[***] = 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.

EXECUTION VERSION

ANNEX A: TERMS AND CONDITIONS

C E PI

Funding Agreement
(CEPI Identification: Valneva 0002)
Agreement Summary

AWARDEE INFORMATION	
Name:	Valneva Austria GmbH
Mailing Address:	Campus Vienna Biocenter 3, 1030 Vienna, Austria
Project Lead:	[***]
Project Management Contact:	[***]
Bank Account Details:	Account Name: Valneva Austria GmbH Name of Bank: [***] IBAN:[***] BIC/Swift Code: [***]

CEPI INFORMATION	
Mailing Address:	Post Box 1030 Hoff, 0218 Oslo, Norway
Project Lead:	[***]
Management Contact:	[***]

AGREEMENT INFORMATION	
Project Name	Expanding the Profile of Live-Attenuated Chikungunya Vaccine
CEPI Program Name	CEPI CfP3iii Chikungunya Vaccines
Effective Date	Date of last signature below

Pre-Activities Start Date	1 September 2023
This Agreement includes and incorporates by reference:	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 including Pre-Award Cost (Annex E) - Payment Request Form and Financial Report Templates (Annex F) - Equitable Access Plan (Annex G)

THIS AGREEMENT is between Valneva Austria GmbH ("Awardee" or "You") and the Coalition for Epidemic Prepared ness 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 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:…….

19-07-2024
Date:…….

Signed for and on behalf of **Valneva Austria GmbH** by:

[***]
Name:……..

[***]
Title:…….

19-07-2024
Date:…….

Signature:……

[***]
Name:……..

[***]
Title:…….

19-07-2024
Date:…….

ANNEX A: TERMS AND CONDITIONS

CfP3iii 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 CfP3iii 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.

1.3 CEPI, Awardee and the Serum Institute of India Private Limited ("SII") are currently discussing and aim to enter into a tripartite side letter ("Side Letter") not later than within two (2) calendar months after the date of this Agreement whereby, provided SII and Awardee fulfil certain conditions included in the Side Letter, [***]. If there is any conflict between the finalized Side Letter and this Agreement, the Side Letter will prevail. For the avoidance of doubt, nothing in this Clause shall be construed as CEPI providing consent to SII becoming a Sub-Awardee until the Side Letter has been executed.

2. Project Organization and Management

2.1 **IPDP and Work Packages**. 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. Awardee will use commercially reasonable endeavours to achieve the associated deliverables, milestones and timelines of each Work Package and achieve agreed upon Technical Review criteria by the agreed deadline (the "Technical Review Point") set forth in Annex C. In accordance with Clause 4.6 below, additional Work Package(s) may be agreed in writing by the Parties after the Effective Date, which, upon execution by both Parties, shall be annexed to and become a part of this Agreement. Work Packages may also be modified or extended with the mutual written consent of both Parties in accordance with Clause 24.14.

2.2 **Technical Reviews.** awardee will notify the JMAG when it is reasonably assured that a technical Review Point will be achieved in the near term, and promptly provide the JMAG with relevant information and agreed upon data. [***]

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. [***] Notwithstanding the foregoing, CEPI shall be entitled to be party to tripartite meetings between CEPI, Awardee and each LMIC Manufacturer [***]

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 and any LMIC Manufacturers, 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;

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. keep the JMAG (until the equitable access group is established in accordance with clause 16.3 in which case Awardee will inform the Equitable Access Group) informed of its adherence to the Equitable Access Plan and its progress in meeting its objectives;

g. 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

h. notify CEPI if the project lead designated in the ipdp becomes unavailable and designate areplacement reasonably satisfactory to CEPI within [***].

i.

3. Sub-Awardee Participation in the Project

3.1 **Sub-Awardees.** Awardee's activities under the project may be undertaken by affiliates, and contracted collaborators, including LMIC Manufacturers (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 **Hungarian Act IX Restriction.** none of the funds provided under this agreement (whether via a sub-contract or otherwise) shall be used in any way directly or indirectly to provide support, resources or assets to any public interest trusts established on the basis of the Hungarian Act IX of 2021 or any entity maintained by such a public interest trust.

3.3 **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.

3.4 **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 Records 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, including the CEPI Policies and Procedures;

d. be consistent with awardee's obligation in this agreement, including without limitation in the sections related to Financial Management and Oversight (Clause 5); Dissemination and Publication of Project Data (Clause 13); Dissemination of Project Materials (Clause 14); Intellectual Property (Clause 15); Equitable Access (Clause 16) and the Equitable Access Plan (Annex G); Sharing of Commercial Benefits (Clause 17); Preparation for Outbreaks (Clause 18); the Public Health License (Clause 19); and Term and Termination (Clause 22); and

e. prohibit the sub-awardee from subcontracting its obligations without CEPI`s consent. such consent not to be unreasonably withheld, conditioned or delayed.

3.5 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 this Agreement and the IPDP;

b. in addition to, and without in any way diminishing or otherwise altering, awardee's obligations under this Agreement 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 3.4.

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 beginning on the date specified in the Budget. The initial payment will additionally cover pre-award costs commencing on the Pre-Activities Start Date, as agreed between the Parties and included in the Budget.

4.3 **Subsequent Tranches**. CEPI will pay the initial tranche of funding within [***] of 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.

4.4 **Payment when there is a Breach**. CEPI is not obliged to pay any tranches of funding for any work Package 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 20 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 **Funding of Additional Work Packages**.

a. CEPI shall have the first right subject to section 4.6 c., in its sole discretion, to provide further funding and other support for the further development, manufacture and deployment of the Product in Non-Traveler's Market countries. Such activities would be negotiated in good faith and set out in an additional Work Package(s) with associated project budget for such additional Work Packages amending Annex C. Nothing in this Clause 4.6 confers any obligation on CEPI to fund additional Work Packages.

b. CEPI may decide not to proceed with any additional work package in accordance with clause 4.6 a. if it is not in the best interest of CEPI's mission. If CEPI decides not to fund additional Work Packages, it will notify Awardee as soon as such a decision is made.

c. in the event that (a) awardee reasonably requires any third party funding for the development, manufacture or deployment of the Product in Non-Traveler's Market countries; or (b) Awardee receives any offer or indication of interest from a third party, or identifies a call for proposal from a third party, to provide funding support for such development, manufacture or deployment, Awardee shall provide prompt written notice to CEPI, including a summary of the amount of funding required or offered and the terms (if any) offered by any potential third party funder (each a "Further Funding Notice"). CEPI shall provide written notice to Awardee that it does, or does not wish to provide such further funding within [***] of receipt by CEPI of a Further Funding Notice. After this period Awardee shall have the right to accept any third party funding support for the development, manufacture and deployment of the Product in Non Traveler's Market countries provided CEPI (i) notifies Awardee that it does not wish to provide additional funding, or (ii) fails to provide Awardee with such notice within the [***] time period.

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 the 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, and for the period between the Pre-Activities Start Date and 30 June 2024 as set forth in the relevant section of Annex E

b. provide a financial report to CEPI within [***] of the end of each six (6) month period during the Term of the Project, regarding its expenditures pursuant to the Project Budget, using the template provided in Annex F. In the first Financial Report Awardee will include details of its expenditures incurred in the period from the Pre-Activities Start Date until the date of the first Financial Report;

c. provide a separate final financial report for a work package within [***] after the completion of any Work Package; and

d. reimburse CEPI for any funding underspend.

5. Financial Management and Oversight

5.1 **Financial Practices**. from the Pre-Activities Start Date, 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 24.4, CEPI, or its designee, will have on-site access to Awardee's Financial Records annually, 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 annually 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. from the Pre-Activities Start Date, keep accurate, complete and reliable records of revenues and expenditures for the period between the Pre-Activities Start Date and 30 June 2024 as set forth in the relevant section of Annex E;

b. from the effective date, keep accurate, complete and reliable records of revenues and expenditures under the Project Budget ("Financial Records") against an individual project code;

c. retain all financial records and details of the pre-activities start date expenditure 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;

d. provide [***] written notice to CEPI before destroying financial records;

e. 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;

f. if requested by CEPI, awardee will permit awardee's external auditors or an independent audit firm appointed by CEPI to conduct a Project audit (on and off site). The audit will be conducted at CEPI's reasonable cost and expense;

g. procure a project audit as identified above from sub-awardees at CEPI's request and at CEPI's reasonable cost and in accordance with relevant audit and assurance standards, including but not limited to, ISA800 or ISRS4400; and

h. 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**. Awardee will comply with relevant national and supranational laws and governmental regulations that apply to Awardee's Project-related activities.

6.2 **CEPI's Third Party Code**. The third party Code is a statement of CEPI's values and of the policies, practices and principles applicable to recipients of CEPI funding. Awardee:

a. acknowledges the statement of CEPI's values in Section 1 of the Code;

b. will adhere to business practices, ethical principles and legal requirements that are at least substantially similar to those described in Sections 2 to 10 of the Code;

c. will comply with the requirements for reporting compliance concerns and misconduct to CEPI (Sections 4 and 11 of the Code);

d. will cooperate as may be reasonably requested by CEPI in the submission of information related to Project activities and expenditures in accordance with the International Aid Transparency Initiative (Section 12 of the Code); and

e. will, for any sub-contractor not listed in the Team Charter or IPDP, comply with the provisions of the Third Party Code related to Sub-Contractors (Section 14 of the Code).

6.3 **Amendment of CEPI Policies and Procedures**. CEPI may notify awardee from time-to-time that the CEPI Policies and Procedures have been amended. Such amended 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 23.1.

6.4 the awardee will:

a. comply with applicable laws and regulations;

b. subject to clause 24.6, comply with CEPI policies and procedures;

c. provide access to information to the EC court of auditors and anti-fraud office as required;

d. 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

For the purposes of this section, where an LMIC Manufacturer will be undertaking clinical studies, and provided such clinical studies have been funded by CEPI under this Agreement, Awardee will obligate the relevant LMIC Manufacturer to comply with the obligations applicable to Awardee, *mutatis mutandis*.

7.1 **Clinical Studies**. if any work package includes research involving human subjects, such activities must comply with applicable laws, the requirements of any relevant regulatory agency and with CEPI's Clinical Trials Policy.

7.2 **Clinical Data**. where applicable, 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;

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 13;

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 14; 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 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 fulfil 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, or ensure that a sub-awardee acting as local sponsor, fulfils all sponsor obligations as detailed below;

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 data safety monitoring board (DSMB);

f. notify the JMAG in writing immediately following any safety issues or similar events;

g. 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

h. subject to the confidentiality provisions contained in clause 24.4, 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:

a. attend meetings of the DSMB for the clinical study as an observer (either in person or by electronic means); and

b. receive all papers that a member of the TSC (as defined in Clause 7.5a) or DSMB would be entitled to receive.

7.5 In order to support the clinical studies funded by CEPI (whether in whole or in part), the awardee:

a. will establish a trial steering committee (TSC) or any other appropriate clinical oversight setting, as agreed between the Parties; and

b. shall use commercially reasonable endeavours to adhere to any further requirements under this Clause 7.5, as agreed between the Parties. Such requirements may be similar to and may include but not be limited to those requirements outlined under Clause 7.4 (f) and 7.4 (h) above.

8. Quality Requirements and Responsibilities

8.1 Awardee shall ensure that all activities performed under this agreement shall be performed in accordance with all applicable safety, legal, ethical and regulatory authority requirements or standards, including the CEPI Third Party Code, any associated regulatory approval, clinical trials application and/or all applicable GxPs.

8.2 During the term, awardee will:

8.2.1 inform CEPI of any significant quality-related issues, events or changes that are reasonably likely to adversely affect the supply of Products to Non-Traveler’s Market Countries;

8.2.2 within [***], notify CEPI of the outcome of GxP regulatory inspections and any material adverse quality findings and any critical quality events (including serious breaches, deviations, audit findings, breaches of data integrity etc.) that are reasonably likely to adversely affect the supply of Products to Non-Traveler’s Market Countries; and

8.2.3 consider in good faith quality recommendations identified by CEPI relating to the Project as may arise throughout the course of the Term in respect of the supply of Products to Non-Traveler's Market Countries.

8.3 Quality-related disputes between the parties that are not resolved in the normal course of business shall be brought to the attention of the JMAG in writing. Both Parties shall use all reasonable endeavours to agree to a prompt resolution of the disagreement and agree to work jointly to develop a strategy for such solution. If the quality-related dispute relates to the LMIC Manufacturer, Awardee shall encourage the LMIC Manufacturer to work jointly with CEPI to develop a strategy for solution. The Parties shall record any such resolution in writing.

8.4 Awardee shall, and shall use commercially reasonable endeavours to facilitate that the LMIC Manufacturers, permit CEPI, or its designee (subject to prior written consent by Awardee and/or the LMIC Manufacturer (as applicable) or such designee, not to be unreasonably conditioned, withheld or delayed), to conduct a detailed due diligence assessment of the relevant party's quality systems on-site, provided such site visits shall be restricted to [***] visit per manufacturer each [***] during the Term. CEPI shall cause its designee to enter into a reasonably acceptable confidentiality agreement with the relevant party obliging such designee to retain all such information in confidence pursuant to such confidentiality agreement. In the event that such assessment identifies any major or critical deficiencies in the relevant party's quality system, Awardee shall, or shall obligate the LMIC Manufacturer to, take all actions reasonably necessary to correct such deficiencies.

8.5 **Pharmacovigilance meetings with sub-awardees.** Awardee will keep CEPI informed about any official meetings between Awardee and Sub-Awardees, or Sub-Awardees and any regulatory authority, concerning significant Pharmacovigilance matters related to the Product. Awardee will schedule regular meetings with each Sub-awardee's Pharmacovigilance Team and with CEPI's Pharmacovigilance Team to share a routine safety update on the Product and to discuss any significant safety related issues, as applicable.

9. Animal and Toxicology Studies

9.1 **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.

9.2 The awardee will:

a. obtain and maintain all regulatory approvals (including ethical committee approvals) necessary or reasonably useful for the conduct of research involving animals;

b. share details of its animal and toxicology protocols with CEPI through the JMAG meetings and provide CEPI with a draft of each trial protocol for any animal or toxicological studies it intends to conduct prior to their initiation and will consult with and consider any reasonable suggestions made by CEPI; and

c. 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.

10. Standards and Assays

10.1 **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.

10.2 **Assay Development.** A work package may include the development of new or improved assays (including immunogenicity and potency/release assays), as will be described in the IPDP.

10.3 **CEPI Service Providers.** CEPI has entered into certain service agreements with CEPI service Providers that have agreed to provide preferential charging to CEPI Awardees. CEPI may make available various laboratory services or other support to Awardee provided by a CEPI Service Provider, for example by providing testing of clinical serum samples, evaluation of immunity of Product in animal models and various analytical services. Awardee may utilise any CEPI Service Provider for the provision of services as may be, and solely if and to the extent, specified in a Work Package and agreed in writing between the Parties. Awardee and the CEPI Service Provider may, at their own discretion, enter directly into an appropriate agreement between themselves setting out the terms on which the services will be provided. CEPI shall, through the JMAG or otherwise, discuss with Awardee protocols and data management related to any services provided by any CEPI Service Provider.

10.4 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 24.4 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.

11. Regulatory Activities

For the purposes of this section, where an LMIC Manufacturer will be undertaking regulatory activities for a particular Product, Awardee will use commercially reasonable endeavours to ensure that the relevant LMIC Manufacturer adhere to the obligations applicable to Awardee, *mutatis mutandis*.

11.1 **Meetings with Regulatory Authorities.** Awardee will keep CEPI informed about any product related official meetings with regulatory authorities (including WHO-PQ). In case Awardee is participating in the meeting with the relevant regulatory authority, the Awardee shall provide an opportunity to have a CEPI representative in the meeting as a silent observer, provided the regulatory authority and the LMIC Manufacturer so accept. At CEPI's reasonable request, Awardee will request a meeting with regulatory authorities to address any significant unresolved issues**.**

11.2 Regulatory Filings. Awardee will regularly inform CEPI regarding its, and the LMIC Manufacturer's, regulatory strategy for the Product and will inform CEPI of any discussions with regulatory authorities that may have a significant impact on future development of the Product through the bilateral and multilateral meetings referred to in the Team Charter. Awardee will provide CEPI with copies of:

11.2.1 key regulatory filings and submissions in respect of the Product, including M1 and M2 of the Common Technical Document (CTD), clinical study reports, proposed product specifications and product label information;

11.2.2 official meeting minutes of meetings between the regulatory authority and Awardee/LMIC Manufacturer relating to the Product, and any written communications from the regulatory authority on significant matters related to the Product which may impact the Project.

11.3 **Cross Referencing.** Awardee will co-operate with CEPI to allow CEPI to cross-reference specific parts of Awardee's Project Results in order to support regulatory pandemic preparedness, to be further discussed and agreed upon between the Parties.

11.4 **Regulatory Approvals in LMICs.** Awardee will ensure the LMIC manufacturer will use commercially 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 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 commercially reasonable endeavours to meet such schedule in such countries**.**

11.5 WHO Prequalification. Awardee will ensure that the LMIC manufacturer will use commercially reasonable endeavours to obtain WHO prequalification for the Product.

12. Project Results and their Ownership

12.1 **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.

12.2 **Ownership of Project Results.** Awardee will own the project results.

12.3 The awardee will:

a. share with CEPI, subject to the confidentiality provisions contained in clause 24.4, all significant Project Results as soon as is practical;

b. record project results accurately, completely and reliably in awardee's IPDP records; and

c. identify project results in the IPDP reports provided to the JMAG.

13. Dissemination and Publication of Project Data

13.1 **Reporting of Project Data.** Subject to the confidentiality provisions contained in clause 24.4, 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 Project Data regularly to the JMAG. Notwithstanding the foregoing, with respect to Project Data produced or arising as a result of any 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.

13.2 **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 [***].

13.3 **Publication of Project Results.** CEPI encourages awardee's timely publication of project data and other Project Results, including pre-clinical studies, in scientific publications and manuscripts, congress posters and congress presentations. 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 any Awardee-Funded Study) shall include a statement that the work was "co-funded by the European Union and CEPI" (translated into local languages, where appropriate) and, provided the relevant publisher accepts, shall display the European flag (emblem):

Co-funded by the European Union

With respect to publications relating to clinical trials other than the Awardee-Funded Studies, 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 [***].

13.4 **Additional requirements for communication and dissemination.** Any communication or dissemination activity (i.e. publications, manuscripts, congress posters and congress presentations) related to the Project must use factually accurate information. Moreover, it must indicate the following disclaimer (translated into local languages, where appropriate): "Co-Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or Horizon Europe. Neither the European Union nor the granting authority can be held responsible for them."

13.5 **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 13.5 shall not be mandatory with respect to clinical data and results arising from any Awardee-Funded Study.

13.6 **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.

13.7 **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 13 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.

13.8 The awardee will:

a. notify the JMAG on an ongoing basis as project data is produced and disseminated in accordance with Clause 13.1;

b. disseminate project data consistent with the requirements set out above in this clause 13; and

c. cooperate in regard to data analysis, to the extent relevant under a given work package, by CEPI's Assessors, subject to Clause 24.4, 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);

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

i. 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).

14. Dissemination of Project Materials

14.1 **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 24.4. For purposes of this Agreement, "Project Materials" means the drug product and the clinical trial materials described in Clause 14.4 (c) (ii). For clarity, "Project Materials" shall not include any intermediates or assays relating to the manufacturing process.

14.2 **Comparator Samples.** The awardee will use commercially reasonable endeavours to make a limited amount of samples of marketed Product and/or Product in use under emergency use license available as comparator for other research in the Field, if reasonably justified by requestor under terms and conditions (including but not limited to the scope of research, protocol and reporting) agreed between the Parties, with the spirit to advance research in the Field.

14.3 **Comparative Evaluation of Samples.** CEPI may engage one or more independent third party laboratories or collaborators ("Assessors") (which may include but is not limited to the Task Force for Global Health and its Safety Platform for Emergency vACcines (SPEAC Project)) to perform additional testing on Project Materials

as specified under Clause 14.4c, 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 24.4. 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. Awardee shall have the right to veto the engagement of an Awardee Competitor that CEPI seeks to appoint as an Assessor. CEPI may appoint any other third party as an Assessor provided that, if Awardee raises reasonable objections to the appointment of an Assessor (other than an Awardee Competitor), the matter shall be submitted to the JMAG for decision. If the JMAG is unable to decide, then the escalation process according to Clause 23.1 shall apply. 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.

14.4 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 14; and

c. cooperate with CEPI's assessor, to the extent relevant under a given work package, subject to Clause 24.4, by:

i. 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 biological samples from clinical studies under the Project funded by CEPI and provided such clinical studies collects biological specimen as samples, (excluding 1) the Awardee-Funded Study and 2) the completed Phase 3 clinical study VLA1553-301) 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 participants 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.

15. Intellectual Property

15.1 **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").

15.2 **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, including the Equitable Access Plan, or the potential use by CEPI of the Public Health License described in Clause 19. The Parties will cooperate in good faith to resolve any such matters.

15.3 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

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.

16. Equitable Access

16.1 **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 Product(s) to public health systems in all Non-Traveler's Market Countries that have a demand for the vaccines at an affordable price (as outlined in Clause 16.4) 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.

16.2 **Equitable Access Plan.** The initial plan to support such Equitable Access commitment (the "Equitable Access Plan") is set out in Annex G and sets out among other things how the Product will be suitable for Non Traveler's Market use and made available to all populations in Affected Territories without undue delay and at an affordable but sustainable price (subject always to Clause 16.4). This Equitable Access Plan shall be reviewed by JMAG no less than every [***] and shall take into account production [***] and shall be updated throughout the Term to reflect such reviews or as otherwise agreed between the Parties. The Parties agree that a more detailed Equitable Access Plan will be agreed promptly after the Equitable Access Group is established. The Awardee will keep the JMAG and, if established, the Equitable Access Group, fully and regularly informed of its adherence to the Equitable Access Plan and its progress, or lack thereof, in meeting its objectives.

16.3 **Equitable Access Group.** Within [***] of the effective date the parties will establish an Equitable Access Group (the "Equitable Access Group") that will meet regularly to monitor the progress of, and advance the Awardee's commitment to, Equitable Access. The LMIC Manufacturer will be a member of the Equitable Access Group and will keep the other members regularly informed of its commitment to Equitable Access.

Within [***] of setting up the Equitable Access Group, the Parties will update the Team Charter to describe the organisation and management of the Equitable Access Group**.**

16.4 Pricing: The parties recognize that the price of the product to public health systems in all non-Traveler's Market Countries is critical to achieving Equitable Access. To the extent that Awardee, a Trusted Collaborator, any Sub-Awardee or LMIC Manufacturer commercializes the Product in public health systems in the Non-Traveler's Market Countries which utilizes or otherwise benefits from, whether directly or indirectly, any Project Result, [***].

16.5 Information about Production, Supply, Pricing and Sales.

16.5.1 Upon written request by CEPI, Awardee will provide, and will procure that its Sub-Awardees, LMIC Manufacturers and Trusted Collaborator provides, reasonable information about its production, supply, pricing and sales of Product, including its audited financial statements sufficient to enable CEPI to evaluate whether such activities are consistent with Awardee's obligations under this Agreement.

16.5.2 Awardee shall ensure that its Sub-Awardee Instituto Butantan provides CEPI with updates on Sub-Awardee's pricing discussions with relevant pricing authorities within Brazil and the other Non-Traveler's Market Countries awarded to Butantan, including public sector procurement agencies such as AVAT, GAVI, , PAHO, and various Ministries of Health, as applicable. Further, Sub-Awardee shall share with CEPI any official pricing data submitted to CMED and CONITEC in Brazil and to other relevant pricing authorities outside of Brazil.

16.6 Supply Commitment.

16.6.1 Awardee shall ensure its Sub-Awardees, to the greatest extent possible, prioritise the supply of Product to public health systems in Non-Traveler's Market Countries taking into consideration public sector demand, production capacity and contractual obligations existing prior to any public sector purchase agreements entered into in accordance with 16.6.2.

16.6.2 Awardee shall ensure its Sub-Awardees shall use all reasonable endeavours to bid on applicable public sector tenders for the supply of Product in Non-Traveler's Market Countries in time and at the price specified in the relevant tender (and [***]). Awardee shall ensure its Sub-Awardees use all reasonable endeavours to deliver the Product in accordance with the tender, or any subsequent purchase agreements with any public sector purchaser and meet the lead-time specified in the tender and/or purchase agreement.

16.6.3 Nothing in this Clause 16.6 shall preclude Awardee and its Sub-Awardees from supplying

Product to the private market in Non-Traveler's Market Countries as long as the Awardee or Sub-Awardee does not discriminate against the public health system in the Non-Traveler's Market Countries in favour of the private market in such countries. In the event there is insufficient Product for Sub-Awardees to be able to fulfil orders to public sector markets, Awardee shall ensure its Sub-Awardees prioritise supply to the public market in accordance with Clause 16.6.1.

16.6.4 Except in the event that Awardee has transferred the manufacturing processes for drug substance to Awardee's Sub-Awardee Instituto Butantan and any potential future Sub-Awardee, Awardee shall use reasonable commercial endeavours to manufacture and supply drug substance in the quantities needed to meet public sector demand in Non-Traveler's Market Countries for the Term and for [***] following the grant of marketing approval for VLA1555 by ANVISA.

16.6.5 Within [***] of the expected launch date of each of VLA1555 and VLA1556, Awardee shall ensure that its Sub-Awardees develop and provide Awardee and CEPI with a launch readiness supply plan for Non-Traveler's Market Countries.

16.6.6 Awardee undertakes to ensure that no LMIC Manufacturer has or will have the right to supply Product in Awardee's Traveler's Market.

17. Sharing of Commercial Benefits

17.1 **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.

17.2 **The Awardee will:** ensure any LMIC manufacturer - other than Instituto Butantan who shall remain bound by the safety stock requirements agreed under the prior funding agreement between the Parties, effective as of 1 April 2019, as amended - shall make the following contributions to CEPI:

i. Until the rolling safety stock has been established by each LMIC Manufacturer in accordance with Clause 17.2(ii), Awardee will ensure that the LMIC Manufacturer, at its own cost, maintain and make available to CEPI an Investigational Product reserve stockpile of [***] doses of drug product

ii. Awardee will ensure the LMIC Manufacturer produces, at its own cost, a one-year rolling safety stock comprised of not less than [***] doses of Finished Drug Product within [***] of receipt of marketing approval for the Product from a competent regulatory authority having jurisdiction over the relevant LMIC Manufacturer. The stock in paragraph 17.2(i) and this paragraph 17.2(ii) is referred to as ("Safety Stock").

iii. Awardee will provide details of the Safety Stock to the global Technical Advisory Group to monitor Global Virtual Pooled Inventory ("TAG-GVPI") once the TAG-GVPI is established.

iv. 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 ensure the LMIC Manufacturer dispatches 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 ensure the LMIC Manufacturer makes no charge for the supply of the Safety Stock allocated to and used by CEPI in accordance with this paragraph 17.2(iv) and the storage costs of such Safety Stock, incurred prior to dispatch to the Affected Territory, shall be borne by the LMIC Manufacturer.

v. 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 the LMIC Manufacturer's facility. If, following the use of the Safety Stock as directed by CEPI, CEPI wishes to replenish the Safety Stock, Awardee shall, or shall obligate its LMIC Manufacturers to, 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.

18. Preparation for Outbreaks

18.1 **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 17.2. or any Product manufactured pursuant to Clause 18.2 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 endeavours 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 endeavours 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 endeavours 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 endeavours 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 endeavours, Awardee shall not be obliged to supply Product to CEPI under this Clause 18.1 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 18.1, Awardee shall not be considered to be in default, and Clauses 18 and 19 shall not apply.

18.2 **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.

18.3 **Multidose presentation.** Awardee shall assist and support each LMIC manufacturer in the potential development of a multi-dose presentation of the Product.

18.4 **Additional Investigational Product or Product Stockpiles.** In addition to the safety stock referred to in Clause 17.2ii., 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.

18.5 **Trusted Collaborator.** promptly after receipt of a written request from (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 18.2 or 18.4 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.

18.6 **Technology Transfer.** As described in the IPDP, awardee will be transferring technology to LMIC Manufacturers. Awardee will promptly and diligently provide all necessary guidance, information, materials

and assistance reasonably required to transfer Awardee's technology to each such LMIC Manufacturer 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 LMIC Manufacturers) 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 18.2 or 18.4 ("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.

18.7 **The Awardee will:** use commercially reasonable endeavours 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. CEPI is engaging with global stakeholders and in the future, it is likely that Outbreak response will be coordinated by a global entity. In such event, Awardee shall use all reasonable endeavours to collaborate with such entity and to comply with its requirements concerning the Outbreak.

18.8 **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 18 and 19 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 lowest supply price of the Product for similar volumes of Product agreed by Awardee with any customer in the Affected Territory in the [***] preceding the receipt of the Outbreak Notice by Awardee. For purposes of this Clause 18.8, "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 18 and 19 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 fulfil due to Awardee´s capacities or (ii) the price proposed by the public health agency would be unsustainable to Awardee, Clauses 18 and 19 shall not apply in such case. In any case, "sustainable price" shall never be below Awardee`s manufacturing costs.

19. Public Health License

19.1 **Grant of a Public Health License.** Awardee hereby grants the public health license to CEPI (subject to Clause 18.8), 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 22.2; and

c. one or more of the triggers set out in clause 19.2 has occurred.

19.2 **Public Health License Triggers.** Consistent with clause 19.1, CEPI's right to exercise the public Health License will be triggered when:

a. awardee or trusted collaborator declines to participate in activities requested by CEPI under Clause 18.1 or 18.2;

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 or Trusted Collaborator will not be able to perform the activities under Clause 18.1 or 18.2 if requested by CEPI;

c. awardee is in material breach of this agreement or the equitable access plan;

d. [***] have passed since an outbreak notice in accordance with clause 18.1 and the Parties including Trusted Collaborator have not signed an agreement or new Work Package for the activities contemplated under Clause 18.1 or Clause, as applicable, despite CEPI's request; or

e. the agreement is terminated by CEPI pursuant to clause 22.2, 22.3a or 22.3d.

19.3 **Agreement with Trusted Collaborator.** In the event that the public health license becomes exercisable in accordance with Clause 19.1, CEPI may endeavour 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.

19.4 The awardee will:

a. 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. promptly provide to CEPI an updated list of enabling rights and project results 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;

d. upon exercise of the public health license by CEPI, promptly and diligently make available to CEPI all guidance, information, Project IP, Enabling Rights, materials and assistance reasonably required to accomplish the Project activities identified by CEPI.

20. Warranties

20.1 **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;

b. it is in material compliance with all statutes, regulations, directives and requirements of any governmental entity that relate to its activities and obligations;

c. 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. it is not a restricted party; in breach of sanctions; or subject to or involved in any complaint, claim, proceeding, formal notice, investigation or other action by any regulatory or enforcement authority or third party concerning any Sanctions;

h. none of the funds provided under this agreement (whether via a sub-contract, sub-grant or otherwise) are used in any way directly or indirectly to provide support, resources, assets or any other benefit to, a Restricted Party in a manner that would violate Sanctions;

i. all financial statements and budgets submitted to CEPI as of the date of signature of this Agreement are true, complete and accurate;

j. to the best of its knowledge and belief, all encumbrances have been disclosed that could affect CEPI's use of the Public Health License; and

k. the pre-award costs that CEPI has agreed to fund commencing on the pre-activities start date and included in the Budget have been performed in accordance with (i) the CEPI Policies and Procedures agreed upon in the prior funding agreement between the parties, effective as of 1 April 2019, as amended and (ii) the principles and requirements contained in the Third Party Code, as agreed between the Parties in the Declaration dated 30 September 2019.

20.2 **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.

21. Indemnification and Insurance

21.1 **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 21.2.

21.2 **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.

21.3 **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 21.1 or Clause 21.2 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 21.1 or Clause 21.2 and shall fully consult the indemnified Party on the nature of any defence to be advanced in advance.

21.4 **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.

21.5 **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 [***]. Awardee's maximum liability in aggregate to CEPI arising out of this Agreement shall not exceed the greater of:(a) the aggregate of the actual funding received from CEPI up to the date on which the claim is brought against Awardee or (b) Awardee's total insurance coverage as set out in Clause 21.8**.**

21.6 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.

21.7 **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.

21.8 The awardee will:

a. satisfy the indemnification obligations arising under this clause 21;

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 A 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 five (5) years 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.

22. Term and Termination

22.1 **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 22 (the "Term").

22.2 **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.

22.3 **Additional CEPI Termination Rights.** In addition to clause 22.2, CEPI shall be entitled to terminate this Agreement with immediate effect, unless otherwise indicated below, 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 23.1 (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;

c. if awardee has committed fraud or a financial irregularity. for the purposes of this clause “Financial Irregularity” includes any and all kinds of corruption, including bribery, nepotism and illegal gratuities; misappropriation of cash, inventory and all other kinds of assets; and making fraudulent financial and non-financial statements to CEPI;

d. 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; or

e. any material changes or amendments are made to the IPDP (including awardee’s traveler’s Market Development Plan) without CEPI’s prior written consent.

22.4 **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 24.4, (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.

22.5 Survival of Rights and Identified Clauses. **Termination of this agreement shall be without prejudice to the rig**hts 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., 4.9d., 5.3, 15, and 21 – 24, as well as any other provision, which by its nature, is intended to survive termination.

22.6 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.

23. Resolving Differences

23.1 **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 23.2.

23.2 **Arbitration.** Any disputes to be resolved by binding arbitration pursuant to clause 23 (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.

23.3 **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 23 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 to seek injunctive relief in addition to any other rights or remedies it may have under this Agreement, at law or in equity.

23.4 The Parties will: cooperate in good faith to resolve differences and disputes pursuant to this clause 23.

24. General Provisions

24.1 **Defined Terms.** The terms defined in these T&Cs shall have the meaning explicitly ascribed to them**.**

24.2 **Announcements.** The parties will agree in writing upon the form of all press releases and public announcements concerning this Agreement except that:

a. either may disclose a description of the project subject to the confidentiality provisions of Clause 1.4 as well as the names of participating organizations and investigators;

b. CEPI may publish the summarized progress and outcomes of the project (provided that the confidentiality provisions of Clause 24.4 shall apply, except to the extent that such publication is made in accordance with the procedures of Clause 13.2 and 13.3), 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.

24.3 **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 24.3 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 24.3 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 24.3b. (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.

24.4 **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 24.4 (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 18.7 and, if applicable, CEPI's exercise of the Public Health License pursuant to Clause 19 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;

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 13, 19 and 24.2.

In the event CEPI exercises its Public Health License pursuant to Clause 19, 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 24.4.

24.5 **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 supersedes and replaces all prior arrangements, whether written or oral, between the Parties relating to the subject matter of this Agreement.

24.6 **Conflicts Between Components of this Agreement.** 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. For clarity, the Funding Agreement between the Parties dated 1 April 2019 remains in full force and effect and shall not be superseded by this Agreement for any Work Packages performed thereunder.

24.7 **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 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.

24.8 **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.

24.9 **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.

24.10 **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.

24.11 **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.

24.12 **Awardee Efforts.** Awardee will use all reasonable endeavours in achieving the milestones and objectives of the Project in the applicable timeframe.

24.13 **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.

24.14 **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.

24.15 **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.

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 14.3.

"**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 commercial entity researching, developing or manufacturing a Chikungunya vaccine for use anywhere in the world.

"**Awardee-Funded Study**" means the VLA1553-304 (HIV+), VLA1553-305 (YF co-vacc), VLA1553-222 (dose finding <1y), VLA1553-323 (pediatric <1y), VLA1553-401 (PASS) and VLA-India (adults) studies of the Product referred to in the IPDP to be conducted, at Awardee's sole expense.

"Awardee's Traveler's Market Development Plan" has the meaning set out in Clause 2.1.

"**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. USA, Canada; and

2. Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom, Andorra, Iceland, Lichtenstein, Malta, Monaco, Norway, San Marino, Switzerland; and

3. Japan, South Korea, Taiwan, Singapore, Hong-Kong; and

4. Australia, New Zealand; and

5. Israel, Bahrain, Turkey, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates.

"**Awardee`s Traveler`s Market Development Plan**" has the meaning set out in Clause 2.1.

"**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 6.3.

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

"**Chikungunya 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 24.4.

"**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.

"**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 19, 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.

"**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.

"**Field**" means Chikungunya virus in humans.

"**Finished Drug Product**" means the finished product formulation, containing drug substance, filled into unit packages together with a diluent, if applicable, and as finally labelled and packaged in a form ready for administration.

"**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.

"**Good Clinical Practice**" or "**GCP**" means (i) all laws, rules, regulations, guidelines and generally accepted standards and requirements regarding the ethical conduct of clinical trials including designing, recording and reporting trials that involve the participation of human subjects as promulgated by any competent authority having jurisdiction in the country in which

the organisation is registered or any country in which the clinical trial is to be conducted, (ii) Good Clinical Practice as set forth in ICH GCP Guidelines E6(R1), as amended (iii) all applicable standards and laws and regulations for current good clinical practices promulgated by the US Food and Drug Administration and the European Medicines Agency and (iv) any other good clinical practice regulations and guidance set out in the applicable Work Package.

"**Good Distribution Practice**" or "**GDP**" means the WHO Good Storage and Distribution Practices for Medical Products Annex 7, WHO Technical Report Series 1025, 2020 and all applicable standards and laws and regulations for current good distribution practices for medicinal products (including vaccines) promulgated by any competent authority having jurisdiction in any country in which the Products are distributed.

"**Good Laboratory Practice**" or "**GLP**" means (i) all laws, rules, regulations, guidelines and generally accepted standards and requirements regarding quality control for laboratories to ensure the consistency and reliability of results promulgated by any competent authority having jurisdiction in the country in which the organisation is registered, or any country in which the laboratory testing is to be conducted, (ii) Good Laboratory Practice as set forth in OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring (iii) all applicable standards and laws and regulations for current good laboratory practices promulgated by the US Food and Drug Administration and the European Medicines Agency and (iv) any other good Laboratory practice regulations and guidance set out in the applicable Work Package.

"**Good Manufacturing Practice**" or "**GMP**" means (i) all applicable standards and laws and regulations for current good manufacturing practices for medicinal products (including vaccines) promulgated by any competent authority having jurisdiction in the country in which the organisation is registered, or any country in which the Product is distributed, (ii) Good Manufacturing Practice as set forth in the World Health Organization's Technical Reports Series TRS 986 - Annex 2 Good Manufacturing Practices for pharmaceutical products: main principles and TRS 999 - Annex 2 WHO good manufacturing practices for biological products (TRS no 999), (iii) all applicable standards and laws and regulations for current good manufacturing practices for medicinal products (including vaccines) ingredients, testing, storage, handling, seed lots, cell banks and intermediates, bulk and finished products promulgated by the US Food and Drug Administration and the European Medicines Agency and (iv) any other good manufacturing practice regulations and guidance set out in the applicable Work Package.

"**Good Practice**" or "**GxP**" means all or any one (as the context requires) of GCP, GDP, GLP or GMP.

"**High Income Countries**" or "**HICs**" means those countries identified by the OECD as having high income economies, as of the Effective Date, as set out at https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending- groups.

"**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.

"**LMIC Manufacturer**" means a manufacturer based in a Non-Traveler's Market country engaged by Awardee to manufacture and/or supply the Product as outlined in the IPDP.

"**Low and Middle Income Countries**" or "**LMICs**" are those countries defined by the Organisation for Economic Co-operation and Development as being least developed or having low-income or lower-middle income economies from time to time, and as of the Effective Date set out at: https://www.oecd.org/dac/financing- sustainable-development/development-finance-standards/daclist.htm under the columns 'Least Developed Countries', 'Low Income Countries' and 'Lower Middle-Income Countries and Territories'.

"**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 deductions allowed by applicable licensing agreements or otherwise customary in the biopharmaceutical industry, 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.

"**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 18.

"**Pre-Activities Start Date**" means the date referred to on the first page of this Agreement.

"**Product**" means a Chikungunya Vaccine under the Project (including, for the avoidance of doubt, VLA1553 VLA1555 and VLA1556 in Non-Traveler's Market countries,) and includes any form or dosage of pharmaceutical composition, including combination products, 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 pursuant to this Agreement.

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

"**Project Data**" has the meaning set out in Clause 13.1.

"**Project IP**" has the meaning set out in Clause 15.1.

"**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 14.1.

"**Project Results**" has the meaning set out in Clause 12.1.

"**Public Health License**" means a non-exclusive, fully paid-up, royalty free, irrevocable, sublicensable license under the Project Results and Enabling Rights that is necessary or reasonably useful 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 the purpose of achieving Equitable Access during the Term and for twenty (20) years thereafter. For the purposes of this

definition, the term 'Product' shall mean the Chikungunya Vaccine in any form or dosage of pharmaceutical composition or preparation for use in humans.

"Restricted Party" means a person that is:

(a) listed on any Sanctions List or targeted by Sanctions (whether designated by name or by reason of being included in a class of persons); or

(b) located in or incorporated under the laws of any country or territory that is the target of country- or territory-wide Sanctions; or

(c) directly or indirectly, in the aggregate, 50% or more owned, or controlled by, or acting on behalf, at the direction, or for the benefit of, one or more persons referred to in (a) and/or (to the extent relevant under Sanctions) (b) above.

"**Retained Amount**" means the ten per cent (10%) of the final payment tranche retained by CEPI under Clause 4.7.

"**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 17.2.

"Sanctions" means any applicable laws, regulations or orders concerning any trade, economic or financial sanctions or embargoes administered by the Sanctions Authorities and any other regime administering trade, economic or financial sanctions applicable to this Agreement;

"Sanctions Authority" means that Norwegian State, the United Nations, the European Union, the Member States of the European Union, the United Kingdom, the United States of America, Australia, Canada and any authority acting on behalf of any of them or their respective legislative, executive, enforcement and/or regulatory authorities or bodies acting in connection with Sanctions.

"Sanctions List" means:

(a) the lists of Sanctions designations and/or targets maintained by any Sanctions Authority; and/or
(b) any other Sanctions designation or target listed and/or adopted by a Sanctions Authority,

in all cases, as amended, supplemented or replaced from time to time.

"**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.

"**Technical Review**" means the mutually agreed milestones that trigger a programmatic review as further detailed in the IPDP.

"**Technical Review Point**" has the meaning set out in Clause 2.1.

"**Technology Transfer**" has the meaning set out in Clause 18.6.

"**Term**" has the meaning set out in Clause 22.

"**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 or co-funded by CEPI means a group of experts that will provide advice on the clinical study design, clinical study protocol including any changes to the protocol and any feedback from regulatory and other national authorities; and monitor the progress of the clinical trial.

"**Trusted Collaborator**" has the meaning set out in Clause 18.

"**VLA1553**" means Awardee's single-shot, live-attenuated vaccine, marketed under the name 'IXCHIQ' in Non-Traveler's Market countries.

"**VLA1555**" means a single-shot, live-attenuated vaccine, to be developed, manufactured and commercialized by Awardee's Sub-Awardee Butantan for specific Non-Traveler's Market countries.

"**VLA1556**" means a single-shot, live-attenuated vaccine, potentially to be developed, manufactured and commercialized by a Sub-Awardee, an LMIC Manufacturer or a Trusted Collaborator in specific Non-Traveler's Market countries, subject to contract with such Sub-Awardee and approval by CEPI.

"**Warranties**" has the meaning set out in Clause 20.

"**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 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.

Schedule B: Effects of Termination

OBLIGATIONS ON TERMINATION BY AWARDEE PURSUANT TO CLAUSE 22.2 *(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 22.3(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 22.2, 22.3a, 22.3b, **22.3c 22.3e OR 22.3d**

(Termination For Default; CEPI's Reasonable Determination that Awardee is or will be Unable to Perform;; Financial

Irregularity; 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 13.2, Awardee shall promptly make all Project Data publicly 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 publicly 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 19.3) 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 19.2d).

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.

Schedule C: CEPI Policies and Procedures as of Effective Date

Animals in Research Policy

Anti-Corruption Policy

Clinical Trials Policy

Cost Guidance

Equitable Access Policy

Information Security Policy

International Sanctions Policy

Managing Conflicts Of Interest Policy

Procurement Policy

Scientific Integrity Policy

Transparency & Confidentiality Policy

Travel Policy

Third Party Code

Annex B: Team Charter

Team Charter

For the CfP-3iii agreement package for project

"Expanding the Profile of Live-Attenuated chikungunya Vaccine"

Awardee: Valneva

This "Team Charter" describes the operation and the governance of the CfP-3iii project titled "Expanding the Profile of Live-Attenuated chikungunya Vaccine".

The aim of this Team Charter is to provide project management and operational guidance. It is designed to function as an operational document to explain the roles and responsibilities of Awardee ("Project Team") and CEPI while also setting out how the Project will operate in practice. In the event of any conflict between this Team Charter and the Terms and Conditions of the Agreement, the Terms and Conditions shall prevail in all circumstances.

Unless specifically defined in this Team Charter, all defined terms shall have the same meaning as set out in the Terms and Conditions.

The objectives of the Project are described in the Integrated Product Development Plan ("IPDP"). For document locations, please refer to section 7 "Document Management and Archiving", below.

1. Project Team Composition and Responsibility

It is the responsibility of the Project Team to perform the work described in the IPDP pursuant to certain Work Packages on the terms of the Agreement.

The Project Team will be comprised of:

	Contact Name	Contact Details
Awardee's Project Lead	[***]	Email: [***] Tlf/mobile:
CEPI Project Lead	[***]	Email: [***] Tlf/mobile:

Additional details of the Project Team members and Project Team structure are set out in Schedule 1 and 2 to this Annex.

2. CEPI Team Composition and Responsibility

The CEPI team will be composed of a Project Lead, a Project Manager, a Project Finance Manager**,** and an Equitable Access lead**.** This team will be supplemented by relevant experts, internal or external to CEPI under appropriate confidentiality arrangements to be parts of the JMAG or sub-teams depending on the specific needs of the project, such as CMC, Regulatory, Clinical subject matter experts.

The responsibility of the CEPI team in the Project is:

1. To mobilize experts and consultants in order to support the Project Team to overcome obstacles during the Project. This function is offered on an ad-hoc basis;
2. To be part of the JMAG and sub committees with its responsibilities
3. To oversee that project milestones and deliverables are met according to the Agreement and its schedules; and
4. To ensure that CEPI's investment is closely monitored and that funds are distributed in accordance with the Agreement.
5. To ensure that Project Continuity and Equitable Access plans are developed and implemented as required throughout the Project life cycle.

3. Project Governance Structure

The Project governance structure is set out in Schedule 2 to this Annex.

1. The Awardee's Project Lead should encourage all Project Team members to contribute to the development strategy.
2. The style of communication is encouraged to be objective, open and direct.
3. Personal accountability in the Project Team should be pre-defined and clearly articulated along with a set of measurable actions and deadlines, together with definition of roles and responsibilities.
4. If there is a risk that deadlines or other Project requirements will not be met, the first approach is for precautions and counter measures to be taken by the Project Team.

4. Joint Monitoring and Advisory Group Composition (JMAG)

JMAG's Remit

The JMAG shall be entitled to:

1. monitor the performance and technical content of each Work Package against the milestones and their dates, and critically assess the results on an on-going basis to identify and address any weaknesses or delays in any Work Package;
2. approve the achievement of milestones and Technical Reviews (but shall not have the right to approve final Project completion);
3. provide a forum for discussion as to whether the activities currently agreed to are sufficient to satisfy CEPI's Mission;
4. Provide a forum for discussion of items and issues raised in the various sub-committee meetings described in Table 1, potentially for JMAG deliberations and decisions where within scope.
5. have the authority to approve extensions to Work Package timelines within [***] of the originally planned timeframe as set out in the relevant Work Package, provided that each such extension is at no cost to CEPI and does not impact the overall completion date of the Project;
6. have the authority to approve transfer of funds between cost categories within a Work Package Project Budget, to the extent that any such changes are cost neutral;
7. review and approve proposed changes and updates to the IPDP;
8. review and discuss pre-clinical/nonclinical and clinical trial protocols including any substantial changes;

9. review and discuss the regulatory strategy for the use of the Product and receive regular updates on regulatory filings and submissions;
10. review the contractual and operational status and capabilities of Trusted Collaborator(s) (if applicable);
11. review and discuss publications;
12. coordinate the sharing of any Project Results identified in the Work Package as intended for use by other CEPI awardees;
13. review and update the Equitable Access plans;
14. discuss plans, as appropriate, for the development and manufacturing and its scale-up and scale-out;
15. approve the progress reports on an agreed upon schedule;
16. review any reports and updates provided by any site visit groups;
17. provide a forum for coordinating the Parties' responses to issues with respect to the Project Vaccine, to the extent relating to CEPI's use in the Field, including unexpected disruptions to the supply of the Project Vaccine, recalls, safety issues or withdrawals of the Project Vaccine;
18. receive written notification of all Project Results; and
19. make such other decisions as may be delegated to the JMAG pursuant to the Agreement or by written agreement of the Parties.

Limitations on JMAG

The JMAG has no right to do any of the acts set out below. These acts can only be done by CEPI or jointly by the Parties as set out in the Agreement:

1. confirm willingness to fund any additional Work Packages (such decision is to be made solely by CEPI);
2. approve the Financial Reports;
3. approve completion of the Project;
4. amend or vary the provisions of the Terms and Conditions,
5. approve any Sub-Awardee(s) to the extent not identified in the IPDP
6. alter the fundamental scope or objectives or agreed completion date of the Project; and
7. approve an overall increase to a Project Budget or timeline.

JMAG Composition

The JMAG Members shall be comprised of the following persons:

1. Two "Voting Members", who will be the Awardee Project Lead (who shall also be the chairperson of the JMAG) and the CEPI Project Lead. The Awardee Project Lead or nominee and the CEPI representative or nominee shall both have the right to vote on matters brought before the JMAG and falling within the JMAG remit. CEPI may, at its sole discretion, appoint or remove the CEPI representative or nominee by notice in writing to the Awardee; and
2. "Non-Voting Members" Each of the Parties may invite those persons whose special skills or knowledge might advance the Project, to attend and address the JMAG meetings as observers. Such Non-Voting Members shall not have a right to participate in the JMAG decision-making process. The Project Lead shall ensure that any such attendees sign confidentiality agreements in a form acceptable to all Parties. Each Party shall pay for the reasonable documented travel expenses and/or consulting fees of the Non-Voting Members it proposed and shall ensure that such travel is conducted in accordance with CEPI's Travel Policy.

Quorum

The quorum for JMAG meetings shall be the two (2) Voting Members. Decisions of the JMAG shall be made by unanimity of the Voting Members. Where consensus cannot be reached, the matter shall be escalated in accordance with Clause 23.1 of the Agreement.

5. Project Team and JMAG Meetings, and committee meetings

Each *new* team, sub-team and JMAG will have a kick-off meeting to start its activities and each team, sub-team and JMAG will have a final close-out meeting to end the operation of the team/sub-team and capture the lessons learned.

The Awardee's Project Lead or his/her designee, shall be responsible for organising all meetings, including preparing meeting agenda, papers and ensuring that minutes of meetings are produced promptly after each meeting and circulated to Members in a timely manner.

For this CfP-3iii grant, and the nature of proposed arrangement with 3 partners including Valneva, Instituto Butantan and Serum Institute of India, the organisation and management of all meetings described in the Table 1 will lie with the awardee, i.e. Valneva, unless stated otherwise. Decisions at submeetings will be brought to the JMAG for information, and for decision where applicable, as described in JMAG remit in Section 4 of this document.

The agreed governance structure in Table 1 follows the principles of allowing enough exchange between all Parties for areas where this is needed, while at the same time keeping committees and meetings limited and as small as possible, to allow efficient management of all collaborations considering the number of Parties and time zones involved. General operational guidelines for the Parties include that (1) presentations are to be shared at a minimum [*** in advance, (2) meeting minutes are to be drafted within [***] following the meeting, and (3) meeting minutes comments are to be received within [***] after distribution of the draft minutes.

Table 1. Overview of Committees Meetings with Member Parties, Frequency and Topics Discussed

Meetings	VLA	CEPI	IB	SII	Frequency	Existing?	Topics Discussed	Comments related to limited member
CEPI Monthly meeting	✓	✓			[***]	Y (CfP-3i)	[***]	
CMC	✓	✓			[***]	Y (CfP-3i)	[***]	
RA	✓	✓			[***]	Y (CfP-3i)	[***]	
JMAG	✓	✓			[***]	Y (CfP-3i)	[***]	
JSC VLA-IB	✓		✓		[***]	Y (CfP-3i)	[***]	
JSC VLA-SII	✓			✓	[***]	New	[***]	
Tech Transfer Committee →Tech Devel. Committee	✓	(✓)	✓		[***]	Y (CfP-3i) → New scope & members	[***]	IB to lead TDC. Assuming IB's consent, 1 person defined by CEPI will join as an observer for relevant and non-confidential info. and until multidose development is complete. CEPI's comments to be followed-up with designated VLA member.
Tech Transfer Committee	✓	(✓)		✓	[***]	New	[***]	One person defined by CEPI will join as an observer for relevant and non-confidential info.. CEPI's comments to be followed-up with VLA chair.
Development Committee	✓	(✓)	✓		[***]	Y (CfP-3i)	[***]	One person defined by CEPI will join as an observer for relevant and non-confidential info.. CEPI's comments to be followed-up with VLA chair.
Development Committee	✓	(✓)		✓	[***]	New	[***]	One person defined by CEPI will join as an observer for relevant and non-confidential info.. CEPI's comments to be followed-up with VLA member.
LMIC Launch Readiness Committee	✓		✓		[***]	Y (CfP-3i)	[***]	
LMIC Launch Readiness Committee	✓			✓	[***]	New	[***]	
Trial Steering Committee	✓	✓	✓	✓	[***]	Y (CfP3.i) → Additional party SII	[***]	
Quadripartite	✓	✓	✓	✓	[***]	New	[***]	

Bipartite Tripartite Quadripartite Member

Limited Member

6. Communication with Stakeholders

Stakeholder communications regarding the Project between CEPI and the Awardee should be reviewed and approved by the JMAG. In order to maintain open communication with these stakeholders, copies of the final minutes will be distributed on request to CEPI and Awardee organization members, who are bound by confidentiality restrictions. The two Project Leads (Awardee and CEPI) will consult each other prior to any communication to third parties, presentations, press releases, conference presentation about the Project.

7. Document Management and Archiving

CEPI shall provide and maintain a secure computer platform (for example Microsoft TEAM site) to serve as a collaborative site repository for Awardee and CEPI to share Project documents during the conduct and until completion of the Project ("the Secure Portal").

It is the responsibility of the Awardee Project Manager to ensure that relevant documents are posted on the Secure Portal in a timely manner, including but not limited to the following: agenda and meeting minutes of JMAGs and Project Team meetings, the IPDP, planning documents, Risk Register, Project Budget, Financial and CPP Reports and organizational charts. The Project Teams will agree to a list of team members that will have access to the Secure Portal.

In addition, CEPI utilizes an electronic Project Management system (Salesforce) for progress and financial reporting to which the Awardee PL, PM, and financial manager will have access.

Such approved access to both the secure Portal and Salesforce will be governed by the terms and conditions of Confidentiality as outlined in the Agreement.

The Awardee is responsible for ensuring that they hold their archive of any required documents related to the Project, in accordance with applicable ICH Guidelines (GLP, GMP, GCP, etc) and local legislation and / or regulation as applicable.

8. Planning

The Project Lead, or their nominated deputy, is responsible for maintaining the following plans for the Project ("Project Plans"), the frequency of updates of which will be agreed by the JMAG:

Project Plans:

1. IPDP: should be regarded as a "living document" and updated regularly (Microsoft Word document). These updates should be reviewed by JMAG.
    a. Project Gantt chart: used for tracking and risk management (Microsoft Project file)
    b. Risk Register

9. Budgets

Within each Work Package, the Awardee Project Lead is accountable for managing the Project budget, and CEPI is accountable for making payments in accordance with the Agreement.

10. Review of Team Charter

This Team Charter may be amended as required by a decision of the JMAG.

11. Appendices

Schedule 1: Awardee Project Team Members at signature
Schedule 2: Awardee Project Governance Structure
Schedule 3: CEPI Project Governance Structure
Schedule 4: Reporting Template

Schedule 1: Awardee Project Team Members at signature (subject to change throughout the project)

Name	Role in Project, Function	Contact details (email / mobile)
[***]	Chief Medical Officer	[***]
[***]	VP Business & Corporate Development	[***]
[***]	Business & Corporate Development Senior Manager	[***]
[***]	Head of Project Management Chikungunya	[***]
[***]	Senior Project Manager	[***]
[***]	VP Clinical Development	[***]
[***]	Director Clinical Strategy and Project Lead Chikungunya Vaccine Development	[***]
[***]	Head of CTM External Manufacturing - Drug Product	[***]
[***]	VP Technical Development & Operations	[***]
[***]	VP Analytical Development	[***]
[***]	VP Regulatory Affairs	[***]
[***]	Director Clinical Serology	[***]
[***]	Director Late-Stage Clinical Development	[***]

Annex C Integrated Product Development Plan (IPDP)

Sensitivity: Official Use

Integrated Product Development Plan (iPDP)

Project Name: "Expanding the Profile of Live-Attenuated chikungunya Vaccine"

For VLA1553, VLA1555, VLA1556, a Lyophilized, Single-Dose, Live-Attenuated Chikungunya Virus Vaccine

VALNEVA Austria GmbH

(July 16th, 2024)

1. Project description

1.1. Introduction and background

Valneva's objective is to make the world's first chikungunya vaccine broadly available in both developed and developing countries, to prevent the impact this disease has on communities and individuals. Our candidate vaccine, a single-shot, live-attenuated vaccine candidate (VLA1553) aiming to provide long-lasting immunity with a single dose, is as of recently approved by the US FDA, and licensure reviews are ongoing in Europe, Canada and Brazil. Based on its live attenuated technology, and corroborated by all clinical data generated to date, VLA1553 is able to induce a fast, strong and long-lasting immune response that will translate into long-lasting protection from chikungunya disease after a single dose.

VLA1553 / brand name IXCHIQ has completed all necessary Phase 3 clinical studies to obtain FDA approval under the accelerated approval pathway in adults. It is Valneva's objective to improve and extend the future use of Valneva's chikungunya vaccine. Planned studies aim at generating evidence for:

1. Data to facilitate and improve the implementation of the vaccine: Such as, antibody persistence long-term safety, safety and immunogenicity in special populations (e.g. pregnant women, immunocompromised; Phase 3 studies), local registration studies as well as data to strengthen the case of effectiveness of the vaccine against chikungunya virus in endemic areas (Phase 4 studies).

2. Paediatric population – a vulnerable and therefore important target population for immunization, since in case of an outbreak they may lack immunity from previous outbreaks and the majority of use of the chikungunya vaccine in the paediatric population is expected to occur in LMIC countries (Dose finding Phase 2 and Phase 3 studies).

Since 2019, with support from CEPI and EU Horizon 2020, Valneva has developed the product with a two-pronged strategy that prioritizes both establishing a vaccine to protect travellers from high-income to endemic countries and immunizing people living in LMIC to reduce the burden of the disease. To provide a sustainable commercial basis and stable market for this vaccine despite the epidemic nature of chikungunya, Valneva has developed the vaccine for high-income traveller's markets like US and Europe. Simultaneously, to combat the huge burden from chikungunya afflicted on endemic regions, we have implemented a partnering strategy as foreseen under our 2019 CEPI grant and partnered with Instituto Butantan of Brazil for making the product available to Low- and Middle-Income Countries (LMICs).

The Butantan-Valneva partnership also enables significant development synergies, whereby data generated with Valneva's chikungunya vaccine VLA1553 will be supporting LMIC partners to achieve licensure. For example, Valneva's pivotal Phase 3 studies with VLA1553 in US adults, complemented by data generated in adolescents in Brazil with VLA1553 and enabled through

CEPI funding, have served as the basis for the ANVISA submission of IXCHIQ, and will continue to support future licensure submission of VLA1555 (which is locally produced after tech-transfer of VLA1553 lyophilisation and packaging to Instituto Butantan). Physical-chemical comparability between the products can be leveraged to ensure that data generated for either vaccine can be used from a regulatory perspective for the other vaccines. FDA has from a scientific perspective agreed to that concept, and also EMA has agreed to this concept. Therefore, any clinical data generated by Valneva for VLA1553 will support any regulatory submission in LMIC, and vice versa. In the case of the post marketing commitments under the accelerated approval, however, FDA has determined during its review process that from a legal perspective, these studies must be carried out with the same (regulatory-wise) product as the one registered under the accelerated approval. Therefore, the post marketing effectiveness studies will be carried out with VLA1553, which, to achieve that, has been submitted for licensure review in Brazil.

Approval of a vaccine without efficacy data is seen as the most important hurdle in LMIC countries. However, with the approval of the product by FDA and in the near future by Health Canada, EMA and ANVISA, it is expected to convince LMIC competent authorities to approve this product based on immunogenicity endpoints, and the support from CEPI is expected to support regulatory alignment across to the LMIC countries.

Valneva does not apply for the CEPI funding as a formal consortium. Instead, as with the last funding agreement, we are proposing to be the awardee and contractual counterpart to CEPI and extend obligations to our subcontractors. This setup has proven very efficient in the current collaboration with IB and will greatly reduce complexity in the future set-up.
In order for VLA and IB to focus their efforts and increase the likelihood of success, VLA and IB have agreed in principle for VLA to take back the India, Asian and Middle Eastern LMICs rights and supply to UNICEF from IB and to enter into a similar partnership as the VLA-IB one with Serum Institute of India (SII), including a DP TT and a clinical, regulatory and commercialization collaboration to make the product available in India, Asian and Middle Eastern LMICs. With the development of this additional CHIKV product, the following codes are used to distinguish between the different products:
•VLA1553: VLA's chikungunya vaccine candidate (IXCHIQ)
•VLA1555: Drug Product manufactured by IB following tech transfer from VLA
•VLA1556: Drug Product manufactured by SII following tech transfer from VLA

In order to make Valneva's, Butantan (IB)'s and Serum Institute of India (SII)'s chikungunya vaccines broadly accessible, all efforts will be made to continue submitting and registering the CHIKV products in HIC and LMIC countries. Health Canada and EMA applications were filed in May and October 2023, respectively, aiming to receive approval in the second half of 2024. For MHRA/UK approval, VLA will follow the reliance route from EMA. The strategy for Brazil submission recently changed; VLA1553 was submitted in December 2023, to comply with FDA's legal requirements to perform the Phase 4 studies with an identical product. This will get the

vaccine to the Brazil market earlier. ANVISA agreed that VLA1555 will be submitted under a separate license, planned in 2024. VLA1555 multidose is to be developed with plans to be submitted to ANVISA in 2026. VLA1556 will be submitted to India and Asian Key Countries by Serum Institute of India.

Valneva remains committed to the further development of its chikungunya vaccine and will continue to drive significant efforts to augment CEPI's effort to ensure broad implementation of a chikungunya vaccine in LMIC. Under the CHIKV CfP3.iii grant, Valneva will continue and expand its collaboration with Instituto Butantan, and Serum Institute of India.

1.2. Work package objectives

1.2.1 WP1- Clinical & effectiveness studies

- Conduct of trial VLA1553-303 to investigate long-term antibody persistence (for up to 10 yrs) following vaccination with VLA1553
    - Conduct of trial VLA1553-321 in Chikungunya endemic regions with Valneva DP to demonstrate safety and immunogenicity of VLA1553 in an adolescent population (12-17 yrs) and individuals previously exposed to ChikV.
    - Conduct of trial VLA1553-221 in Chikungunya endemic regions with Valneva DP to identify the optimal dose level of VLA1553 in a paediatric population aged 1-11 years based on safety and immunogenicity.
    - Conduct of trial VLA1553-322 in Chikungunya endemic regions with Valneva DP to establish safety and immunogenicity of VLA1553 in a paediatric population aged 1-11 years
    - Conduct an effectiveness study (VLA1553-402) in Brazil to estimate vaccine efficacy of VLA1553, Valneva DP/Ixchiq, in the prevention of symptomatic laboratory-confirmed CHIKV cases after a single vaccination with VLA1553 in Brazil; the pilot vaccine program, a prerequisite for running this effectiveness study, will be accompanied by a serosurvey and prospective safety cohort study.
    - Conduct a pregnancy surveillance study (VLA1553-403) as part of the pilot vaccination program in Brazil to monitor women who have inadvertently been vaccinated during pregnancy.
    - Conduct an effectiveness study (VLA1553-404) using Valneva DP/Ixchiq, a pragmatic randomised controlled trial to assess vaccine effectiveness in preventing symptomatic virologically-confirmed Chikungunya virus (CHIKV) disease among adults; in addition, safety of the vaccine will be monitored (chikungunya-like adverse reactions)

1.2.2 WP2- CMC & Technology Transfer activity

- Transfer of documentation and complete a risk assessment
- Lyo cycle successfully developed
- Transfer DP Lyo process to Indian Lyo manufacturer
- Successful PPQ campaign
- Analytical transfer of CHIK vaccines analytical method successfully completed
- Comparability report between VLA1553 and VLA1556 accepted by Indian Regulatory authorities

1.2.3 WP3 – Regulatory engagement and licensure (***Activity*** *not funded by CEPI, included for visibility/completeness and alignment with milestone & deliverable table as linked to Technical Reviews #1, #2 and #3 listed in following section)*

- IXCHIQ (VLA 1553) to be approved in Brazil (dossier submitted in Dec 2023)
- Butantan will, in collaboration with Valneva, apply for the Brazilian licensure of the Butantan Product (VLA1555) after completion of the Drug Product Technology Transfer and apply for and use reasonable endeavors to apply for WHO pre-qualification of the Butantan Product immediately following but no later than twelve (12) months after obtaining ANVISA Regulatory approval and use reasonable endeavors to obtain WHO pre-qualification of the Butantan Product
- SII will, in collaboration with Valneva, apply for the Indian licensure of the SII product (VLA1556)

1.2.4 – 1.2.5
WPS4 and WPS5 are not included in this grant.

1.2.6 WP6 – Project management

- Lead program management of the entire chikungunya program throughout the duration of the contract. This will include total project lifecycle management, comprising project planning, execution, monitoring, controlling, and closure
- Monitoring and maintaining the Scope of Work (SOW)
- Monitoring the program budget and timelines
- Coordinating project communications internally and with external project stakeholders
- Preparing of reports, and assist in satisfying the CEPI reporting requirements

1.3. Expected work package outcome (Milestones, Deliverables and Technical Reviews)

(WPS1: Clinical & effectiveness studies, WPS2: CMC & Tech Transfer activity and WPS3: Project Management)

Work Package	Milestones	Deliverable/s	Expected by
WP1 #1	[***]	[***]	[***]
WP1 #2	[***]	[***]	[***]
WP1 #3	[***]	[***]	[***]
WP1 #4	[***]	[***]	[***]
WP1 #5	[***]	[***]	[***]
WP1 #6	[***]	[***]	[***]
WP1 #7	[***]	[***]	[***]
WP1 #8	[***]	[***]	[***]
WP1 #9	[***]	[***]	[***]
WP1 #10	[***]	[***]	[***]
WP1 #11	[***]	[***]	[***]
WP1 #12	[***]	[***]	[***]

WP1 #13	[***]	[***]	[***]
WP1 #14	[***]	[***]	[***]
WP1 #15	[***]	[***]	[***]
WP1 #16	[***]	[***]	[***]
WP1 #17	[***]	[***]	[***]
WP1 #18	[***]	[***]	[***]
WP1 #19	[***]	[***]	[***]
WP1 #20	[***]	[***]	[***]
WP1 #21	[***]	[***]	[***]
WP1 #22	[***]	[***]	[***]
WP1 #23	[***]	[***]	[***]
WP1 #24	[***]	[***]	[***]
WP1 #25	[***]	[***]	[***]

WP1 #26	[***]	[***]	[***]
WP2 #1	[***]	[***]	[***]
WP2 #2	[***]	[***]	[***]
WP2 #3	[***]	[***]	[***]
WP2 #4	[***]	[***]	[***]
WP2 #5	[***]	[***]	[***]
WP2 #6	[***]	[***]	[***]
WP2 #7	[***]	[***]	[***]
WP2 #8	[***]	[***]	[***]
WP2 #9	[***]	[***]	[***]
WPS2 #10 (***Not funded by CEPI,*** *included for completeness)*	[***]	[***]	[***]

WPS3 activities not in scope of CHIKV CfP3.iii. Milestones and deliverables included for visibility/completeness			
WPS3 #1	[***]	[***]	[***]
WPS3 #2	[***]	[***]	[***]
WPS3 #3	[***]	[***]	[***]
Technical Review Criteria and Technical Review Points for CfP3.iii, with milestones and deliverables to be submitted for CEPI review – CEPI to be notified 2 months in advance of expected TR which is to take place within 3 months of the respective licensure			
Technical Review #1	[***]	**Technical Review** [***]	**Technical Review Point:** [***]
Technical Review #2	[***]	**Technical Review Criteria**: [***]	**Technical Review Point:** [***]
Technical Review #3	[***]	**Technical Review Criteria**: [***]	**Technical Review Point:** [***]

2. Target Product Profile

Vaccine Target Product Profile: VLA1553

Vaccine characteristic	**Expected**
Product	Live-attenuated chikungunya Vaccine (VLA1553,)
Indication for use	Active immunization for the prevention of disease caused by chikungunya virus in individuals aged 1 year and above. Initial approval: 18 yrs (US/EU/CAN) and 12 years (ANVISA)
Target population	Travelers (US EU CAN) / Outbreak use (US EU BRA) / Endemic areas (BRA)
Safety/Reactogenicity	Generally safe and well tolerated, comparable to other licensed Vaccines: Safety was already evaluated in 3,610 participants who received at least one dose of VLA1553 (3 clinical studies)
Protective efficacy	VLA1553 has shown to induce a fast, strong, and persistent immune response following a single-dose vaccination across all age groups evaluated in the clinical studies (individuals ≥18 years of age): - Seroresponse rate of 99% 28 days after a single dose, in adults and adolescents. - Persistence demonstrated with 97% seroresponse retained after 24 months
Dose regimen	Each approximately 0.5-mL dose contains not less than 3.0 log10 TCID50 (Tissue Culture Infectious Dose 50%) of live, attenuated chikungunya virus.
Duration of protection	Potentially lifelong protection, based on Live Attenuated Virus (LAV) Technology. Up to 10 years demonstrated in clinical trials.
Route of administration	Intramuscular administration
Product stability and storage	Shelf life: 24 months (at launch)
Presentation	Lyophilized requiring reconstitution; storage at +2 to 8°C
Cost of Goods / Cost per Dose	Confidential
Registration and prequalification	Registered in a broad range of countries, including HIC / travellers markets and Brazil

Vaccine Target Product Profile: VLA1555/1556

Vaccine characteristic	Expected
Product	Live-attenuated chikungunya Vaccine (VLA1555 and VLA1556)
Indication for use	Active immunization for the prevention of disease caused by chikungunya virus in individuals aged 1 year and above. Initial approval: 12 years and above
Target population	Outbreak use / Endemic areas
Safety/Reactogenicity	Generally safe and well tolerated, relying on the clinical data generated with VLA1553, see above, in addition to physico-chemical comparability data.
Protective efficacy	99% Seroresponse, relying on the clinical data generated with VLA1553, see above, in addition to physico-chemical comparability data.
Dose regimen	Each approximately 0.5-mL dose contains not less than 3.0 log10 TCID50 (Tissue Culture Infectious Dose 50%) of live, attenuated chikungunya virus.
Duration of protection	Potentially lifelong protection, based on Live Attenuated Virus (LAV) Technology. Up to 10 years demonstrated in studies, relying on the clinical data generated with VLA1553, see above, in addition to physicochemical comparability data.
Route of administration	Intramuscular administration
Product stability and storage	Shelf life: 24 months (at launch)
Presentation	Lyophilized requiring reconstitution; storage at +2 to 8°C
Cost of Goods / Cost per Dose	Confidential
Registration and prequalification	Registered in a broad range of LMICs with medical need, who pre-qualified, suitable presentation for use in NIP's (e.g., multi-dose, diluent in vial)

. Non-clinical strategy

WP	Non-clinical strategy
	The safety, immunogenicity and protective potency of the CHIKV vaccine candidate VLA1553 have been assessed in numerous non-clinical studies. The non-clinical development program has focused on the establishment of a small animal as well as non-human primate (NHP) model allowing for the evaluation of the CHIKV candidate vaccine with respect to safety and efficacy, i.e., immunogenicity and protection (*Hallengärd et al. 2014*). To this end, mouse models have been investigated and were shown to be permissive for infection with a wild-type (wt) CHIKV isolate, LR2006 OPY-1. Thus, infection of mice with wt CHIKV was shown to cause significant viremia, a major sign also in humans (*Couderc and Lecuit 2009*). In addition, NHPs serve as excellent animal models for understanding CHIKV pathogenesis as they are a natural amplification host for CHIKV and share significant genetic and physiological homology with humans. CHIKV infection in NHPs results in acute fever, rash, viremia and the production of CHIKV-specific neutralizing antibodies, type I interferon and pro- inflammatory cytokines. CHIKV establishes a persistent infection in NHPs, particularly in cynomolgus macaques (*Broeckel, Haese et al. 2015*). Valneva's preclinical data package generated with the CHIKV vaccine candidate demonstrates that a single dose of the CHIKV del5nsP3 vaccine/VLA1553: • is highly immunogenic and induces a strong and long-lasting neutralizing antibody response in a mouse and NHP model; • protects NHPs from a high-dose wt CHIKV challenge; • causes no clinical manifestations typically associated with wt CHIKV infections in the NHP model; • shows a delayed and strongly reduced viremia as compared to wt CHIKV infection in a mouse and NHP model; • shows strongly reduced cytokine production compared to wt CHIKV infection; • shows a more sporadic, transient and lower dissemination in tissues of VLA1553 immunized NHPs compared to wt CHIKV infected NHPs; • confirms the stability of the virus del5nsP3 attenuation in humans post vaccination; • is able to protect NHPs from CHIKV infection based on passive transfer of human immune sera to NHPs followed by wt CHIKV challenge and;

- shows a negligible risk of VLA1553 virus transmission from vaccinated to non-vaccinated humans by mosquitoes.

An overview of further non-clinical studies can be found in Table 2 below.

Table 2. Non-clinical Studies with VLA1553

Study	**Species**	**Summary**
Repeat-Dose Toxicity	Rabbits (New Zealand Whites)	Upon two high dose vaccinations at a two-week interval, all findings were transient and resolved within the 30 days recovery period; No adverse findings.
Persistence of infection and biodistribution	NHPs (Cynomolgus macaques)	• VLA1553 replication in blood was 3 logs lower than replication of wt CHIKV; • shedding of VLA1553 in saliva and vaginal fluids was much lower than wt CHIKV; • in cerebrospinal fluid, synovial fluid and urine, no shedding of VLA1553 nor wt CHIKV was detected; • VLA1553 dissemination in tissues, when detected, was more sporadic, transient and lower than observed for wild-type CHIKV; • VLA1553 was not detected in joints and muscles.
Mosquito Transmission Study	Mosquitos (Aedes albopictus)	Probability of mosquitoes transmitting VLA1553 virus from a human vaccinated with the vaccine appears to be very low (threshold titer of 3.875 log10 CCID50/mL).
Passive transfer in NHPs using human serum from VLA1553-101	NHPs (Cynomolgus macaques)	After vaccination with VLA1553 a neutralizing antibody titer of ≥50 determined by µPRNT50 is proposed as a titer reasonably likely to predict protection.

4. Clinical strategy

WP	Clinical strategy (Phase 3-4)
WP 1	Valneva's objective is to improve and extend the future use of Valneva's chikungunya vaccine. Planned studies aim at generating evidence to: **1.** Facilitate and improve the implementation of the vaccine: Such as, antibody persistence, long-term safety, safety and immunogenicity in special populations (e.g. pregnant women, immune- compromised); very importantly, data to demonstrate effectiveness of the vaccine against chikungunya virus in endemic areas, as well as – if necessary - local registration studies (e.g. India) • **VLA1553-303: Antibody persistence study:** [***] • **VLA1553-304: Trial in moderately immunocompromised HIV patients:** ***(Not in scope of CHIKV CfP3.iii, included for visibility/completeness)*** [***]

Three real-world evidence Phase 4 studies will include:

- **VLA1553-401, Post-Authorization Safety Study [PASS]:** ***(Not in scope of CHIKV CfP3.iii, included for visibility/completeness)***
  [***]

- **VLA1553-402, Effectiveness study:** [***]

- **VLA1553-403, Pregnancy study:**
  [***]
- **VLA1553-404, Effectiveness study 2:**
  [***]

2. Extend the licensure to the paediatric population – a vulnerable and therefore important target population for immunization, since in case of an outbreak they may lack immunity from previous outbreaks. Paediatric use of a chikungunya vaccine is primarily expected to occur in LMIC.

- **VLA1553-321, Adolescent study:**
  [***]

- **VLA1553-221, Dose-finding study:**
  [***]

- **VLA1553-322, Pediatric study:**
  [***]

VLA1553-222, Dose-finding study (<1y) / VLA1553-323 Pediatric study (<1y): ***(Not requested for CEPI funding, included for visibility/completeness)***

	Within each study arm subjects will be stratified 3:1, in two age subsets: - 6 months to 12 months of age (n=150); - <6 months (n=150).
	Clinical sample analysis: All testing of neutralizing antibody titer will be performed at Nexelis in the validated µPRNT in order to ensure comparability of results (this includes specimens from any studies performed by IB or SII). The WHO international standard (1502/19) for anti-chikungunya virus immunoglobulin G will be used to determine a correlation factor to allow conversion of results reported in $\mu PRNT_{50}$ into International Units. For the Phase 4 effectiveness studies, a serological method and a molecular diagnostic method using dried blood spots will be developed and validated with a local Brazilian lab that will serve as a central laboratory for those trials.

. Regulatory strategy

WP	Regulatory strategy
	• FDA/US: VLA1553 was awarded FDA Fast Track designation and FDA Breakthrough Therapy Designation. BLA submission was completed end of 2022 and reviewed under an accelerated review pathway with a Prescription Drug User Fee Act (PDUFA) action date at the end of November 2023. On Nov. 09th, the FDA approved VLA1553, IXCHIQ. • EMA/EU: EMA Priority Medicines (PRIME) designation was obtained in October 2020. MAA submission was performed in October 2023, with approval expected H2/2024. Based on the discussions with EMA, Valneva agrees to the OPEN procedure for the MAA. • ANVISA and WHO have agreed to participate in the OPEN procedure from EMA regarding review of the MAA dossier. VLA and IB would benefit from including ANVISA as it is a very public health focused agency and this way, they get more familiar with the vaccine. CHMP opinion is expected on May 30th, 2024, according to the timelines and assumptions on stop clocks. Based on the CHMP opinion in May, EC/EU approval will follow 2 months later. • Health Canada/Canada: Regulatory application has been filed end of May 2023. Dossier was validated on Aug. 25th 2023, which initiated the review process of 300 days. The Approval is expected end of June 2024. • MHRA/UK: The submission in UK will follow a reliance process: the International Recognition Process (IRP) with EMA as reference authority. VLA will submit the dossier after the positive CHMP opinion. Assuming no clock stops /questions, the approval is expected within 2024. • **Label Extension (VLA1553-321):** Label extension variation for use in adolescent population (above 12 yrs of age) will be submitted to NRAs that have approved VLA1553. o US FDA: Q4/2024 o EU: Q4/2024 o ANVISA: Q1/2025 (can be earlier if approval of VLA1553 is earlier than expected) o UK: Q1/2025 o CAN: Q4/2024 • LMICs: o Brazil: Due to legal requirements FDA requested in October 2023 to perform the phase 4 study (-402) with exactly the same product as the one approved in US (VLA1553 VLA and IB agreed to register VLA1553 in Brazil. As a next step, VLA1555 is also planned to be licensed in Brazil. ANVISA agreed that VLA1555 will be a separate license. VLA1553 was submitted in Dec 2023 (under Open procedure). The VLA1553 dossier is currently under review at ANVISA.

- Valneva & IB are currently working out strategies for approval of VLA1553 & VLA1555.
- VLA1555 multidose is to be developed with plans to be submitted to ANVISA later.
- After ANVISA approval of VLA1553, engagement will be sought rapidly with WHO to discuss VLA1555.Based on the current assumption, VLA1555 will be submitted for WHO PQ by Q2 2026. Earlier submission is also possible provided WHO is willing to accept the submission.
- The new territories split between IB and SII are as follows (amendments and agreements not yet signed):
  - IB Territory is to include all LatAm countries, China, Africa, plus PAHO and GAVI; and
  - SII Territory is to include India, Asia LMICs, Middle East LMICs, plus UNICEF.
- Valneva and IB finalized the re-negotiations of IB's territory, which was agreed to include all LatAm countries, including, for avoidance of doubt, LatAm HICs, China Africa, PAHO and GAVI.
- Meanwhile, Valneva and SII are negotiating a full deal like that of Valneva/IB wherein SII will be an exclusive licensee to VLA for the development, manufacturing (including a DP tech transfer), and commercialization of a Chikungunya vaccine in India, Asian and Middle Eastern LMICs, and UNICEF.
- The way GAVI, PAHO and UNICEF operate is currently being evaluated to decide on the best solution, especially in light of the new 2024 GAVI investment strategy.
- Latin America
  - Private market: Butantan to perform NRA submissions to different countries directly or via partners (selection of distributors is ongoing). Submission and approval timelines TBD.
  - Public market: Butantan to follow the regulatory processes in LatAm via WHO PQ + PAHO, which gains access to most countries. In case of WHO PQ absence, NRA submissions to different countries to be performed directly or via partners. Submission and approval timelines TBD.
- India/Asia
  - Local route to licensure will entail safety and immunogenicity evaluation in a clinical study with VLA1556. VLA and SII are of the opinion that comparability between the products will be acceptable to DCGI at a biophysical and biochemical level without any clinical comparison to VLA1553 (no immunobridging required between the two products, but only data to bridge immunogenicity and safety data from foreign to Indian population). Furthermore, since this is

based on the consideration that the DS will be identical for VLA1553 & VLA1556, therefore no immunobridging is expected to be required. SII expects to have first interactions with DCGI after preliminary data from tech transfer. Prior to the registration in India, which will need local clinical data, our partner SII will obtain to achieve an approval of VLA1556 for export use; based on the clinical dossier of VLA1553 and the local PPQ and physico-chemical comparability. This way, the vaccine could reach other markets that do not require local clinical data potentially before an approval in India. This regulatory strategy has been applied for other vaccines from SII in the past.

- NRA submission and review timelines for the rest of Asia TBD will be worked out with SII.
- Public market: Following WHO PQ, the Indian partner will supply any Asian LMIC public market.
- Our future partner SII will also push for 'Export Only' license for VLA1556 whereby the product can be exported out of India without product approval in India.

- Africa: IB to stockpile and supply outbreaks via WHO PQ and supranationals (GAVI, UNICEF). African private and public markets to be further assessed.
- Supranationals (PAHO/GAVI/UNICEF): interactions have started and will continue in parallel to the WHO PQ process, so that once WHO PQ is available, the product is considered eligible for all supranational procurement.

2. Pharmacovigilance strategy

The Corporate Pharmacovigilance Team at Valneva is responsible for managing all pharmacovigilance tasks and activities worldwide.

The Valneva's Corporate PV Team is located at Valneva Austria and is led by the Director Pharmacovigilance & QPPV. The Director Pharmacovigilance & QPPV reports directly to the Chief Medical Officer. The Corporate PV department is divided into two divisions – Global PV Strategy lead by the Director Pharmacovigilance & QPPV and in global PV Operations overseen by Head of Global PV Operations & Deputy QPPV.

As member of the Global PV Strategy team, the Director Pharmacovigilance & QPPV is involved in planning and set up of projects with other Valneva Departments and international partners. The global PV Operations team tasks include routine pharmacovigilance activities as well as the continuous development of the pharmacovigilance system.

With the help of international partners and specialized PV service providers, the Corporate Pharmacovigilance Team operates a state-of-the-art global pharmacovigilance system around the core PV activities, like collection, and management of safety data and the continues monitoring of the risks and benefits of Valneva's vaccines. For more than ten years now, Valneva has outsourced case management and processing of ICSRs into Valneva's global safety database to the PV service provider SCRATCH. The dedicated team at SCRATCH handles all case management activities as well as the medical assessment and submission of ICSRs to regulatory Authorities. Although the activities are outsourced, the Corporate PV Team has the full oversight about all cases handled by the SCRATCH team.
In addition to the global responsibilities, Valneva's Corporate PV team is responsible for local PV activities in Germany, Austria, the United Kingdom and the United States. In those countries the Corporate PV team is conducting all local PV activities like literature screening, regulatory intelligent screening and any communication related to safety topics with authorities.
Since some countries require a dedicated local PV person (who is also able to speak the local language) Valneva has teamed up with the service provider Propharma Group to be able to fulfil this local requirement. Propharma Group handles the local PV person (LPPV) network, including local literature search, local regulatory intelligent screening and supports with any communication to local authorities if necessary. In countries where no local PV representative is necessary or Propharma Group cannot cover the territory, Valneva's local partner covers basic PV tasks like safety information reporting, local literature screening and communication to local authorities on behalf of Valneva.
Although, Valneva's Corporate PV team conducts and oversees all audit activities of the PV system, Valneva works with PV auditors provided by Propharma Group to conduct PV system audits of partners.

Each partner who is considered part of Valneva's PV system has concluded a corresponding contract with the Corporate PV team for the tasks or services assumed.

Furthermore, Valneva's Corporate PV Team ensures that all safety relevant data received from any global source, is entered into Valneva's global safety database, and is processed in accordance with current legal requirements. All computerized systems used by the Corporate PV Team are validated and are regularly audited. Valneva utilizes an integrated Quality Management System (QMS) to facilitate, integrate and manage its quality processes and systems. The QMS facilitates the development, revision, review and approval of

controlled documents, subsequent training and any required archival of controlled documents. All procedural documents are reviewed, approved, and version controlled. Periodic review is performed at a minimum every 2 (two) years to ensure continued accuracy. All pharmacovigilance activities are covered in standard operating procedures (SOP) in the QMS and controlled by a dedicated QA team in terms of compliance with current quality standards. In addition to the core activities, the Corporate PV Team performs the qualification of new business partners, plans, and oversees the audits of the PV system of partners and service providers and conducts the yearly global pharmacovigilance training for all Valneva employees and external work force if applicable.

Furthermore, the performance of key PV activities (defined as KPIs) is monitored and reviewed by the Director Pharmacovigilance & QPPV on a quarterly basis.

The key aspiration of Valneva's Corporate PV Team is to operate an appropriate safety system, to enable Valneva to optimize the monitoring of the benefit-risk of its vaccines, so that we can better serve and safeguard our patients.

Signal and Risk Management procedures

Continuous monitoring of the risk benefit profile includes the following processes:

- Each ICSR or other safety information is assessed and fully processed by qualified personnel at the service provider; medical assessment is documented in the electronic case file
- For serious ICSRs, the respective CIOMS I form is forwarded from the service provider to Valneva Corporate PV Department (QPPV or delegate) for review and approval of the medical assessment before submission to the relevant competent authorities is performed by service provider according to respective timelines.
- Signal detection is performed on a regular basis, i.e., at least quarterly, or ad hoc. This includes comparison to the previous quarter and cumulative information.
- PSURs are prepared and reviewed according to regulatory requirements.
- Information from other sources, including but not limited to product technical complaints, QA investigations, regulatory information (e.g., from regulator websites), or publications is continually reviewed, and appropriate measures initiated, as needed.
- The Director Pharmacovigilance & QPPV is actively involved in the compilation / update of RMPs and approves the final version of the RMP. The Director Pharmacovigilance & QPPV is responsible for the monitoring of RMP commitments, as well as for monitoring the effectiveness of risk minimization measures, if applicable.

Routine signal detection is performed by the PV Operations team on a regular basis. The PV Operations team generates a list of ICSRs received from worldwide sources of the previous quarter from the global safety database, for analysis and evaluation.
Data are analyzed as follows:

- by absolute figures
- by rates, i.e., ICSR rate per 100.000 doses of Valneva product sold.

- by batch number where available
- the rates of the current quarter are compared to the previous quarter as well as to cumulative data.
- by country / region

For further evaluation, serious unexpected Adverse Drug Reactions (ADRs) are covered as narratives, including the company medical assessment. If any peculiar / unusual ICSRs have been received - irrespective if serious or non-serious - these are also discussed in the SD report.

To complete the report a signal evaluation and a risk evaluation of the new data is performed. The analysis includes the interval data as well as cumulative information available.

A conclusion and summary section are covered at the beginning of the SD Report for fast orientation of the members of the Quality & Product Safety Management Board (Q&PSMB) as Valneva's decision making body for quality and safety related matters, receive the SD reports for information.

In case a potential signal or risk is identified, the PV Operations team performs a preliminary signal evaluation. All information from routine signal detection and the preliminary signal evaluation are compiled and forwarded to the QPPV. The QPPV and the Chief Medical Officer, will assess the evidence for causality and perform an analysis. External experts or consultants may be involved in such evaluation. If this assessment verifies that there is sufficient evidence for the existence of a new potentially causal association, or a new aspect of a known association, the signal is considered validated, requiring further analysis.

Validated signals are escalated to the Q&PSMB as Valneva's decision making body for quality and safety related matters. For signals that may impact Public Health, an ad hoc Q&PSMB meeting is scheduled immediately, but no later than within 24 hours.

For other signals, an ad hoc Q&PSMB meeting is scheduled no later than within 3 business days. During the Q&PSMB meeting, the validation of a signal is confirmed. Depending on the potential impact on Public Health, the type of actions and the corresponding timelines are agreed.

3. Quality management strategy

Quality management strategy

The Global Valneva Quality Management System (QMS) defines the quality governance structure including roles and responsibilities.

Preclinical manufacturing:

Since the VLA1553 vaccine was designed by reverse genetics all relevant ICH guidelines (especially ICHQ5A-Q5E, ICHQ6A-Q6B, ICHQ7; ICHQ8, ICHQ9, ICH Q10 and ICH Q11) were considered in pharmaceutical development, subsequent technology transfer, GMP manufacturing and later commercial manufacturing.

For product development strategies outlined in the ICHQ8 guideline were considered. A design space for the proposed manufacturing process as well as for the lyophilisation development was established and critical process parameters were tested in comprehensive design of experiments studies, before transfer to a CMO.

The preclinical material for example was produced under GMP conditions using the same production scale, production method, production site and panel of QC test methods like the later GMP material for clinical Phase 1. Scientific advices from several Competent Authorities including FDA were considered in the final process design and for control of materials. The Vero cell bank derives from the commercial IXIARO production process and is fully characterized and approved. The viral seed banks were fully characterized using the ICHQ5 guideline series. Process and formulation development was followed using the ICHQ11 guidelines. The process robustness and high product quality was confirmed meanwhile by running the process at different sites and scales under PD and GMP conditions. The CEPI/Wellcome NC3Rs was provided for guidance and considered by Valneva.

GMP manufacturing:

The well designed and robust manufacturing process is complemented by a control and risk management strategy, embedded into a GMP compliant pharmaceutical quality system according to ICH Q7, ICHQ9 and ICHQ10, respectively. Suitable analytical test methods, in-process controls and product specifications are established to control each stage of the product (please refer to Figure 8 & 9). All involved sites for GMP production have implemented a Pharmaceutical Quality System according to ICH Q7, ICH Q10, current EU and US GMP regulations. The GMP manufacturing and testing sites have appropriate GMP licenses, are regularly inspected by EU GMP Authorities and successfully passed FDA inspections. According to the EU GMP legislation each batch of VLA1553 Drug Substance and VLA1553 Drug Product for clinical or commercial supply have to be released by a registered Qualified Person having the appropriate product knowledge, quality oversight, experience and education. Qualified Persons are fulfilling these requirements at Valneva Austria GmbH.

Finally, a manufacturing strategy was chosen to develop a scalable, efficient, high yield process of excellent product quality and robustness.

Clinical conduct:

Valneva performs its clinical studies in compliance with ICH and its applicable regulation. Adherence of the involved parties is being assured applying different measures:

a) Vendors (e.g., CRO, Central lab) selected for Valneva's project have to undergo a formal vendor selection and qualification process which routinely includes a system audit; if an already qualified vendor is contracted for study conduct, the vendor still has to undergo routine audits according to time intervals defined in Valneva's standard operating procedure (SOP).

a) Study sites qualification for study participation is reviewed and evaluated: prior to study site selection, site qualification visits are performed to understand the site's previous experience in performing (vaccine) clinical studies, their knowledge of GCP and applicable regulation, their resources (in terms of staff as well as equipment); if necessary, specific training is performed early on prior to study execution in order to assure compliance. During study conduct, on top of routine monitoring visits, Valneva selects sites for the performance of study site audits in line with Valneva's respective SOP.

b) As per ICH-E6 requirement, risk-based quality management is applied. A risk management plan and risk log is developed for each study to allow timely identification of risks, to identify appropriate risk mitigation measures and to track risks, changes thereof as well as effectiveness of defined measures.

c) Analysis of clinical samples is performed in GCLP certified laboratories following Standard Operating Procedures. Assay validation is done according to ICH Q2 (R1) guidelines.

4. Management

Valneva operates according to the most stringent compliance rules, including all applicable GxP requirements, business compliance requirements, corporate social responsibility, and environmental sustainability rules, and is a participant of the United Nations Global Compact. Based on this fundament of expertise Valneva plans to drive the project via the below mentioned key employees supporting the project with existing staff. In addition, we will be

expanding the team bringing on board a highly experienced individual to steer the efforts on the post-marketing studies, expected to on-board in January 2024.

A. Project governance

Refer to Team charter for governance arrangements and meeting cadence

Valneva´s project management will lead program management of the entire chikungunya program throughout the duration of the contract. This will include total project lifecycle management, comprising project planning, execution, monitoring, controlling, and closure. Project management will monitor and maintain the Scope of Work (SOW), monitor the program budget and timeline, coordinate project communications internally and with external project stakeholders, prepare reports, and assist in satisfying the CEPI reporting requirements.
Governance bodies with Butantan have been set-up in order to oversee the new Technical Development activities, the Butantan Development plan, the interactions with ANVISA and WHO-PQ as well as the clinical activities in Brazil. The governance bodies encompass:

- A Joint Steering Committee to oversee the development of the BUTANTAN Product based on the BUTANTAN Development Plan
- A Development Committee to (i) approve updates and changes to the BUTANTAN Development Plan; (ii) supervise the activities of the Development Team and the development of the VLA1555 Vaccine Candidate; (iii) resolve issues referred by members of the Development Team; (iv) make strategic

decisions related to the BUTANTAN Development Plan; (v) review the progress of the BUTANTAN Development Plan and any related activities; (vi) approve budgets associated with the BUTANTAN Development Plan; (vii) otherwise oversee the BUTANTAN Development Plan, and (vii) monitor the LatAm Studies.

- The former Tech Transfer Committee evolved into the Technical Development committee to oversee the next development activities for VLA1555. This committee and the activities associated are led by Butantan with the support of VLA if needed.

A Joint Steering Committee, Development Committee and Tech Transfer Committee will also be set up with Serum Institute of India.

B. Valneva's management team

[***]

This dedicated Valneva team is representing a vast range of capabilities and expertise in state-of-the- art vaccine development from bench to global licensure. It will be supported by all functions at Valneva, which are needed to successfully conduct the proposed Project, leveraging the company´s unique and proven development experience.

i. **. Planning**

1. Annex A: Work Breakdown Structure.

ii. Annex B: RASCI chart:

R- Responsible
A- Approve
S-Support
C-Consulted
I-Informed

iii. Annex C: High level Gantt chart with stage gate decisions for the work packages described above.

iv. Annex D: Detailed Gantt chart, with milestones.

v. Annex E: Risk Table.

Appendix A

Work Breakdown Structure for activities under current funding application

[***]

Appendix B

The outlined RASCI Chart reflects the Valneva project team environment responsible for execution of the project. Valneva internal approvals will be done by the outlined committees:

The Research & Development Operational Committee (RDOC) oversees and steers VLA´s global research & development programs within agreed strategies and budgets ensuring most appropriate, cross-functionally aligned scientific, medical and technical execution of R&D activities, including the company´s innovation agendas

The Operations Committee (OpsCo) oversees and steers VLA's global industrial operations including manufacturing, supply, quality & regulatory compliance, EH&S and facilities (global), ensuring most appropriate manufacturing & site operations and product supply to demand & quality to internal and external customers.

The Management Board (MB) beside its responsibility for overall corporate and financial strategy and its reporting obligations to the Supervisory Board will focus on the legal representation of the company under the relevant jurisdictions. Further key aspects covered by the MB will be organizational structure, top management and governance development, corporate development, business compliance, investor relations and communications. Functional representatives will also be invited as needed for relevant topics.

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