CEPI's request and at CEPI's reasonable cost and expense; and
- g. provide information required by the European Communities Court of Auditors and Anti-Fraud Office.

6. Compliance with Applicable Laws and CEPI Policies and Procedures

- 6.1 Compliance Requirements. Relevant national and supranational laws and governmental regulations will apply to Awardee's Project-related activities. Awardee must also comply with the CEPI Policies and Procedures listed in Schedule C to this Agreement, as the same may be amended or updated pursuant to Clause 6.2, which include specified procurement requirements. Notwithstanding the foregoing, CEPI's Procurement Policy and Travel Policy will not apply to the Awardee-Funded Study. This Agreement incorporates requirements from CEPI's own funders, and CEPI will cooperate with Awardee to ensure that it is able to fulfill its obligations as found in the CEPI Policies and Procedures and this Agreement. For clarity, the CEPI Policies and Procedures shall not apply retroactively.
- 6.2 Amendment of CEPI Policies and Procedures. CEPI may notify Awardee from time-to-time that the CEPI Policies and Procedures listed in Schedule C to this Agreement have been amended or updated, including by the addition of CEPI policies and procedures. Such amended or updated CEPI Policies and Procedures will become effective with respect to Awardee and Sub-Awardees [***] after notification from CEPI, absent notification of objection by the Awardee. In case Awardee sends CEPI a notification of objection, the compliance officers from Awardee and CEPI shall decide on the matter. If the compliance officers are unable to make a decision within [***] from the date of receipt by CEPI of the notification of objection from Awardee, the Parties shall initiate the escalation process described in Clause 21.1.

6.3 The Awardee will:

- a. comply with applicable laws and regulations;
- b. subject to Clause 6.1 and Clause 22.6, comply with CEPI Policies and Procedures;
- c. provide access to information to the EC Court of Auditors and Anti-Fraud Office as required;

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- d. to the extent that the Project involves relevant activities, comply with Good Laboratory Practices ("GLP"), Good Clinical Practices ("GCP") and Good Manufacturing Practices ("GMP") as defined either in the CEPI Policies and Procedures or otherwise under applicable law or best practice; and
- e. notify CEPI promptly to discuss any amended CEPI Policies and Procedures that raise concerns about Awardee's ability to perform its obligations under this Agreement.

7. Clinical Studies

- 7.1 **Clinical Studies**. If any Work Package includes research involving human subjects, such activities must comply with applicable laws, relevant regulatory agencies and with CEPI's Clinical Trials Policy.
- 7.2 Clinical Data. The data arising in the conduct of a clinical trial will be collected in a way that ensures that each subject, prior to enrolment and in accordance with all applicable laws and regulations, including the EU's General Data Protection Regulation (GDPR), provides informed consent to allow:
 - a. direct access to her or his medical records;
 - b. the processing of data relating to her or him and to the movement of that data to other countries, including countries outside of the European Economic Area;
 - c. the transfer of such data to Awardee;
 - d. the transfer of anonymised data to CEPI in accordance with Clause 11;
 - e. the collection and use of clinical study data (duly anonymised and, at CEPI's request, blinded) in accordance with and for the purposes indicated in Clause 11;
 - f. the collection and use of biological samples and the use of data (duly anonymised and, at CEPI's request, blinded) derived from such samples by CEPI or its designated Assessors in accordance with and for the purposes indicated in Clause 12; and
 - g. the use of such data for the purpose of obtaining approval from applicable regulatory agencies.
- 7.3 **Priority for Certain Clinical Studies.** Awardee acknowledges that the pool of subjects available in areas of Outbreak to participate in a clinical study to test products such as the Product may be limited. Accordingly, if CEPI reasonably determines in consultation with experts (for example a sub-group or subcommittee of CEPI's Scientific Advisory Committee that CEPI determines has

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appropriate expertise) that a product other than the Awardee's Product has substantially greater potential, as determined in accordance with WHO guidance or relevant local regulatory guidance and should be used for a particular clinical study of subjects in areas of Outbreak, the Awardee agrees that it shall abide by such decision and will not proceed with any clinical study of the Product with subjects from areas of Outbreak unless agreed with CEPI. In the event that Awardee must discontinue a clinical study of the Product in areas of Outbreak according to CEPI's determination pursuant to this Clause 7.3, then CEPI shall (i) cooperate with Awardee in an appropriate wind down of the study and (ii) to the extent not funded in advance by CEPI, reimburse Awardee for Awardee's reasonably incurred non-cancellable expenses relating to such discontinued clinical study. For clarity, Awardee shall not pay back any sums already received from CEPI that have been actually spent by Awardee in connection with such discontinued clinical study. For the purposes of this Clause, CEPI agrees that nothing in this Clause 7.3 will prevent (i) Awardee from undertaking a Pivotal Study in any country; or (ii) Awardee fulfilling its obligations under its risk management plan prepared by Awardee in connection with its biologics license application in any country, including but not limited to post registration efficacy trials or any other commitment with any relevant regulatory authority to conduct a clinical study that would support the development of the Product . For the purposes of this Agreement, "Pivotal Study" shall mean a clinical study designed to fulfill the requirement for the filing of an application for a marketing authorization for a Product and that is acceptable to the relevant regulatory authority as a basis for the grant of a marketing authorization.

7.4 The Awardee will:

- a. be the sponsor of any clinical study (unless CEPI and Awardee otherwise agree in writing);
- b. be responsible for obtaining and maintaining all regulatory approvals (including ethical committee approvals) necessary or reasonably useful for the conduct of the clinical trial and appropriate clinical trial insurance cover;
- c. publish details of any clinical study in a publicly accessible clinical study register, where patient privacy is upheld, as required under law and, as applicable, prior to the commencement of patient recruitment for such clinical study;
- d. ensure that any informed consent form permits the use of Project Results described in these T&Cs and in the IPDP;
- e. establish a Trial Steering Committee (TSC) for clinical studies funded by CEPI (whether in whole or in part);

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- f. establish a Data Safety Monitoring Board (DSMB);
- g. notify the JMAG and TSC in writing immediately following any Safety Issues or similar events;
- h. verify that the clinical study data are complete and include all completed case report forms and all other clinical study documentation required to be in the possession of a clinical trial sponsor by applicable law; and
- i. subject to the confidentiality provisions contained in Clause 22.4, permit a CEPI representative or nominee (except for any matters that should remain blinded to CEPI in the interests of the integrity of the clinical study and except for closed sessions) to:
 - i. attend meetings of the TSC and the DSMB for the clinical study as an observer (either in person or by electronic means); and
 - ii. receive all papers that a member of the TSC or DSMB would be entitled to receive.

8. Animal Studies

8.1 **Animal Studies**. If any Work Package includes studies using animals, such activities must comply with applicable laws as well as CEPI's Animals in Research Policy. Upon request by Awardee, CEPI shall provide further guidance on CEPI funded animal studies promptly so that no delay in the agreed Project timelines occurs.

8.2 The Awardee will:

- obtain and maintain all regulatory approvals (including ethical committee approvals) necessary or reasonably useful for the conduct of research involving animals; and
- b. inform JMAG of any anticipated deviations from the original design of animal studies described in the IPDP and obtain JMAG approval before implementing those changes.

9. Standards and Assays

9.1 **Standards Development**. If any Work Package relates to the development of biological reference materials, Awardee will provide relevant materials and data and shall grant rights to their use for International Standards development, to one of either the WHO or the Paul-Ehrlich-Institute (PEI) in Germany or, if agreed by the Parties, another independent standards development agency.

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9.2 Assay Development. A Work Package may include the development of assays (including immunogenicity and potency/release assays), as will be described in the IPDP.

9.3 The Awardee will:

- a. as described in the IPDP, participate in collaborative interlaboratory studies for evaluation of a candidate reference material. Such studies ultimately will be included in reports to the WHO Expert Committee on Biological Standardization; and
- b. provide written Standard Operating Procedures ("SOPs") for any assays developed and qualified with CEPI funding (in whole or in part) or with the use of samples or biological material facilitated by CEPI. Transfer capacity and technology relating to such assays to a designated, independent third party laboratory if required by CEPI for the assay to be validated for Phase 3 clinical trials. If and to the extent any SOPs incorporate Trade Secret Information or Confidential Information within Awardee Background IP, CEPI will maintain the confidentiality of such information in accordance with Clause 22.4 and Awardee and the designated third party laboratory shall first enter into a customary confidentiality agreement with Awardee governing the use and non-disclosure of such information, provided that Awardee and such third party laboratory shall not delay the execution of such agreement.

10. Project Results and their Ownership

- 10.1 **Project Results**. The Project Results, meaning the outcomes and results of the Project, may comprise biological samples, data, intellectual property, materials, any Product and Investigational Product, publications, reference standards, technology and other results and shall include all Project IP. Project Data and Project Materials.
- 10.2 Ownership of Project Results. Awardee will own the Project Results.
- 10.3 The Awardee will:
 - a. record Project Results accurately, completely and reliably in Awardee's IPDP Records; and
 - b. identify Project Results in the IPDP Reports provided to the JMAG.
- 11. Dissemination and Publication of Project Data
- 11.1 **Reporting of Project Data**. Subject to the confidentiality provisions contained in Clause 22.4, Awardee shall provide CEPI with access to all data and information, including all pre-clinical and clinical study data, produced or arising as a result of the Project ("Project Data"), and will report

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Project Data regularly to the JMAG. Notwithstanding the foregoing, with respect to Project Data produced or arising as a result of the Awardee-Funded Study, Awardee shall provide summaries of such Project Data to the JMAG and, at CEPI's request (including through CEPI's members of the JMAG), Awardee shall provide additional information and details relating to such Project Data as reasonably requested by CEPI.

- 11.2 Sharing of Project Data with the Research Community. Awardee will share with the research community Project Data relevant to topics of interest to the research community, such as disease-specific assays, animal models, correlates of protection or diagnostics and epidemic preparedness mechanisms, as described in the IPDP and agreed in the JMAG, subject to the Awardee's right, prior to such Project Data entering the public domain, (i) to remove Trade Secret Information and Confidential Information within Awardee Background IP, if any, included in such Project Data and (ii) in case there is any patentable subject matter included in such Project Data, to delay such Project Data entering the public domain for a reasonable period of time, not to exceed [***].
- 11.3 **Publication of Project Results**. CEPI encourages Awardee's timely publication of Project Data and other Project Results in scientific literature. With regard to pre-clinical studies, the Parties agree that Awardee shall be required to publish (i) correlate of protection data no later than [***] after the date of submission of such data to the relevant regulatory authorities; and (ii) the results of the NHP and mosquito studies no later than [***] after the date of the final report for such studies. No less than [***] prior to submission of any such proposed publication, Awardee shall submit such publication to CEPI for review. In the event that CEPI has any comments on the proposed publication, Awardee shall cooperate with CEPI in good faith to incorporate CEPI's comments prior to publication. All such publications (other than publications that relate exclusively to the Awardee-Funded Study) shall include a statement that the work was "funded in whole or in part by CEPI and EU Horizon 2020." With respect to publications relating to clinical trials other than the Awardee-Funded Study, Awardee shall credit where appropriate the country in which the clinical trials were performed and make the results of such clinical trials available to the relevant country's Ministry of Health or equivalent. In the event CEPI wishes to publish any Project Results, CEPI shall submit such proposed publication to Awardee for review no less than [***] prior to submission for publication and if, within [***] after receipt of such proposed publication, (i) Awardee notifies CEPI of specific content in such proposed publication that constitutes Trade Secret Information or Confidential Information within Awardee Background IP, then CEPI shall remove such specific content from the proposed publication, or (ii) Awardee notifies CEPI that there is patentable subject matter contained in such proposed publication, CEPI shall delay submission of the proposed publication for a reasonable period of time requested by Awardee, not to exceed [

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- 11.4 Clinical Study Data. CEPI's Clinical Trials Policy requires that clinical data and results (including negative results) must be disclosed publicly in as close to real time as possible. Accordingly, such data and results must be shared through an easily discoverable public route (website or system) that includes a metadata description, where patient privacy is upheld, and the system follows a request-for-information approach (where requests are fulfilled subject to an independent review and approval step). Clinical study data will be submitted for publication within [***] after each final study report or report submitted to CEPI unless Awardee has reasons for a delay of the publication of the clinical study data and said delay is agreed in writing with CEPI. The Clinical Trial ID or registry identifier code/number shall be included in all publications of clinical trials. Notwithstanding the foregoing, the terms of this Clause 11.4 shall not be mandatory with respect to clinical data and results arising from the Awardee-Funded Study.
- 11.5 **Outbreak-Related Publications**. Additionally, Project Data will be shared in accordance with WHO's 2016 Guidance for Managing Ethical Issues in Infectious Disease Outbreaks and WHO's 2016 Guidance on Good Participatory Practices in Trials of Interventions Against Emerging Pathogens.
- 11.6 **Open Access**. CEPI requires "Open Access" for Project Data. This means that a copy of the final manuscript of all research publications, journal articles, scholarly monologues and book chapters published under this Clause 11 must be deposited into PubMed Central (or Europe PubMed Central) or otherwise made freely available upon acceptance for publication or immediately after the publisher's official date of final publication. Moreover, all peer-reviewed published research that is funded, in whole or in part, by CEPI shall be published in accordance with the principles of "Plan S" Accelerating the transition to full and immediate Open Access to scientific publications, a UK and European data sharing initiative for research funded by public grants.

11.7 The Awardee will:

- a. notify the JMAG on an ongoing basis as Project Data is produced and disseminated in accordance with Clause 11.1;
- b. disseminate Project Data consistent with the requirements set out above in this Clause 11; and
- c. cooperate in regard to data analysis, to the extent relevant under a given Work Package, by CEPI's Assessors, subject to Clause 22.4, by:
 - i. providing data or other information generated under this Agreement to CEPI's designated Assessor as CEPI may reasonably request, including data regarding the results of any of its pre-clinical or clinical trials (duly anonymized and, upon CEPI's request, blinded);

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- ii. providing CEPI's designated Assessor with other data (duly anonymised and, upon CEPI's request, blinded) as CEPI may reasonably request in order to conduct comparative assessments; and
- iii. providing CEPI's designated Assessor with clinical study data (duly de-identified and, at CEPI's request, blinded) for the purposes of signal detection or meta-analyses of safety data (including across candidate vaccines).

12. Dissemination of Project Materials

- 12.1 **Dissemination and Sharing of Project Materials**. Awardee will share with CEPI Project Materials produced under the Project. CEPI undertakes to keep the Project Materials confidential in accordance with the terms of Clause 22.4. For purposes of this Agreement, "Project Materials" means the drug product and the clinical trial materials described in Clause 12.3 (c) (ii). [***].
- 12.2 Comparative Evaluation of Samples. CEPI may engage one or more independent third party laboratories or collaborators ("Assessors") to perform additional testing on Project Materials as specified under Clause 12.3c, at CEPI's expense, in order to provide CEPI with directly comparable evaluations of similar materials produced under CEPI's portfolio of awarded projects. All such Assessors shall be bound by confidentiality obligations at least as stringent as those contained in Clause 22.4. CEPI shall inform Awardee through the JMAG about potential Assessors prior to their engagement by CEPI. CEPI may not engage Awardee Competitors as Assessors without Awardee's consent, such consent not to be unreasonably withheld, delayed or conditioned. [***]. CEPI may, in its sole discretion and at its own expense, also engage certain independent third party entities to transport the samples from Awardee to the Assessor, address import/export issues, or provide any documentation CEPI may determine is required for such samples. The results of the testing, analysis, meta-analysis or other assessments ("Results") will be subject to the confidentiality obligations under this Agreement. CEPI will provide to the Awardee the Results as are relevant to Awardee's activities under the Project. In no event will CEPI publish or otherwise disclose any Results without Awardee's consent, such consent not to be unreasonably withheld, delayed or conditioned.

12.3 The Awardee will:

- a. notify the JMAG on an ongoing basis as Project Materials are produced under the IPDP;
- b. disseminate and share Project Materials consistent with the requirements set out above in this Clause 12; and

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- c. cooperate with CEPI's Assessor, to the extent relevant under a given Work Package, subject to Clause 22.4, by:
 - providing CEPI's designated Assessor a reasonable number of doses of a candidate vaccine (Product) representative of the final Product, for animal immunogenicity studies;
 - ii. providing CEPI's designated Assessors with an agreed number of samples from clinical studies under the Project (excluding the Awardee-Funded Study) for use in future research carried out by or on behalf of CEPI including agreed volumes of biological samples (for example, serum, and peripheral blood mononuclear cells (PBMCs)) from human subjects vaccinated with the Project vaccines (excluding subjects vaccinated in Awardee's Phase 1 clinical trial completed prior to the Effective Date or in the Awardee-Funded Study) at specified timepoints agreed with CEPI for immunology testing; and
 - iii. ensuring that any samples to be transferred or exported by or on behalf of Awardee from a clinical trial site or sample storage site are transferred and/or exported pursuant to the terms and conditions of a suitable to-be-agreed-upon material transfer agreement (containing, among other terms, confidentiality and use restrictions) to be entered into between Awardee and the Assessor in addition to any other applicable laws and regulations.

13. Intellectual Property

- 13.1 **Protection for Project IP**. Awardee has the right, but not the obligation, to seek protection, at its own cost, for the discoveries, inventions, know-how, patents, trademarks and other forms of intellectual property that arise under the Project ("Project IP").
- 13.2 **Third Party Patents**. The Parties will notify each other promptly regarding any third party intellectual property they become aware of that raises concerns about Awardee's ability to perform its obligations under this Agreement or the potential use by CEPI of the Public Health License described in Clause 17. The Parties will cooperate in good faith to resolve any such matters.

13.3 The Awardee will:

a. notify the JMAG as Project IP is created, discovered or made; any applications for any rights to Project IP are submitted or are otherwise prosecuted; any application regarding the registration of any Project IP is granted, including the granting of any patent or trade mark, as part of its regular IPDP reports; and

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b. ensure that it has enforceable policies or written agreements with all of its employees, agents and subcontractors which assign to the Awardee ownership of all Project IP.

14. Equitable Access

- 14.1 **Equitable Access**. CEPI is committed to achieving equitable access to the outputs of all CEPI-supported programmes, including access to all applicable Project Results in accordance with this Agreement, pursuant to CEPI's "Equitable Access" Policy. Equitable Access to Chikungunya vaccines means the regular supply of the vaccines in all Non-Traveler's Market Countries that have a demand for the vaccines at an affordable price (as outlined in Clause 14.2) and, in the context of an Outbreak or Increased Outbreak Preparation Need, means that appropriate vaccines are first available to populations in the Affected Territory when and where they are needed, including to end an Outbreak or curtail an epidemic, regardless of ability to pay. Consistent with CEPI's Equitable Access Policy, CEPI is also committed to supporting Equitable Access so that the economics are sustainable to the manufacturer.
- 14.2 With respect to pricing, the Awardee will ensure that: to the extent that Awardee commercializes Product which utilizes or otherwise benefits from, whether directly or indirectly, any Project Result, (i) the distribution of the Product in Non-Traveler's Market Countries that are LMICs will be [***], and (ii) the distribution of the Product in Non-Traveler's Market Countries that are not LMICs will be at [***]. In any case, "sustainable price" shall never be below Awardee's manufacturing costs.
- 14.3 **LMIC Manufacturer**. To facilitate achievement of the conditions set out in Clauses 14.1 and 14.2, Awardee has agreed to transfer its technology to an LMIC manufacturer as outlined in the IPDP. Without limiting Awardee's obligations under the IPDP, Awardee will, within [***] of the signature date of this Agreement, or within such other time period as may be set out in the IPDP if the IPDP is amended in accordance with Clause 2.4, sign a Sub-Awardee agreement with an LMIC manufacturer, which Sub-Awardee agreement shall meet the requirements of Clause 3.3 and shall obligate such LMIC manufacturer to manufacture the Product for regular supply in all Non-Traveler's Market Countries that have a demand for Product and to supply the Product to Non-Traveler's Market Countries under the conditions of Clause 14.2. Prior to signing such Sub-Awardee agreement with an LMIC manufacturer and prior to completion of technology transfer to enable such LMIC manufacturer to manufacture and supply the Product to Non-Traveler's Market Countries, Awardee shall fulfill manufacturing and supply obligations for Non-Traveler's Market Countries as set out in the IPDP.
- 14.4 **Regulatory Approvals in LMICs**. Awardee will, or will obligate its Sub-Awardee(s) to, use reasonable endeavours to obtain regulatory approvals and licensure for the Product in Non-Traveler's Market Countries where there is a demand for the Product. The Parties, through the JMAG, may discuss

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and agree on a list of such Non-Traveler's Market Countries in which to seek such approvals and licensure and on a schedule for seeking such approvals and licensure, and Awardee will, or will obligate its Sub-Awardee(s) to, use reasonable endeavours to meet such schedule in such countries

15. Sharing of Commercial Benefits

- 15.1 **Sharing of Commercial Benefits**. CEPI has committed to its own funders to obtain a share of Awardee's Commercial Benefits as a contribution to support CEPI's programme activities.
- 15.2 **The Awardee will**: make the following contributions to CEPI in recognition of the Commercial Benefits that Awardee will receive from its sale of the Products:
 - a. Until the rolling safety stock has been established by Awardee in accordance with Clause 15.2(ii), Awardee will make available to CEPI, at Awardee's cost, any Investigational Product which is not needed by Awardee for Awardee's Investigational Product lot-to-lot clinical trial(s).
 - b. Within [***] of receipt of marketing approval for the Product from the FDA, Awardee will produce, at Awardee's own cost, a [***] safety stock comprised of not less than two hundred thousand (200,000) doses of final Drug Product. For clarity, Awardee will use commercially reasonable best efforts to keep such deadline of [***], however, it will be subject to the lead times of Awardee's contract manufacturers and the time required for the release testing of the Product. Awardee may use such safety stock to supply the Awardee's Traveler's Market and will replenish such stock on a rolling basis at Awardee's cost. The stock in paragraph 15.2(i) and this paragraph 15.2(ii) is referred to as ("Safety Stock").
 - c. In case of an Outbreak or Increased Outbreak Preparation Need, CEPI may utilize such Safety Stock in the Affected Territory by giving notice in writing to Awardee and Awardee will dispatch all or some only of the Safety Stock, as instructed by CEPI and CEPI shall pay any reasonable costs incurred in connection with the utilization of the Safety Stock, including but not limited to transportation, distribution and storage in the Affected Territory. For clarity, Awardee shall make no charge for the supply of the Safety Stock allocated to and used by CEPI in accordance with this paragraph 15.2 (iii) and the storage costs of such Safety Stock, incurred prior to dispatch to the Affected Territory, shall be borne by Awardee.
 - d. If the Safety Stock is used by CEPI in the case of an Outbreak or Increased Outbreak Preparation Need, CEPI or such third parties as CEPI may nominate shall be responsible for the costs of transportation of such Safety Stock from Awardee's facility. If, following the use of the Safety Stock as directed by CEPI, CEPI wishes to replenish the Safety Stock, Awardee shall produce such quantities of Product as are required to replenish the Safety Stock and CEPI shall pay Awardee for the costs of the production of such Product.

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- 15.3 Awardee Milestone Payments. Awardee shall pay to CEPI the following milestone payments:
 - a. [***] within [***] of the date of achievement by Awardee of Net Sales of the Product in the United States of America of, [***];
 - b. [***] within [***] of the date of achievement by Awardee of Net Sales of the Product in the United States of America of, [***];
 - c. [***] within [***] of the date of achievement by Awardee of Net Sales of the Product in the EU of, [***];
 - d. [***] within [***] of the date of achievement by Awardee of Net Sales of the Product in the EU of, [***];
 - e. if Awardee is [***] as a result of its development of the Product, [***] on the first to occur of: (x) [***]; and (y) [***].
- 15.4 **Currency conversion.** Where calculation of milestone payments due under this Agreement requires the conversion to US dollars of Net Sales generated in any other currency, the following shall apply. As Awardee reports Euro Net Sales in the group financial statements (all currencies converted into Euro according to the International Financial Reporting Standards), these amounts from the group financial statements will be converted using the annual average rate as quoted by the European Central Bank on the website. http://sdw.ecb.europa.eu/
- 15.5 Awardee shall keep, and cause its Affiliates and sublicensees to keep, complete and accurate records relating to all Net Sales and by [***] in each year following launch of the Product, shall provide CEPI with a report setting out the amount of Net Sales made in the previous calendar year. CEPI shall, upon reasonable notice to Awardee, be entitled to send an independent auditor at CEPI's cost, who shall be under obligations of confidentiality no less onerous than those set out in this Agreement, to access and review all documents, information, data and materials in the possession of Awardee directly relating to the calculation of Net Sales. If the review of such records reveals that Awardee has failed to accurately report information pursuant to this Clause 15.5 or to make any payment (or portion thereof) required under this Clause 15.5, then Awardee shall pay, within [***] after receipt of a written request, any underpaid amounts due under this Clause 15.5 together with interest thereon applied to the period from the date the amount should have been paid to the date it is actually paid at an interest rate equal to [***]. In the event the review reveals an underpayment of [***] or more of the amounts due under this Clause 15.5. Awardee shall pay all

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reasonable costs incurred in conducting such review. In the event the review reveals an underpayment of less than [***], then all costs incurred in conducting such review shall be borne by CEPI.

16. Preparation for Outbreaks

- 16.1 Outbreak, CEPI will notify Awardee in writing in the event of an Outbreak or if there is an Increased Outbreak Preparation Need, in each case identifying the Affected Territory ("Outbreak Notice"). Once an Outbreak Notice has been provided by CEPI, CEPI shall have the right to direct how the Safety Stock referred to in Clause 15.2 a. or any Product manufactured pursuant to Clause 16.3 Error! Reference source not found. may be used and to whom it may be provided in the Affected Territory. In consultation with relevant public health authorities in the Affected Territory. CEPI may request that Awardee discuss in good faith whether and how the Project Results could be utilized in response to the Outbreak Notice. Awardee is committed to use commercially reasonable best efforts to address Outbreaks and Increased Outbreak Preparation Need wherever they occur in the world. Following receipt of an Outbreak Notice, Awardee will use its commercially reasonable best efforts to increase the supply of Product available for use by CEPI or its nominees to an amount which equals at least [***] of the production forecast for the Products prepared by Awardee immediately prior to service of the Outbreak Notice and Awardee will use its commercially reasonable best efforts to ensure that such increased capacity is available for delivery to CEPI within [***] of the date of service of the Outbreak Notice. For clarity, Awardee will use commercially reasonable best efforts to keep such deadline of [***] (including discussing with Awardee's contract manufacturers how they can meet the proposed deadlines), however, Awardee's ability to meet deadlines will be subject to the lead times of Awardee's contract manufacturers and the time required for the release testing of the Product. In the event that CEPI's request for Product to meet the increased demand during an Outbreak or Increased Outbreak Preparation Need is in excess of the quantities that Awardee is able to supply to CEPI based on Awardee's commercially reasonable best efforts, Awardee shall not be obliged to supply Product to CEPI under this Clause 16.1 to the extent that the supply of such quantities of Product to CEPI would result in Awardee being in breach of any binding contracts in existence on the date of service of the Outbreak Notice (which for the avoidance of doubt may include the supply of Products to customers for Awardee's Traveler's Market or in connection with any clinical trials). In such event, provided that Awardee has supplied Product in accordance with this Clause 16.1, Awardee shall not be considered to be in default, and Clauses 16 and 17 shall not apply.
- 16.2 Additional Product Development. Pursuant to an Outbreak Notice, CEPI may request that Awardee undertake additional Product development at CEPI's expense or undertake other activities, including the pursuit of regulatory approvals and licensure to the extent not already obtained, with the aim of addressing the needs of the Affected Territory. An additional Work Package covering these activities will be negotiated expeditiously and in good faith by the Parties.

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- 16.3 Additional Investigational Product or Product Stockpiles. In addition to the Safety Stock referred to in Clause 15.2 a., CEPI may request that Awardee undertake, at CEPI's expense, the manufacturing and maintenance of an additional stockpile of Investigational Product or Product for use in or for the Affected Territory. Such Product may be used for further clinical trials in Outbreak conditions to advance vaccine development, or pursuant to an emergency use authorization, in each case in emergency situations based on national or international guidance (such as WHO), or in such other manner within an Affected Territory as CEPI may reasonably determine. An additional Work Package covering this activity will be negotiated expeditiously and in good faith by the Parties.
- 16.4 **Trusted Collaborator**. Promptly after receipt of a written request from CEPI (or at any earlier time), Awardee will propose a third party, for example, a Sub-Awardee, as a preferred alternative to itself ("Trusted Collaborator"), that is capable of performing the work and would be prepared to undertake activities pursuant to Clause 16.2 or 16.3 in the event that Awardee declines CEPI's request to do so, or if Awardee and CEPI do not reach agreement on a new Work Package. CEPI may also propose a Trusted Collaborator to Awardee. Neither Party may unreasonably decline to accept the designation of a proposed Trusted Collaborator.
- 16.5 **Technology Transfer**. As described in the IPDP, Awardee will be transferring technology to two Sub-Awardees (IDT and an LMIC manufacturer) and the costs of such technology transfers are included in the Project Budget. Awardee will promptly and diligently provide all necessary guidance, information, materials and assistance reasonably required to transfer Awardee's technology to each such Sub-Awardee as outlined in the IPDP. Pursuant to an Outbreak Notice, CEPI may request to accelerate the timelines for transfer of Awardee's technology to one or both of such Sub-Awardees and/or CEPI may request an expansion of the transfer to another Trusted Collaborator (other than such Sub-Awardees) if that would achieve the transfer more quickly. If CEPI requests transfer of Awardee's technology to another Trusted Collaborator, Awardee will promptly and diligently provide all necessary guidance, information, materials and assistance reasonably required by such Trusted Collaborator to accomplish the activities that may be requested by CEPI under Clause 16.2 or 16.3 ("Technology Transfer") at CEPI's cost. Awardee shall carry out the Technology Transfer to such other Trusted Collaborator pursuant to the terms and conditions of a to-be-agreed-upon confidentiality agreement in accordance with this Agreement to be entered into between Awardee and the Trusted Collaborator governing the Trusted Collaborator's use and non-disclosure of information and materials provided in connection with the Technology Transfer, provided that Awardee and the Trusted Collaborator shall not delay the execution of such agreement.

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- 16.6 The Awardee will: use commercially reasonable best efforts to cooperate with CEPI in developing a response to an Outbreak or Increased Outbreak Preparation Need which may include opportunities for Awardee and its Sub-Awardees to receive additional Work Packages and funding from CEPI.
- 16.7 **Outbreak in Awardee's Traveler's Market.** Notwithstanding anything to the contrary herein, in the event any country in the Awardee's Traveler's Market is included in the Affected Territory, Clauses 16 and 17 shall not apply to such country in the Awardee's Traveler's Market on the condition that Awardee shall, at the request of public health agencies in such country in the Awardee's Traveler's Market, supply the Product to all such public health agencies that request the Product in a quantity and at a price as agreed with the relevant public health agencies. The price agreed with the relevant public health agency shall not exceed the [***]. For purposes of this Clause 16.7, "similar volume" shall mean a volume within the range of [***]. For clarity, if Awardee fails to comply with the foregoing supply obligation with respect to any country in the Awardee's Traveler's Market that is included in the Affected Territory, the terms of Clauses 16 and 17 shall apply to such country in the Awardee's Traveler's Market that is included in the Affected Territory. However, if the reason why Awardee cannot comply with the supply obligation is that (i) the quantity of Product requested by the relevant public health agency is impossible to fulfill due to Awardee's capacities or (ii) the price [***] would be unsustainable to Awardee, Clauses 16 and 17 shall not apply in such case. In any case, "sustainable price" shall never be below Awardee's manufacturing costs.

17. Public Health License

- 17.1 **Grant of a Public Health License**. Awardee hereby grants the Public Health License to CEPI (subject to Clause 16.7), on the condition that CEPI may only exercise the rights granted under the Public Health License in the following circumstances:
 - a. Awardee's activities supported by CEPI under the Project have meaningfully advanced the Product; and
 - b. the Awardee has not notified CEPI that it wishes to terminate the Agreement pursuant to Clause 20.2; and
 - c. one or more of the triggers set out in Clause 17.2 has occurred.
- 17.2 Public Health License Triggers. Consistent with Clause 17.1, CEPI's right to exercise the Public Health License will be triggered when:
 - a. Awardee declines to participate in activities requested by CEPI under Clause 16.1 or Error! Reference source not found.16.2,

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- b. CEPI determines, in good faith and having taken expert advice (for example from a sub-group or subcommittee of CEPI's Scientific Advisory Committee that CEPI determines has appropriate expertise), that Awardee will not be able to perform the activities under Clause 16.1 or 16.2 if requested by CEPI,
- c. [***] have passed since an Outbreak Notice in accordance with Clause 16.1 and the Parties have not signed an agreement or new Work Package for the activities contemplated under Clause 16.1 or Clause, as applicable, despite CEPI's request; or
- d. the Agreement is terminated by CEPI pursuant to Clause 20.2, 20.3a) or 20.3c).
- 17.3 **Agreement with Trusted Collaborator**. In the event that the Public Health License becomes exercisable in accordance with Clause 17.1, CEPI may endeavor in good faith to reach agreement with a Trusted Collaborator to perform such activities as CEPI may deem necessary. If despite CEPI's good faith efforts those negotiations do not result, or CEPI reasonably deems that such negotiations are unlikely to result, in an agreement on a timely basis, then CEPI may grant rights under its Public Health License to a third party unilaterally designated as a Trusted Collaborator by CEPI.

17.4 The Awardee will:

- identify Enabling Rights to CEPI as of the signature date of this Agreement and provide updates to the JMAG regarding the Enabling Rights during the course of the Project;
- b. provide an updated list of Enabling Rights to CEPI in the event that the Public Health License becomes exercisable.
- c. make no encumbrances regarding ownership or access to Project Results or Enabling Rights that would conflict or interfere with the Public Health License without the express written permission of CEPI, such permission not to be unreasonably withheld, conditioned or delayed.

18. Warranties

- 18.1 Warranties. As of the date of signature of this Agreement, Awardee warrants that the following statements ("Warranties") are true and correct:
 - a. it has the full power and authority to enter into and assume its obligations under this Agreement;

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- b. it is in material compliance with all statutes, regulations, directives and requirements of any governmental entity that relate to its activities and obligations;
- to the best of its knowledge and belief, it does not infringe, misappropriate or violate the intellectual property, privacy or publicity rights of
 any third party that are relevant to the Project;
- d. it has not granted rights to any third party in respect of Project Results (other than in accordance with the terms of this Agreement);
- e. to the best of its knowledge and belief, no person has any right or claim to any payment or other compensation in respect of the use or exploitation of the Project Results, except as set out in pre-existing or contemplated licence agreements with third parties, copies of which have been provided to CEPI prior to the date of signature of this Agreement;
- f. to the best of its knowledge and belief, none of Awardee and its Sub-awardees, nor any officer or employee of the foregoing has been debarred or is subject to debarment by a regulatory authority or funding agency anywhere;
- g. all financial statements and budgets submitted to CEPI as of the date of signature of this Agreement are true, complete and accurate; and
- h. to the best of its knowledge and belief, all encumbrances have been disclosed that could affect CEPI's use of the Public Health License.
- 18.2 **The Awardee will:** undertake during the Term of this Agreement that all of the statements warrantied above will remain true and correct, and shall notify CEPI promptly in the event that this changes.

19. Indemnification and Insurance

19.1 Awardee Indemnification for Third Party Claims. Awardee will indemnify and defend CEPI, its Affiliates, third party contractors and employees from and against any and all claims, damages, and liabilities asserted by third parties (including claims for negligence) which arise directly or indirectly from: (i) Awardee's, or its Sub-Awardee's activities under this Agreement, or (ii) the use of the Product, Project Results or Enabling Rights (including for the avoidance of doubt, the use of the Product in development activities and clinical studies), save to the extent such claim, damage or liability is caused by CEPI's negligence or intentional misconduct or is required to be indemnified by CEPI pursuant to Clause 19.2.

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- 19.2 **CEPI Indemnification for Third Party Claims**. Solely in the event that CEPI has exercised the Public Health Licence, CEPI will indemnify and defend Awardee, its Affiliates, Sub-Awardees, third party contractors and employees from and against any and all claims, damages, and liabilities asserted by third parties (including claims for negligence) which arise directly or indirectly from the use of the Product, Project Results or Enabling Rights by CEPI or a Trusted Collaborator designated by CEPI in the course of exercising the Public Health Licence, save to the extent such claim, damage or liability is caused by Awardee's or its Sub-Awardee's activities under this Agreement (including manufacture of drug substance or Product) or by Awardee's negligence or intentional misconduct.
- 19.3 Conduct of Responses to Third Party Claims. Each Party shall use its reasonable endeavours to inform the other Party promptly of any circumstances that are likely to give rise to a third party claim which may be covered by Clause 19.1 together with copies of all relevant papers and official documents. The indemnifying Party shall not take any material action in respect of any third party claim without the consent of the indemnified Party, including settlement of any such third party claim, provided such consent is not unreasonably conditioned, withheld or delayed. The indemnifying Party will keep the indemnified Party fully informed of the progress of all relevant third party claims which are covered by Clause 19.1 and shall fully consult the indemnified Party on the nature of any defence to be advanced in advance.
- 19.4 **Exclusions**. Neither Party shall be liable to the other Party for any loss of profits or economic loss; or indirect, incidental or consequential damages, whether in contract, warranty, negligence, tort, strict liability or otherwise, arising out of any breach of or failure to perform any of the provisions of this Agreement.
- 19.5 **Liability Cap.** CEPI's maximum liability in aggregate to Awardee arising out of this Agreement shall not exceed the aggregate of the total Work Package budget unless CEPI has exercised the Public Health Licence in which event CEPI's maximum liability to Awardee arising out of this Agreement shall not exceed [***]: (i) [***] or (ii) [***]. Awardee's maximum liability in aggregate to CEPI arising out of this Agreement shall not exceed [***]: (a) [***] or (b) [***].
- 19.6 Exclusions from Liability Cap. Notwithstanding the foregoing, nothing in this Agreement shall limit the liability of either Party in respect of:
 - a. personal injury or death arising out of that Party's negligence or intentional misconduct; or
 - b. fraud or fraudulent misrepresentation.

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19.7 Clinical Studies by CEPI under the Public Health License. In the event that the Public Health License becomes exercisable and CEPI intends to exercise such rights, CEPI will procure insurance protection consistent with the requirements for Awardee below.

19.8 The Awardee will:

- a. satisfy the indemnification obligations arising under this Clause 19;
- b. obtain and continuously maintain, until [***] after completion of the Project, insurance on a claims-made basis with an insurance company of a credit rating of [***] or better to cover reasonably foreseeable claims that may arise in connection with its activities under the Project;
- c. if Awardee is the sponsor of a clinical trial pursuant to this Agreement, it will obtain and will ensure that any Sub-awardee that is the sponsor of a clinical trial will obtain, clinical trial insurance on a claims-made basis pursuant relevant local guidelines for the country in which the clinical study is conducted. Such insurance is to be effective from the commencement date of the clinical study until [***] after completion of the clinical study:
- d. without limiting the foregoing, Awardee shall maintain the following insurance coverage: General Third Party and Products Liability Insurance limited to [***].
- e. if requested by CEPI, Awardee will:
 - i. ensure that the insurer records CEPI's interest on each such insurance policy;
 - ii. provide CEPI with a copy of each such certificate of insurance and annually on renewal;
 - iii. notify CEPI of any claims made under these policies relating to the subject matter of this Agreement during the Term and for at least the duration of any applicable statutory period of limitation afterwards; and
 - iv. comply with the terms of these insurance policies for the Term and for at least the duration of any applicable statutory period of limitation afterwards.

20. Term and Termination

20.1 **Term**. This Agreement shall commence on the Effective Date identified in the Agreement Summary and will continue in full force and effect until the activities set out in the IPDP and all agreed Work Packages have been completed, or as otherwise terminated pursuant to this Clause 20 (the "Term").

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- 20.2 **Termination for Default**. If either Party (the "Defaulting Party"):
 - a. breaches a material obligation in this Agreement and either fails to cure that breach within a cure period of [***] (or longer time agreed in writing) after notice from the other Party (the "Terminating Party") or if that breach is not capable of cure; or
 - b. makes any arrangement with its creditors, resolves to or undergoes any insolvency proceeding anywhere in the world (except for the purpose of solvent amalgamation or reconstruction);

then the Terminating Party may terminate this Agreement by giving written notice of termination to the Defaulting Party effective immediately or at the end of any cure period if later.

- 20.3 **Additional CEPI Termination Rights**. In addition to Clause 20.2, CEPI shall be entitled to terminate this Agreement with immediate effect by providing written notice to Awardee in the following circumstances:
 - a. if following escalation to the Senior Officers pursuant to the process referred to in Clause 21.1 (for clarity, excluding submission to arbitration), CEPI reasonably determines, in good faith, that Awardee is unable or will become unable to discharge its obligations under this Agreement, for example if key personnel or technology resources required for successful completion of the Project become unavailable to Awardee, and Awardee does not promptly and reasonably alleviate CEPI's concerns;
 - b. there are safety, regulatory or ethical issues with continuing the Project, as reasonably determined by CEPI; or
 - c. Awardee does not satisfy the criteria in Clause 4.5 required for CEPI to pay funding tranches under the Project and fails to satisfy those criteria in full within a cure period of [***] (or longer time agreed in writing) after written notice from CEPI.
 - d. Any material changes or amendments are made to the IPDP (including Awardee's Traveler's Market Development Plan) without CEPI's prior written consent.
- 20.4 **Additional Awardee Termination Rights**. In addition to Clause 20.2, Awardee shall be entitled to terminate this Agreement by providing written notice to CEPI in the following circumstances:
 - a. After ten (10) years following the grant of marketing approval for the Product by the FDA, Awardee may terminate this Agreement without cause, with regard to either or both of: (i) the whole of the Awardee's Traveler's Market; and/or (ii) all of the Non-Traveler's Market Countries, provided that Awardee fulfils its obligations set out in Clause 20.4 e.

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- b. At any time after three (3) years following the grant of marketing approval for the Product by the FDA, Awardee may terminate this Agreement, with regard to either or both of (i) the whole of the Awardee's Traveler's Market; and/or (ii) all of the Non-Traveler's Market Countries, if Awardee is unable to sell the Product at [***]. In the event of any dispute between Awardee and CEPI regarding whether the events described in this paragraph b have occurred, the matter shall be referred to the escalation process set out in clause 21.1 provided that if the Parties are unable to resolve such dispute through negotiations by the Senior Officers within [***] of such dispute being escalated to the Senior Officers, then such dispute shall be referred for determination to a independent certified public accountant selected by both Parties (or if the Parties are unable to agree on such appointment as nominated by the Chairman of the Institute of Chartered Accountants) (the "Expert"). The Expert shall provide each Party with a report setting out the Expert's conclusions within [***] of the date on which the dispute was referred to the Expert.
- c. Following the last to occur of (i) the granting of marketing approval for the Product by the FDA; and (ii) the granting of marketing approval in the first LMIC country, in case of a Change of Control of Awardee, Awardee shall be entitled to terminate this Agreement by giving not less than [***] notice in writing to CEPI within a period of [***] from the date of completion of the Change of Control event, provided that Awardee pays to CEPI (within [***] of the receipt by CEPI of the termination notice by Awardee) the total amount of funding received by Awardee from CEPI under this Agreement. For the purposes of this Agreement, "Change of Control"shall mean a transaction or a series of transactions by which a third party acquires ownership, directly or indirectly, of more than fifty percent (50%) of the outstanding voting securities or capital stock of Awardee.
- d. Following the last to occur of: (i) the granting of marketing approval for the Product by the FDA; and (ii) the granting of marketing approval in the first LMIC country, in the event of the sale of the entire Chikungunya business operated by Awardee, Awardee shall be entitled to terminate this Agreement by giving not less than [***] notice in writing to CEPI within a period of [***] from the date of completion of the sale of the business provided that Awardee pays to CEPI (within [***] of the receipt by CEPI of the termination notice from Awardee) the total amount of funding received by Awardee from CEPI under this Agreement.

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- e. The following provisions shall apply in case of termination according to Clauses 20.4 a. to 20.4 d. above:
 - 1. Awardee will collaborate with CEPI in good faith for [***] following receipt by CEPI of the termination notice from Awardee, to find a third party to which Awardee's obligations under this Agreement with regard to Awardee's Traveler's Market and/or the Non-Traveler's Market Countries (depending on which market is affected by the termination) will be assigned (a "Third Party Supplier").
 - 2. If within such [***] period such a Third Party Supplier is identified, Awardee shall:
 - a. transfer all of the technology and intellectual property (with the exception of trademarks) required by CEPI and the Third Party Supplier to manufacture both the drug substance and the drug product including all necessary guidance, information, materials and assistance reasonably required by CEPI and such Third Party Supplier. Any reasonable costs related to such transfer shall be borne by CEPI. Notwithstanding the foregoing, Awardee may decide in its sole discretion whether any Product-related trademark should be transferred to a Third Party Supplier.
 - b. grant the Public Health License to CEPI and to the Third Party Supplier or such other third party as CEPI may direct.
 - 3. If the Parties are unable to identify a Third Party Supplier within the period of [***] following receipt by CEPI of the termination notice, Awardee's obligations under this Agreement shall cease (except for any continuing olbgiations as provided for pursuant to Clause 20.6) and the performance of the obligations of each Party under this Agreement shall be suspended for an indefinite period of time. The Parties shall agree the reasonable steps to be taken to suspend the manufacture of the Products and any agreed costs incurred in connection with such suspension shall be borne by CEPI. Reactivating the suspended Agreement shall require both Parties written agreement.
 - 4. In case of termination of this Agreement in accordance with this Clause 20.4, Awardee will supply to CEPI such quantities of drug substance and drug product as may be reasonably required by CEPI to create a stock pile of Product to meet its requirements for the Product until the technology transfer described in Clause 20.4 e 2 is complete. The delivery deadline of such safety stock shall be agreed by the Parties taking into consideration the volume request by CEPI and Awardee's and its contract manufacturer's capacities. CEPI shall pay for the the supply of such drug substance and drug product in accordance with the pricing provisions included in Clause 16.7 or as otherwise agreed by the Parties.

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20.5 Effects of Termination. In all termination events:

- a. CEPI will not be required to make any further payments to Awardee under this Agreement or any Work Package other than to reimburse Awardee for any non-cancellable expenses incurred in accordance with the Work Package in accordance with Schedule B;
- b. Awardee will return any CEPI funds which are unspent at the date of termination within [***] of the date of termination;
- c. each Party shall return or destroy, as requested by the other Party, the Confidential Information of the other Party except (i) CEPI may retain the Project Results subject to the obligations of confidentiality set out in Clause 22.4, (ii) each Party may keep one (1) copy of such Confidential Information for monitoring compliance and, (iii) solely in the event that the Public Health License has been exercised, CEPI may retain such other Confidential Information which embodies the Enabling Rights as may be required by CEPI to exercise and benefit from the Public Health License. Neither Party shall be required to delete copies of Confidential Information stored on automatic electronic backup systems;
- d. if there is an on-going clinical study funded by CEPI (whether in whole or in part), unless Awardee decides in its sole discretion to continue such clinical study at Awardee's cost or unless agreed otherwise by the Parties in writing, Awardee will ensure that no additional trial subjects are enrolled and the Parties will work together to plan and implement a wind-down of the study in an orderly fashion, with due regard for patient safety and the rights of any participating subjects; and
- e. the Parties will give effect to the relevant termination or expiration obligations described in Schedule B to these T&Cs.
- 20.6 **Survival of Rights and Identified Clauses**. Termination of this Agreement shall be without prejudice to the rights and duties of either Party accrued prior to termination. The following sections will continue to be enforceable notwithstanding termination or expiration: Clauses 2.5c), 2.5d), 4.9, 5.3, , 13, and 19 22, as well as any other provision, which by its nature, is intended to survive termination.

20.7 The Parties will

- a. perform all acts necessary to comply with the relevant effects of termination described above; and
- b. honour the rights and duties that survive termination.

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21. Resolving Differences

- 21.1 **Escalation process.** Any question, difference or dispute which may arise concerning the construction, meaning or effect of this Agreement, or concerning the rights or liabilities of the Parties hereunder, or any other matter arising out of or in connection with this Agreement shall first be submitted to the Chief Executive Officer of CEPI and to the Chief Executive Officer of the Awardee (the "Senior Officers") for resolution (each of whom may call on others to advise them as they see fit). The Senior Officers shall discuss the matter arising in good faith and in a timely manner and endeavour to reach a mutually agreeable solution. If the Parties are unable to resolve such dispute through such negotiations within [***] of such dispute being escalated to the Senior Officers, then in respect of any dispute, controversy or claim the Parties irrevocably submit to arbitration in accordance with Clause 21.2.
- 21.2 **Arbitration**. Any disputes to be resolved by binding arbitration pursuant to Clause 21 (including any question regarding its existence, validity or termination or this Agreement), shall be referred to and finally resolved by arbitration under the Rules of the London Court of International Arbitration, which Rules are deemed to be incorporated by reference into this Clause. The number of arbitrators shall be one. The seat, or legal place, of arbitration shall be London, England. The language to be used in the arbitral proceedings shall be English. Notwithstanding the foregoing, any Party may seek specific performance, interim or final injunctive relief or any other relief of similar nature or effect in any court of competent jurisdiction.
- 21.3 **Public Health License**. If CEPI invokes its rights under a Public Health License, then the Parties will pursue an expedited resolution of any differences under Clause 21 within [***]. However, because of the exigent circumstances when there is an Outbreak, Awardee agrees that CEPI may proceed under a Public Health License, but Awardee retains its right right to seek injunctive relief in addition to any other rights or remedies it may have under this Agreement, at law or in equity.
- 21.4 The Parties will: cooperate in good faith to resolve differences and disputes pursuant to this Clause 21.

22. General Provisions

- 22.1 **Defined Terms**. The terms defined in these T&Cs shall have the meaning explicitly ascribed to them.
- 22.2 **Announcements**. The Parties will agree in writing upon the form of all press releases and public announcements concerning this Agreement except that:
 - either may disclose a description of the Project subject to the confidentiality provisions of Clause 22.4, as well as the names of participating organizations and investigators;

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- b. CEPI may publish the summarized progress and outcomes of the Project (provided that the confidentiality provisions of Clause 22.4 shall apply, except to the extent that such publication is made in accordance with the procedures of Clause 11.2 and 11.3), a summary of the terms and conditions of this Agreement, the name of Awardee and the Project Lead, and the amount of the CEPI funding; and
- c. as required by law or any competent regulatory authority.
- 22.3 **Assignment**. Neither Party will, without the prior written consent of the other Party assign, transfer, convey or declare a trust over this Agreement or make any other disposition (whether in whole or in part) of any of its rights and obligations to any third party, including by novation except that:
 - a. CEPI may transfer its rights and obligations under this Agreement to an organisation of equivalent charitable mission, if CEPI determines (in good faith) that CEPI will not be in a position to fulfil its obligations or exercise its rights in the future. Except if the organization to which CEPI is transferring its rights and obligations is either The Wellcome Trust Limited or the Bill and Melinda Gates Foundation or their respective successors in title, Awardee shall have the right to terminate this Agreement without cause by giving [***] written notice to the assignee. Awardee may exercise its termination right under this Clause 22.3 a. within [***] of receipt of CEPI's notification of the assignment.
 - b. Awardee may transfer its rights and obligations under this Agreement as part of a sale of the entire business required for the satisfaction of Awardee's obligations under this Agreement either:
 - i. to an Affiliate of Awardee, provided that, if the assignee ceases to be an Affiliate of Awardee at any time the other provisions of this Clause 22.3 will apply, then CEPI will have the right to terminate this Agreement at any time unless and until the novation agreement referred to in Clause 22.3(b)(ii) has been entered into; or
 - ii. to a third party provided that (a) the assignee has, in CEPI's reasonable opinion, sufficient capital, expertise and commitment to carry on that business as a going concern and to meet Awardee's obligations under this Agreement at least at the same level as Awardee prior to such transfer, and (b) the assignee, Awardee and CEPI enter into a novation agreement in a form reasonably acceptable to CEPI at the time of the assignment or other conveyance in the event of the transfer of all or a substantial part of Awardee's activities related to the Project.

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- 22.4 Confidential Information. "Confidential Information" means any and all non-public information disclosed on or after the Effective Date of this Agreement by one Party to the other Party whether orally or in writing or in any other form. Each Party undertakes that both during the term of this Agreement and for a period of [***] after its termination or expiry, it shall keep confidential and not disclose to any person other than its employees, agents, consultants, professional advisers, Sub-Awardees, permitted subcontractors and regulatory authorities, and, in the case of CEPI, its funders, other members of the CEPI Group and Assessors (all of the foregoing, other than regulatory authorities, "Representatives"), in each case who have a need to know any Confidential Information of the other Party disclosed to or obtained by it in connection with this Agreement. Each Party shall take commercially reasonable security precautions to protect against unauthorized access to or disclosure of such Confidential Information. Each Party shall ensure that all Representatives to which Confidential Information of the other Party is disclosed are: (i) informed of the confidentiality provisions of this Agreement; and (ii) bound by confidentiality and non-use obligations at least as stringent as these. Notwithstanding the foregoing, (A) the obligations of confidentiality under this Clause 22.4 (x) with respect to Trade Secret Information shall continue for as long as Awardee maintains such information as trade secret in accordance with applicable laws, rules or regulations, and (y) with respect to Confidential Information within Awardee Background IP shall continue for a period of [***] after disclosure of such Awardee Background IP, and (B) Trade Secret Information shall not be disclosed to third parties except in connection with a Technology Transfer pursuant to Clause 16.6 and, if applicable, CEPI's exercise of the Public Health License pursuant to Clause 17 and, in each case, subject to the preceding clauses (i) and (ii); provided, that nothing herein shall restrict any rights of reference and access to Confidential Information within the Project Results for regulatory purposes, including for purposes of seeking, obtaining and maintaining regulatory approvals for the Product; and provided. further, that the reference to "third parties" in clause (B) (with respect to disclosure of Trade Secret Information) shall not mean or include CEPI's employees, agents, consultants and professional advisers who receive the information for internal use by CEPI and who are informed of the confidentiality provisions of this Agreement and are bound by confidentiality and non-use obligations at least as stringent as these. Confidential information will not include:
 - a. information that is or was already known to the receiving Party at the time of disclosure, as shown by written records, without any obligation to keep it confidential;

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- b. information that is independently developed by employees, agents, consultants and professional advisers of the receiving Party who have not had access to the Confidential Information of the disclosing Party as evidenced by contemporaneous written records;
- c. information that at the time of being disclosed or obtained by the receiving Party or at any time thereafter, is published or otherwise generally available to the public other than due to default by the receiving Party of its obligations hereunder;
- d. information properly obtained by the receiving Party from a source which, to the best knowledge of the receiving Party, is not known to be bound by a confidentiality agreement, fiduciary obligation or other legal or contractual restriction that may prohibit the disclosure of such Confidential Information; and
- e. information to the limited extent that is required to be disclosed by a competent Court or regulatory authority or otherwise by applicable law (including any requirements for disclosure under the Freedom of Information Act 2000); provided, that where it is free to do so, the receiving Party shall give notice of such disclosure to the disclosing Party as soon as reasonably practicable.

For clarity, Project Results shall be considered Awardee's Confidential Information, but may be disclosed and utilized by the Parties to the extent as set out in this Agreement and, in particular, pursuant to Clauses 11, 17 and 22.2.

- In the event CEPI exercises its Public Health License pursuant to Clause 17, CEPI and/or its designated Trusted Collaborator may use Awardee's Confidential Information to the extent required to give effect to such license, but shall otherwise comply with the provisions of this Clause 22.4.
- 22.5 **Entire Agreement**. This Agreement, including its Agreement Summary and Annexes, including CEPI Policies and Procedures, constitutes the entire agreement and understanding between the Parties relating to its subject matter and together they supersede and replace all prior arrangements, whether written or oral, between the Parties relating to the subject matter of this Agreement.
- 22.6 **Conflicts Between Components**. If there is any conflict between the provisions of this Agreement, any Work Package or the CEPI Policies and Procedures, then the provisions of this Agreement will prevail, followed by the provisions of the Work Package and finally the terms of the CEPI Policies and Procedures.
- 22.7 **Force Majeure**. Neither Party shall be deemed to have defaulted under or to be in breach of this Agreement for failure or delay in fulfilling material obligations when such failure or delay is directly

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caused by an event outside of their reasonable control, including but not limited to acts of war, insurrections, acts of terrorism, acts of God or acts, omissions or delays in acting or failure to act by any of CEPI's funders (collectively a "Force Majeure Event"). Each Party shall inform the other promptly and in writing of any Force Majeure Event and the Parties will discuss the situation, and acting in good faith, agree on the appropriate course of action under the circumstances. Notwithstanding the foregoing, in the case of an Outbreak or Increased Outbreak Preparation Need, the Parties will be expected to continue to carry out their obligations pursuant to applicable Work Packages with all due health and safety precautions.

- 22.8 **Further Assurances**. Each Party will perform such acts and execute such documents as reasonably may be required for securing to or vesting in the other Party the rights agreed to be granted to it pursuant to this Agreement.
- 22.9 **No Rights for Third Parties**. A person who is not a Party to this Agreement has no right under the Contracts (Rights of Third Parties) Act 1999 or otherwise to enforce or to enjoy the benefit of any term of this Agreement.
- 22.10 **Notices**. Any notice to be given pursuant to this Agreement shall be in writing in the English language and shall be delivered by overnight courier, by registered, recorded delivery or certified mail (postage prepaid) to the address of the recipient Party provided in the Agreement Summary or such other address as a Party may from time to time designate by written notice. Any notice given pursuant to this clause shall be deemed to have been received on the day of receipt, provided receipt occurs on a Business Day of the recipient Party or otherwise on the next following Business Day of the recipient. The Parties agree that email and fax are not valid methods of giving notice under this Agreement.
- 22.11 **No Waiver**. Neither Party shall be deemed to have waived any of its rights or remedies under this Agreement unless the waiver is expressly made in writing and signed by a duly authorized representative of that Party.
- 22.12 Awardee Efforts. Awardee will use all reasonable endeavors in achieving the milestones and objectives of the Project in the applicable timeframe.
- 22.13 **Relationship of the Parties**. Neither Party shall by reason of this Agreement be empowered to act as agent for the other Party or to pledge the credit of the other Party. Neither Party will be held liable for or incur liability in respect of the acts or defaults of the other Party.
- 22.14 **Variation**. No variation, amendment, modification or supplement to this Agreement will be valid unless and until it is made in writing and signed by a duly authorised representative of each Party.

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22.15 **Choice of Law**. This Agreement and any Dispute arising out of this Agreement or its formation will be governed by and construed in accordance with the laws of England and Wales without giving effect to any choice of law or conflict of law provisions or rules that would cause the application of the laws of any other jurisdiction.

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Schedule A: Glossary of Defined Terms

"Affected Territory" means any country, or any geographic area within a country, in which there is an Outbreak or for which there is an Increased Outbreak Preparation Need. For clarity, the Affected Territory includes any country in Awardee's Traveler's Market and any Non-Traveler's Market Countries, in each case in which there is an Outbreak or for which there is an Increased Outbreak Preparation Need.

"Affiliate" means any business entity Controlled by, Controlling or under common Control with a Party. For the purposes of this definition, "Control" (with correlative meanings, "Controlled by" or "Controlling") means direct or indirect beneficial ownership of more than fifty percent (50%) of the voting interest in an entity, or more than fifty percent (50%) interest in the income of the entity in question, or the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of an entity.

"Agreement Summary" means the cover page to this Agreement signed by the Parties.

"Assessor" has the meaning set out in Clause 12.2.

"Awardee Background IP" means discoveries, inventions, know-how, patents and patent applications, trademarks and trademark applications, copyrights and copyrightable materials and other intellectual property rights that are owned or controlled by Awardee at the Effective Date or that Awardee develops, acquires or otherwise comes to own or control after the Effective Date outside the scope of the Project and without any CEPI funding.

"Awardee Competitor" means any [***].

"Awardee-Funded Study " means the pivotal Phase 3 study of the Product referred to in the IPDP to be conducted, at Awardee's sole expense, to demonstrate safety and immunogenicity in adults aged 18 years and above in non-endemic regions.

"Awardee's Traveler's Market Development Plan" has the meaning set out in Clause 2.2.

"Awardee's Traveler's Market" means those countries listed below and any country that is defined by the Organization for Economic Co-operation and Development from time to time as a high income country; provided that if any such country becomes an LMIC, such country will no longer be included in the Awardee's Traveler's Market and will become a Non-Traveler's Market Country.

- 1. [***]; and
- 2. [***]; and
- 3. [***]; and
- 4. [***]; and

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5. [***].

"Awardee's Traveler's Market Development Plan" has the meaning set out in Clause 2.2.

"Business Day" means a day on which banks are normally open for business and which is not a Saturday or Sunday, or a bank or public holiday in Norway and Austria.

"CEPI Group" means the nodes of CEPI established in Norway, England, India, the United States of America and any other node of CEPI which may be established from time to time.

"CEPI Policies and Procedures" means the policies and procedures listed in Schedule C of this Agreement, as updated (including by the addition of CEPI policies and procedures) or amended from time to time pursuant to Clause 6.2.

"CfP3i Programme" means the first phase of CEPI's award programme under its Third Call for Proposals to develop vaccines against Chikungunya.

"Chikungunya Investigational Vaccine" means a candidate vaccine that induces a specific immune response against at least one Chikungunya antigen in the prophylaxis of infection or therapeutic use against Chikungunya virus.

"Commercial Benefits" means any economically quantifiable benefits that arise from the commercial exploitation of the Project Results other than in preparation for or in response to an Outbreak or Increased Outbreak Preparation Need. Examples of Commercial Benefits include the commercial licensing of Project IP, receipt of government-granted incentives such as Priority Review Vouchers and revenue from the commercialization of combination, derivative or follow-on products (including antibody products, assays and vaccines) or application of production technology.

"Confidential Information" has the meaning set out in Clause 22.4.

"Data Safety and Monitoring Board" or "DSMB" means an independent group that reviews and evaluates clinical study data for participant safety and makes recommendations concerning the continuation, modification, or termination of a study.

"Effective Date" means the start date of this Agreement referred to on the first page of this Agreement and in clause 2.1.

"Enabling Rights" means any and all rights owned or controlled by the Awardee at the Effective Date, together with those which arise on or after the Effective Date, which in each case, relate to the development, manufacture, supply or marketing of the Product, including improvements to the Project Results and Product existing at the date that CEPI is first entitled to utilize the Public Health License pursuant to Clause 17, whether or not arising under the Project. Enabling Rights include applicable Awardee Background IP but do not include any rights that Awardee is contractually precluded from granting to CEPI.

"Equitable Access" means that vaccines and other products developed, in whole or in part, with CEPI's financial support must be first available to populations when and where they are needed to end an outbreak or curtail an epidemic, regardless of ability to pay, while at a price that is sustainable to the manufacturer, as further detailed in CEPI's "Equitable Access" Policy.

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"EU" means the economic, scientific, and political organization of member states known as the European Union, as its membership may be altered from time to time, and any successor thereto. For clarity, the United Kingdom shall be considered part of the EU at all times for the purposes of this Agreement.

"Financial Records" has the meaning set out in Clause 5.3.

"Financial Report" means Awardee's report to CEPI of its expenditures under the Project Budget on the Financial Report Template in Annex F and Awardee's report of its activities under the IPDP.

"Financial Report Template" means the form of report in Annex F to be used by Awardee for its reports to the JMAG.

"Increased Outbreak Preparation Need" means when, having considered all reasonably accessible and relevant information including epidemiological data, travel and migration patterns and the likely availability of other products or product candidates, CEPI determines, in its sole discretion in consultation with experts (for example a sub-group or subcommittee of CEPI's Scientific Advisory Committee that CEPI determines has appropriate expertise), that there is a heightened need for the Product to address potential Outbreaks.

"Integrated Product Development Plan" or "IPDP" means the document in Annex C that describes the research and development activities related to the Product and associated deliverables, milestones and timelines, as may be amended from time-to-time.

"International Standard" means a biological standard accepted by WHO for use as an International Reference Preparation.

"Investigational Product" means a Product that has not received a marketing authorization.

"IPDP Records" has the meaning set out in Clause 2.5.

"IPDP Reports" has the meaning set out in Clause 2.3.

"IPDP Report Template" means the form of report in Annex D to be used by Awardee for its reports to the JMAG.

"Joint Monitoring and Advisory Group" or "JMAG" has the meaning set out in Clause 2.4.

"Low and Middle Income Countries" or "LMICs" are those countries defined by the Organisation for Economic Co-operation and Development.

"Net Sales" means the gross amount invoiced or received by Awardee, its Affiliates, licensees or assignees in respect of sales of Product to third party purchasers in bona fide arm's length transactions less [***], booked on an accrual basis pursuant to Generally Accepted Accounting Principles (GAAP) or International Financial Reporting Standards (IFRS), as relevant.

"Non-Traveler's Market Countries" means all countries of the world other than the countries in the Awardee's Traveler's Market.

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"Outbreak" means a Public Health Emergency of International Concern declared by WHO, or a public health emergency on a national or regional scale declared by one or more public health agencies, in each case as a result of a material increase in the number of cases of people infected with CHIK including any regional out-break, an epidemic or a pandemic.

"Outbreak Notice" has the meaning set out in Clause 16.

"**Product**" means a Chikungunya Investigational Vaccine under the Project and includes any form or dosage of pharmaceutical composition or preparation for use in humans that is developed in whole or in part as part of the Project, including any Investigational Product.

"Project" means Awardee's activities as described under the IPDP or as otherwise funded by CEPI.

"Project Budget" means the documents in Annex D that describes CEPI's funding award, payment schedules, and any co-funding or in-kind contributions by Awardee.

"Project Data" has the meaning set out in Clause 11.1.

"Project IP" has the meaning set out in Clause 13.1.

"Project Lead" means the principal investigator named by Awardee in the IPDP or otherwise agreed by the Parties.

"Project Materials" has the meaning set out in Clause 12.1.

"Project Results" has the meaning set out in Clause 10.1.

"Public Health License" means a non-exclusive, fully paid-up, sublicensable license under the Project Results and Enabling Rights to develop, manufacture, market and/or supply the Product worldwide, provided that all end users of the Product are located in the Affected Territory; in each case for use in preparation for or response to an Outbreak or Increased Outbreak Preparation Need. For the purposes of this definition, the term 'Product' shall mean the Chikungunya Investigational Vaccine in any form or dosage of pharmaceutical composition or preparation for use in humans.

"Retained Amount" means the ten per cent (10%) of the final payment tranche retained by CEPI under Clause 4.9.

"Safety Issues" means any material concerns regarding safety or efficacy of any Product studied under the Project, including serious adverse events or serious adverse reaction, safety-related signals, product recalls or relevant recommendations from the Data Safety Monitoring Board to place a hold on or to end a clinical study.

"Safety Stock" has the meaning set out in Clause 15.2.

"Sub-Awardee" has the meaning set out in Clause 3.1.

"Team Charter" means the description of how the Project will be organized and managed as described in Annex B.

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ANNEX A: TERMS AND CONDITIONS - SCHEDULE A

"Technology Transfer" has the meaning set out in Clause 16.55.

"Term" has the meaning set out in Clause 20.

"Terms and Conditions" or "T&Cs" shall have the meaning set out in Clause 1.1.

"Trade Secret Information" means Confidential Information that Awardee maintains as trade secret in compliance with applicable laws, rules or regulations and that is labeled as confidential or proprietary or, if not so labeled, is of a nature that a reasonable person with knowledge of the subject matter would recognize, based upon its content and/or the context of its disclosure, to be a trade secret.

"Trial Steering Committee" or "TSC" solely with regard to clinical studies funded by CEPI means a group of independent experts who are not involved in the clinical study that will provide advice on the clinical study protocol and monitor the progress of the clinical trial, including any changes to the protocol.

"Trusted Collaborator" has the meaning set out in Clause 16.

"Warranties" has the meaning set out in Clause 18.

"WHO" means the World Health Organization.

"Work Package" means the complete Project (as a single Work Package consisting of the Work Package Streams set out in the IPDP) or any additional activities related to research, development, manufacture or supply of a Chikungunya Investigational Vaccine that CEPI may decide to proceed with or request to be performed hereunder.

"Work Package Stream" has the meaning set out in Clause 4.

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ANNEX A: TERMS AND CONDITIONS - SCHEDULE B

Schedule B: Effects of Termination

OBLIGATIONS ON TERMINATION BY AWARDEE PURSUANT TO CLAUSE 20.2

(Termination for Default)

CEPI shall reimburse Awardee for all reasonably incurred non-cancellable expenses relating to the Project which were authorised by CEPI and which arise after the termination date, solely to the extent they are not otherwise covered by CEPI funding.

OBLIGATIONS ON EXPIRATION OR TERMINATION PURSUANT TO CLAUSE 20.3(b)

(Termination due to Safety, Regulatory or Ethical Issues)

CEPI shall reimburse Awardee for all reasonably incurred non-cancellable expenses which were authorised by CEPI and which arise after the termination date, solely to the extent they are not otherwise covered by CEPI funding, and the Parties will work together to plan and implement a wind-down of the Work Package in an orderly fashion relating to the Project.

OBLIGATIONS ON TERMINATION BY CEPI PURSUANT TO CLAUSES 20.2, 20.3a) OR 20.3c)

(Termination For Default; CEPI's Reasonable Determination that Awardee is or will be Unable to Perform; or Failure to Satisfy Clause 4.5, respectively)

Solely at CEPI's discretion, CEPI may reimburse Awardee for some or all or Awardee's reasonably incurred non-cancellable expenses relating to the Project which were authorised by CEPI and which arise after the termination date.

Subject to Clause 11.2, Awardee shall promptly make all Project Data publically available in such manner as CEPI may direct, save to the extent that to do so would result in the public disclosure of Enabling Technology which would not otherwise be publically disclosed.

CEPI shall have the right to require Awardee, at CEPI's discretion, to either: (i) perform Technology Transfer to a Trusted Collaborator (including any Trusted Collaborator appointed pursuant to Clause 17.3) on an expedited basis at the Awardee's cost, or (ii) if Technology Transfer has already occurred at the date of termination and certain costs in relation to such Technology Transfer were borne by CEPI, reimburse CEPI for such costs.

CEPI shall have the right to exercise the Public Health License, pursuant to Clause 17.2.c).

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ANNEX A: TERMS AND CONDITIONS - SCHEDULE B

Awardee shall use all reasonable endeavours to promptly transfer to CEPI (or its nominee), at Awardee's cost, any regulatory approvals and applications for regulatory approvals relating to the Product.

Awardee shall ship to CEPI (or its nominee) all Project Materials within [***] of CEPI requesting such Materials.

Awardee shall provide CEPI with a list of all sub-license, contract manufacturing agreements and other agreements and arrangement to which Awardee is a party which relate to the development and marketing of the Product (the "Contracts"), within [***] of the Termination Date. CEPI may request copies of any Contracts, which Awardee will promptly provide.

CEPI shall have the right to require Awardee to: (i) assign the benefit (subject to the assumption of the burden) of one or more Contracts to CEPI or its nominee and, where consent of a third party is required, seek to obtain such consent; (ii) novate one or more Contracts to CEPI or its nominee; or (iii) terminate one or more Contracts in accordance with its terms at Awardee's cost.

Where termination is due to any financial irregularity or fraudulent or illegal activity by Awardee, Awardee shall repay to CEPI the amount of funds related to such financial irregularity or fraudulent or illegal activity within [***] of the notice of termination. "Financial irregularity" refers to all kinds of: corruption, including bribery, nepotism and illegal gratuities; misappropriation of cash, inventory and all other kinds of assets; and financial and non-financial fraudulent statements.

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ANNEX A: TERMS AND CONDITIONS – SCHEDULE C

Schedule C: CEPI Policies and Procedures as of Effective Date

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Annex B: Team Charter

[***]

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Annex C: Integrated Product Development Plan (IPDP)

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Annex D: IPDP Reporting Template

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Annex E: Budget

[***]

ANNEX A: TERMS AND CONDITIONS - SCHEDULE A

Annex F: Payment Request Form and Financial Report Template

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