

SUBJECT TO CONTRACT

DRAFT:

DATE:

DATED

2017

**FRAMEWORK PARTNERING
AGREEMENT**

BETWEEN

FUNDER

AND

(2) [PARTNER]

[Project Lead Surname]/[Project Title]

Award Ref: [XX]

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THIS AGREEMENT is made the day of 2017,

BETWEEN:

1. **FUNDER**, a not-for-profit international association existing under _____ law with address at -----(**"FUNDER"**); and
2. **[Partner LEGAL NAME]**, **[partner structural details including any registration number and registered address]** (the **"Partner"**).

WHEREAS:

- A. FUNDER is a public-private not-for-profit organization including civil and philanthropic organisations formed to:
 - i. fund, co-fund, co-ordinate and support the development of new vaccines with chosen partners to prevent and contain infectious disease epidemics;
 - ii. work with its partners and relevant agencies to ensure the vaccines developed are provided to all populations who need them on an equitable basis;
 - iii. work with its partners and relevant agencies to ensure adequate stockpiles and manufacturing capacity of vaccines developed for epidemic situations;((i), (ii) and (iii) together, the **"FUNDER Mission"**).
- B. The Parties recognize that vaccines can play a critical role in containing epidemics to help avert humanitarian crises and that: (i) the risks and costs of vaccine development are especially great for epidemic diseases affecting poorer countries, countries that have fragile health systems and countries with vulnerable populations; (ii) clinical trials of such vaccines are particularly complex to conduct; (iii) vaccines designed for epidemic diseases typically have limited market potential; and (iv) vaccine delivery is often delayed due to complex regulatory frameworks.
- C. The Partner has applied to FUNDER for funding to undertake **"[insert Project title]"** led by **[Project Lead Name]** of **[the Partner]** (the **"Project"**). FUNDER wishes to fund the Project as optional phases of work to further the FUNDER Mission. The

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anticipated work phases are: [Pre-clinical Work Phase, First in Man, Phase I Work Phase, Phase II Work Phase, Pivotal Trial Work Phase and Stockpiling Work Phase].

- D. This Agreement sets out the terms and conditions: (i) under which the Partner will carry out each proposed Work Phase of the Project, (ii) under which FUNDER will fund and support the Partner in carrying out each optional Work Phase of the Project and (iii) which set out how the results of each Work Phase of the Project will be used to further the FUNDER Mission .

IT IS AGREED as follows:

1. DEFINITIONS AND INTERPRETATION

1.1. In this Agreement:

- 1.1.1. “**Affiliate**” means any corporation or other business entity Controlled by, Controlling or under common Control with the relevant Party;
- 1.1.2. “**Affected Territory**” means the geographic area of any country (i) where there is an Outbreak or (ii) for which there is an Increased Outbreak Preparation Need or (iii) the Parties otherwise agree in writing and in each case, including healthcare workers providing healthcare in such a country regardless of their home country;
- 1.1.3. “**Agreement**” means this agreement including any Schedules attached hereto and any Work Phase Statements;
- 1.1.4. “**Application**” means the Partner’s application to FUNDER as attached at Schedule 3;
- 1.1.5. “**Approved Regulatory Authority**” means the EU European Medicines Agency, the US Food and Drug Administration, SwissMedic, Japanese PMDA, Australian Therapeutic Goods Agency, South Korean Ministry of Drug Safety, Health Canada or Singapore Health Sciences Authority and in each case any successor authority;
- 1.1.6. “**Background Intellectual Property**” means any Intellectual Property owned or controlled by the Partner at the Effective Date or which the Partner develops or acquires independently of the work under the Project, in each

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case which is necessary or useful for undertaking any Work Phase, or the protection or exploitation of Foreground Intellectual Property. Background Intellectual Property in existence , at the Effective Date is described in Schedule 4; **[Note: Partner to please provide draft Schedule 4]**

- 1.1.7. **“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, or England and Wales;
- 1.1.8. **“FUNDER Funding”** means the funding provided by FUNDER to the Partner pursuant to this Agreement and any Work Phase Statements;
- 1.1.9. **“FUNDER Group”** means FUNDER, its Affiliates, and the FUNDER Nodes;
- 1.1.10. **“FUNDER Mission”** has the meaning given to it in Recital A;
- 1.1.11. **“FUNDER Nodes”** means:
- i. the node of FUNDER established in Norway (being the contracting Party to this Agreement);
 - ii. the node of FUNDER established in London which is hosted by Wellcome and is a subsidiary undertaking of FUNDER **([FUNDER UK, [number]])** and which is a FUNDER Affiliate;
 - iii. the node of FUNDER established in India which is hosted by the Translational Health Science and Technology Institute of NCR Biotech Science Cluster 3rd Milestone, Faridabad – Gurgaon Expressway, PO box #04, Faridabad – 121001 (HARYANA), India; and
 - iv. any other FUNDER nodes which may be established from time to time.
- 1.1.12. **“FUNDER Policies”** means the FUNDER policies made available on FUNDER’s website (as amended from time to time);
- 1.1.13. **“FUNDER Policy on Site Access”** has the meaning given to it in Clause 3.1.2ii;
- 1.1.14. **“Clinical Trial”** means any clinical trial(s) carried out as part of the Project including in the Phase I Work Phase and the Phase II Work Phase, to be carried out by the Partner;

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- 1.1.15. **“Clinical Trial Cover”** means a clinical trial liability insurance policy which will cover the relevant Clinical Trial;
- 1.1.16. **“Conditions Precedent”** shall have the meaning given to it in Clause 9.1, where each sub-clause of Clause 9.1 is a “Condition Precedent” and together, these are the “Conditions Precedent”;
- 1.1.17. **“Confidential Information”** means any and all non-public data, results, Know-How, software (including non-open source code), plans, details of research work, discoveries, inventions, intended publications, intended or pending patent applications, designs, technical information, business plans, budgets and strategies, business or financial information or other information in any medium and in any form, and any physical items, prototypes, compounds, samples, components, non-public Regulatory Filings or other articles or Materials 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;
- 1.1.18. **“Control”, “Controlled” and “Controlling”** shall mean: (i) direct or indirect beneficial ownership of fifty percent (50%) or more of the voting interest in an entity or (ii) possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of that entity (whether through ownership of securities or other ownership interests, by contract or otherwise);
- 1.1.19. **“Cost of Goods”** means the formula for calculating the cost of goods set by the Gates Foundation attached at Schedule 6 but excluding all FUNDER Funding for and work included in the Work Phases;
- 1.1.20. **“Data”** means any and all scientific, technical or test data pertaining to Product that is generated by or on behalf of the Partner in the course of performance of studies or activities contemplated in any Work Phase, the Development Plan or this Agreement including Know-How, research data, clinical pharmacology data, CMC data (including analytical and quality control data and stability data), pre-clinical data, clinical data, information concerning clinical trials, pharmacoeconomic data, and also including any

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and all such data in publications, presentations or submissions made in association with a Regulatory Filing with respect to Product;

- 1.1.21. **“Defaulting Party”** shall have the meaning set out at Clause 15.2;
- 1.1.22. **“Develop”** or **“Development”** means, with respect to a Product, those pre-clinical and clinical vaccine development activities that are necessary or useful to obtain Marketing Approval, from at least one Approved Regulatory Authority and in applicable regulatory jurisdictions including stability testing, toxicology, formulation and process development, CMC development, manufacturing process validation, statistical analysis, pre-clinical and clinical studies, regulatory filing submissions and approval, pharmacovigilance and post-marketing commitments;
- 1.1.23. **“Development Plan”** means the written plan setting out the studies and other activities to be performed by the Parties with respect to the Development of a Product, established by the Partner with input from the FUNDER Group and as reviewed and approved by the JMAG, and as may be amended from time to time;
- 1.1.24. **“Disclosure Letter”** means a letter from the Partner to FUNDER and accepted by FUNDER setting out fair and accurate disclosures by the Partner against the warranties in Clause 14 of this Agreement;
- 1.1.25. **“Documents”** means reports, research notes, charts, graphs, comments, computations, analyses, recordings, photographs, paper, notebooks, books, files, ledgers, records, tapes, discs, diskettes, CD-ROMs, computer programs and documents thereof, computer information storage means, samples of material, other graphic or written data and any other media on which Know-How can be permanently stored;
- 1.1.26. **“DSMB”** means the data safety monitoring board for the Clinical Trial;
- 1.1.27. **“Effective Date”** means the date set out at the top of page 1 of this Agreement;
- 1.1.28. **“Escrow Materials”** means Confidential Information, Data, Materials and Regulatory Filings that is retained by an escrow agent in accordance with Clause 9.4;

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- 1.1.29. **“Ethical Committee”** means a group formally designated to protect the rights, safety and well-being of humans involved in a clinical trial by reviewing all aspects of the trial and approving its start-up. These groups are also known as Institutional Review Boards or independent ethics committees (IECs). Ethical Committees review the appropriateness of the clinical trial protocol as well as the risks and benefits to study participants. It ensures that clinical trial participants are exposed to minimal risks in relation to any benefits that might result from the research;
- 1.1.30. **“Existing Data”** means with respect to a Product, those pre-clinical and clinical vaccine development activities that are necessary or useful to obtain Marketing Approval, from at least one Approved Regulatory Authority and in applicable regulatory jurisdictions including stability testing, toxicology, formulation and process development, CMC development, manufacturing process validation, statistical analysis, pre-clinical and clinical studies, regulatory filing submissions and approval, pharmacovigilance and post-marketing commitments and that exist as at the Effective Date;
- 1.1.31. **“Field”** means [disease area];
- 1.1.32. **“Financial Documents”** means (i) the Financial Summary and Reporting Form, (ii) the most recent audited financial statement of the Partner, auditor’s report for such financial statement and management letter to the auditors for such financial statement, (iii) the Partner’s current treasury policy and (iv) an outline of the Partner’s risk management strategy for currency fluctuations;
- 1.1.33. **“Financial Summary and Reporting Form”** means a report by the Partner to FUNDER in the prescribed form providing up-to-date details of Work Phase costs;
- 1.1.34. **“Final Financial Summary and Reports”** means a report by the Partner to FUNDER in the prescribed form providing details of Work Phase costs, any underspend and an up-to-date calculation of the Partner Contribution;
- 1.1.35. **“Foreground Intellectual Property”** means any Intellectual Property (including the Project Patents and Project Inventions) arising out of the undertaking and performance of any Work Phase of the Project;

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- 1.1.36. **“Gates”** means the Bill & Melinda Gates Foundation of P.O. Box 23350, Seattle WA 98102, USA;
- 1.1.37. **“GCP”** means Good Clinical Practice as defined by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and further set forth in ICH Guideline E6-(R2), adopted by CHMP 15 December 2016, issued as EMA/CHMP/ICH/135/1995, as amended, or analogous standards utilised by the relevant Approved Regulatory Authority,
- 1.1.38. **“GHSI”** means the Global Health Security Initiative, an informal, international partnership among like-minded countries to strengthen health preparedness and response globally to threats of biological, chemical, radio-nuclear terrorism (CBRN) and pandemic influenza;
- 1.1.39. **“GLP”** means Good Laboratory Practice, as defined by Guidelines on the website of the Organisation for Economic Cooperation and Development (OECD) and European directives 2004/9/EC and 2004/10/EC as amended, or analogous standards utilised by the relevant Approved Regulatory Authority,
- 1.1.40. **“GMP”** means Good Manufacturing Practice as set forth in the ICH Good Manufacturing Guide for Active Pharmaceutical Ingredients Guideline Q7, as adopted by CPMP November 2000 as CPMP/ICH/4106/00, as amended or analogous standards utilised by the relevant Approved Regulatory Authority;
- 1.1.41. **“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 in the Field, FUNDER determines, in its sole discretion, that there is a heightened need for the Product;
- 1.1.42. **“Intellectual Property”** means, whether or not registered:
- i. patents, designs, trademarks and trade names , copyright and related rights, database rights and Know-How;
 - ii. all other intellectual property rights and similar or equivalent rights anywhere in the world which currently exist or are recognised in the future; and

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iii. applications, extensions and renewals in relation to any such rights;

- 1.1.43. **“Investigational Stockpile”** means a quantity of doses of the Product adequate for the planned Clinical Trials in the Development Plan or as described in a Work Phase Statement which is manufactured and stored according to GMP, where the Product has been approved for use in clinical trials in humans, which has not received Marketing Approval;
- 1.1.44. **“Joint Monitoring and Advisory Group”** or **“JMAG”** means the group constituted in accordance with Clause 5.3 for the purposes of monitoring and advising on any Work Phase of the Project, and the Development and Marketing Activities relating to any Product;
- 1.1.45. **“Know-How”** means any technical and other information used in the Project which is not in the public domain, including information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, assays, research plans, procedures, designs for experiments and tests and results of experimentation and testing (including results of research or development), processes (including manufacturing processes, specifications, and techniques), laboratory records, chemical, pharmacological, toxicological, clinical, analytical and quality control data, trial data, case report forms, data analyses, reports, manufacturing data or summaries and information contained in submissions to and information from ethical committees and Regulatory Authorities (including the Master File) and computer programs or algorithms including those relating to manufacturing and source code for manufacturing processes. Know-How includes Documents containing Know-How, including any rights such as trade secrets, copyright, database or design rights protecting such Know-How. The fact that an item is known to the public shall not be taken to preclude the possibility that a compilation including the item, or a development relating to the item, is not known to the public;
- 1.1.46. **“Licences”** shall have the meaning given to it in Clause 9.3;
- 1.1.47. **“Manufacturing”** or **“Manufacture”** means the production, subject to GMP, of Product or constituents thereof, including active ingredients, excipients, adjuvants, preservatives or other additives, for use in Clinical Trials or

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finished dosage form of the Product as well as the fill and finish or packaging thereof;

- 1.1.48. **“Market”** means, in relation to a Product, importing, exporting, marketing, selling, promoting, distributing or otherwise utilising or commercially exploiting the Product or licensing the right to do so or offering to do the any of the foregoing as well as any variations, licenses, or post-marketing obligations pursuant thereto;
- 1.1.49. **“Marketing Activities”** means, with respect to a Product, to promote, market, distribute, offer for sale, sell, import, utilise or otherwise exploit (for a profit or otherwise) and provide product support for such Product;
- 1.1.50. **“Marketing Activities Plan”** shall have the meaning given to it in Clause 8.1;
- 1.1.51. **“Marketing Approval”** : means a marketing authorisation granted by the European Commission in accordance with the procedure for the authorisation and supervision of medicinal products for human use set forth in Regulation (EC) No. 726/2004, or any Approved Regulatory Authority and any corresponding Regulatory Approval necessary to manufacture, use , sell or store a Product in any other country or jurisdiction, but not including pricing and reimbursement approvals.
- 1.1.52. **“Master File”** means all drug master files relating to Product in the Field that may be filed with any Regulatory Authority in any country in the Affected Territory or with an Approved Regulatory Authority;
- 1.1.53. **“Material”** means any chemical or biological substance used in or created, devised or generated during the Project including any:
- i. organic or inorganic element;
 - ii. nucleotide or nucleotide sequence including DNA and RNA sequences;
 - iii. gene;
 - iv. vector or construct including plasmids, phages or viruses;
 - v. host organism including bacteria, fungi, algae, protozoa and hybridomas;

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- vi. eukaryotic or prokaryotic cell line or expression system or any development strain or product of that cell line or expression system;
- vii. protein including any peptide or amino acid sequence, enzyme, antibody or protein conferring targeting properties and any fragment of a protein or a peptide enzyme or antibody;
- viii. drug or pro-drug including bulk drug substance, filled product and any manufacturing intermediates;
- ix. assay or reagent;
- x. any other genetic or biological material or micro-organism;
- xi. transgenic animals; and
- xii. clinical samples.

1.1.54. **“Members”** shall have the meaning set out at Clause 5.5;

1.1.55. **“Milestones”** means for each Work Phase, the milestones which the Partner must achieve to FUNDER’s reasonable satisfaction by the relevant Milestone Dates in order for FUNDER to release further tranches of the Work Phase Budget; the Milestones for each Work Phase will be described in the relevant Work Phase Statement;

1.1.56. **“Milestone Date”** means a date set out in the relevant Work Phase Statement for the achievement of a Milestone;

1.1.57. **“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 national governments and in each case for a material increase in the number of cases of people infected in the Field including any regional outbreak, an epidemic or a pandemic;

1.1.58. **“Outbreak Preparation Activities”** has the meaning given to in Clause 3.2.1;

1.1.59. **“Outbreak Response Activities”** include:

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- i. the collection and sharing of trial subject information in accordance with FUNDER Policies, including information about pathogens such as sequence data;
 - ii. engagement with affected communities to establish mutual trust;
 - iii. integration of Partner research efforts into Public Sector Agencies' epidemic response;
 - iv. manufacture of additional investigational doses of Product (if necessary) or manufacture to replenish Investigational Stockpile;
 - v. negotiation of clinical trial contracts;
 - vi. performance of independent ethics reviews; and
 - vii. implementation of prepared clinical trial designs;
- 1.1.60. **"Outbreak System Activities"** has the meaning given to it in Clause 3.1.2;
- 1.1.61. **"Parties"** means the parties to this Agreement and **"Party"** shall be interpreted accordingly;
- 1.1.62. **"Partner Contribution"** means the financial and in-kind contributions to be made by the Partner to any Work Phase as set out in Schedule 2 and individual Work Phase Statements, but excluding any of the Partner's sunk costs as at the Effective Date in any platform or product technology used for the Product as at the Effective Date;
- 1.1.63. **"Pivotal Trial"** means a pivotal human clinical trial in any country the results of which could be used or is intended to be used to establish safety and efficacy of a Product sufficient to provide the basis for an application for a Marketing Approval submitted to the European Medicines Agency, or any successor authority, or other Approved Regulatory Authority;
- 1.1.64. **"Product"** means any form or dosage of pharmaceutical composition or preparation for use in humans which is intended to prevent or treat disease in the Field and which incorporates, comprises or relies on either the Background Intellectual Property or the Foreground Intellectual Property;
- 1.1.65. **"Project Lead"** means [individual's name] of the Partner;

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- 1.1.66. **“Project”** means the activities that the Partner will undertake pursuant to the terms of this Agreement, entitled “[Project title]” (as more particularly detailed in the Application and each Work Phase Statement);
- 1.1.67. **“Project Inventions”** means any discovery, development, Know How, invention or improvement created, devised or arising out of the undertaking and performance of any Work Phase;
- 1.1.68. **“Project Patents”** means any patent applications made which claim any Project Inventions, any patents resulting from any such applications, utility certificates, improvement patents and models and certificates of addition and all foreign counterparts of them in all countries, including any divisional applications and divisional patents, refiling, renewals, continuations, continuations-in-part, patents of addition, extensions (including patent term extensions), reissues, substitutions, confirmations, registrations, re-validations, pipeline and administrative protections and additions, and any equivalents of the foregoing in any and all countries of or to any of them, as well as any supplementary protection certificates and equivalent protection rights in respect of any of them;
- 1.1.69. **“Public Sector Agency”** means a public government or a government department or agency or a recognised not-for-profit organisation or entity, such as registered charities or registered faith-based organisations including:
- i. government or department or agency thereof, including ministries of health;
 - ii. intergovernmental organisations such as the United Nations, its specialised agencies including the WHO and its programmes or funds such as the United Nations Children’s Fund;
 - iii. non-profit organisations or entities organised under the laws of a government or department or agency thereof, such as Medecins Sans Frontieres and faith-based organisations; and
 - iv. non-profit organisations or foundations that are funded by governments or other non-profit organisations such as the World Bank, UNITAID or the US Agency for International Development or the GAVI Alliance, but

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specifically excluding hospitals and clinics who wish to purchase the Product directly for their own use.

The term “Public Sector Agency” excludes any military organisations except for: (a) any military organisation operating in the area affected or likely to be affected by the Outbreak or Increased Outbreak Preparation Need at the date the Affected Territory is declared; and (b) any military personnel providing healthcare or healthcare related services to the population affected by or at risk of the Outbreak or Increased Outbreak Preparation Need;

- 1.1.70. “**PubMed Central**” means an archive of life science journal literature operated by the National Center for Biotechnology Information, a division of the US National Library of Medicine accessible at <http://www.pubmedcentral.nih.gov/>;
- 1.1.71. “**Quarterly Report**” means a written report to the JMAG and FUNDER outlining Work Phase progress, key risks and risk mitigation strategies and up to date financial details relating to the Project in a form specified by FUNDER;
- 1.1.72. “**Regulatory Authority**” means any governmental authority whose review or approval is necessary for the Development and/or Marketing Activities of the Product in a given country in the Affected Territory or under Clause 4;
- 1.1.73. “**Regulatory Filing**” means all approvals, licenses, registrations, variations applications, submissions and authorisations made to or received from a Regulatory Authority necessary for the Development and Marketing Activities of the Product including INDs, Marketing Approvals and the Master File;
- 1.1.74. “**Reasonable Efforts**” means:
- i. with respect to the Partner, making no less effort and committing no less resources than those commonly used by the Partner or, if greater, a company of similar size and with similar resources to the Partner and its Affiliates in the vaccine industry when applied to compounds, vaccines and products at a similar stage of development, life cycle and healthcare potential to the Product being developed, taking into account (a) all

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relevant factors including issues of safety and efficacy, product profile, difficulty in developing or manufacturing the applicable product or sourcing raw materials necessary therefor, regulatory approvals, the patent or other proprietary position of the applicable Product and the regulatory requirements involved; and (b) the Parties' joint aim of developing the Product in a diligent and timely manner as indicated by the Milestones and Milestone Dates for the FUNDER Mission;

- ii. with respect to the FUNDER Group, the use of reasonable efforts and resources, in good faith, in the exercise of prudent legal, medical, scientific judgement (as applicable) considering the FUNDER Mission and the healthcare potential of the applicable Product;

- 1.1.75. "**Retained Amount**" means ten percent (10%) of the Total Work Phase Budget being the amount of the Total Work Phase Budget which is retained by FUNDER until all the conditions set out at Clause 3.10 have been met;
- 1.1.76. "**Secondary Manufacturer**" means a manufacturer capable of Manufacturing the Product and regulated by and meeting the standards of either (i) an Approved Regulatory Authority or (ii) another Regulatory Authority acceptable to FUNDER in its sole discretion;
- 1.1.77. "**Site Visit Group**" means the group constituted in accordance with Clause 7;
- 1.1.78. "**Terminating Party**" shall have the meaning set out at Clause 15.2;
- 1.1.79. "Third Party Claims" has the meaning given to it in Clause 14.6;
- 1.1.80. "**Total Work Phase Budget**" means the aggregate of all Work Phase Budgets agreed under Clause 3.5;
- 1.1.81. "**TSC**" means the trial steering committee for the Clinical Trial;
- 1.1.82. "**USD**" means US Dollars;
- 1.1.83. "**Wellcome**" means The Wellcome Trust Limited as trustee of the Wellcome Trust of 215 Euston Road, London NW1 2BE;
- 1.1.84. "**WHO**" means the World Health Organization; and
- 1.1.85. "**Work Phase**" means a defined stage of Development of the Product;

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- 1.1.86. **“Work Phase Budget”** means the maximum amount of funding to be provided by FUNDER to the Partner for the relevant Work Phase, as set out in the Work Phase Statement; and
- 1.1.87. **“Work Phase Statement”** means the final statement of activities, timeline, Partner contribution, milestones and budget for the relevant Work Phase agreed pursuant to Clause 3.5 using the template at Schedule 1 and in the case of the Pre-Clinical Work Phase, attached at Schedule 5.
- 1.2. References in this Agreement to any statutory provisions shall be construed as references to those provisions as respectively amended consolidated or re-enacted (whether before or after the Effective Date) from time to time and shall include any provisions of which they are consolidations or re-enactments (whether with or without amendment).
- 1.3. Reference to any statute, statutory instrument, regulation, by law or other requirement of English law and to any English legal term for any actions, remedy, method of judicial proceeding, legal document, legal status, court, official or any legal concept or doctrine shall, in respect of any jurisdiction other than England, be deemed to include that which most nearly approximates in that jurisdiction to the relevant English term.
- 1.4. The Schedules and Recitals form part of this Agreement and any reference to this Agreement shall include the Schedules and Recitals.
- 1.5. In this Agreement:
- 1.5.1. the masculine gender shall include the feminine and neuter and the singular number shall include the plural and vice versa;
- 1.5.2. references to persons shall include bodies corporate, unincorporated associations, partnerships and individuals;
- 1.5.3. except where the contrary is stated, any reference in this Agreement to a Clause or Schedule is to a Clause of or Schedule to this Agreement, and any reference within a Clause or Schedule to a sub-Clause, paragraph or other sub-division is a reference to such sub-Clause, paragraph or other sub-division so numbered or lettered in that Clause or Schedule; and

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- 1.5.4. the headings are inserted for convenience only and shall not affect the construction of the provision to which they relate.
- 1.6. Any reference to books, records or other information includes books, records or other information in any format or medium including paper, electronically stored data, video or audio recordings and microfilm.
- 1.7. Any phrase introduced by the terms “including”, “include”, “in particular” or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms.
- 1.8. Where reference is made in this Agreement to FUNDER’s prior written consent being required in respect of any matter, the Partner shall give not less than twenty (20) Business Days’ written notice to FUNDER of the matter for which such consent is required.

2. PARTNERING AND COLLABORATION

- 2.1. **Collaboration.** Each Party shall conduct their obligations under this Agreement in a collaborative manner and in accordance with the terms and conditions of this Agreement.
- 2.2. **FUNDER Mission.** Both Parties acknowledge and agree that:
 - 2.2.1. they are entering into this Agreement with the intention to further the FUNDER Mission by developing a vaccine for a disease with epidemic potential to address global health concerns;
 - 2.2.2. markets for vaccines with epidemic potential are very unusual in that successful vaccines may never be used and, if they are used, the demand for such vaccines may be erratic, unpredictable and unlikely to be at a sufficient level to allow manufacturers to be able to benefit from larger economies of scale;
 - 2.2.3. the Product is being developed using FUNDER’s public and philanthropic funds and may be a product that would otherwise be uneconomic to develop due to disease epidemiology and other factors; and
 - 2.2.4. the most significant benefits anticipated to arise from this Agreement will be public healthcare benefits. Neither Party is entering into this Agreement in

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anticipation of receiving significant commercial benefits from the exploitation of the Product in the Affected Territory.

3. CONTRIBUTIONS AND WORK PHASES

3.1. **FUNDER Obligations.** FUNDER shall:

3.1.1. Provide FUNDER Funding under Clause 3.4; and

3.1.2. Use Reasonable Efforts to do the following:

- i. work with WHO and other stakeholders to address the issues of product liability for unlicensed products used in an Outbreak in the Field;
- ii. work with Public Sector Agencies to develop and adopt ethical structures for the conduct of clinical trials of investigational vaccines in an Outbreak situation and establish and implement policy on access to trial sites in Affected Territories by FUNDER funded programs (“**FUNDER Policy on Site Access**”);
- iii. facilitate stakeholder coordination for preparation for and response to potential future Outbreaks;
- iv. collaborate with Public Sector Agencies to prioritize vaccines in the Field for Investigational Stockpile and Outbreak preparedness stockpile;
- v. promote a smooth and well-understood regulatory process for investigational vaccines; and
- vi. raise funding in advance for the funding of clinical trials in an Affected Territory if needed;

(together the “**Outbreak System Activities**”).

3.2. **Partner Obligations.** The Partner shall:

3.2.1. before an Outbreak,

- i. Develop the Product in accordance with the Development Plan and as more particularly detailed in the Work Phase Statements;
- ii. provide free of charge or at a discounted rate the services and facilities outlined in Schedule 3 in accordance with the timeframe (if any) set out at

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Schedule 3, the Application, and in more detail in specific Work Phase Statements; and

- iii. use its Reasonable Efforts either to establish directly or to enter into an agreement with FUNDER, a Public Sector Agency or another third party, for supply of Product into an Investigational Stockpile before the first subject receives the first dose in a Phase II Clinical Trial and perform the related obligations detailed at Clause 8.4;

(together the “**Outbreak Preparation Activities**”) in a timely manner and use Reasonable Efforts to achieve each Milestone by the relevant Milestone Date;

- 3.2.2. in the event of an Outbreak or Increased Outbreak Preparation Need, perform the Outbreak Response Activities detailed in any and all Work Phase Statements; and

- 3.2.3. in each case, use each Work Phase Budget solely for the purposes described in the relevant Work Phase Statement unless otherwise agreed in writing by FUNDER in advance.

- 3.3. **Mutual Obligations.** Each Party shall comply with all applicable laws and all relevant FUNDER policies.

- 3.4. **Approach to Work Phases.** The Parties will target the completion of the Project by [date] and if successful, expect the continued Development, Manufacture and supply of the Product as necessary by the Partner to meet the needs of Affected Territories. FUNDER shall fund the Pre-Clinical Work Phase in accordance with the Work Phase Statement attached at Schedule 5 and shall have the option to:

- 3.4.1. fund any future Work Phase of the Development Plan under an agreed Work Phase Statement;

- 3.4.2. accelerate the Development of the Product [or for a Portfolio of Products any one of the Products], in the event of an Increased Outbreak Preparation Need; and

- 3.4.3. require and fund any Outbreak Response Activities under an agreed Work Phase Statement;

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each at FUNDER's sole discretion. The Parties shall agree each individual Work Phase Statement in accordance with the process described at Clause 3.5. Each Work Phase Statement will include Milestones and Milestone Dates.

- 3.5. **Agreeing Work Phase Statements.** Each Work Phase Statement shall be agreed in the following manner:
- 3.5.1. For the Pre-clinical Work Phase, the Work Phase Statement agreed to by the Parties is attached at Schedule 5.
- 3.5.2. Except where Clause 3.5.1 applies, six (6) months prior to the completion of any individual Work Phase, the Partner shall provide to FUNDER such information as the FUNDER Group may reasonably request about the next planned Work Phase and FUNDER reserves the right to conduct a formal stage-gate review that shall include a face-to-face meeting with the Partner and/or otherwise request further information prior to the exercise of FUNDER's option to fund any subsequent Work Phase Partner agrees to participate in any face-to-face stage-gate review and to provide such requested information in a timely fashion, so as to avoid disruption between Work Phases;
- 3.5.3. Following FUNDER's receipt of the information from the Partner, FUNDER shall, as soon as reasonably practicable, inform the Partner that:
- i. it is willing in principle to provide funding for the next planned Work Phase; or
 - ii. it declines to provide funding for the next planned Work Phase.
- 3.5.4. If Clause 3.5.3i applies, FUNDER shall provide the Partner with the draft Work Phase Statement and the Parties shall discuss such draft in good faith. An indication in principle that FUNDER is willing to provide funding for the planned Work Phase is not an exercise of FUNDER's option to do so, exercise only occurs when the Work Phase Statement has been agreed and both Parties have signed it. The Parties shall work together in good faith and in a timely manner to ensure smooth transition between Work Phases.
- 3.5.5. During the course of a given Work Phase, clinical trial results or other factors may arise, which necessitate amendment of a Work Phase Statement. If this

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should occur, Partner undertakes to communicate such need together with adequate written justification for same to FUNDER. The Parties agree to use reasonable endeavours to agree on any such revisions or amendments by negotiating in good faith and in a timely manner so as to ensure the continuity of the Project and the Work Phase.

- 3.6. **Payments.** FUNDER shall pay the first tranche of the Work Phase Budget as defined in any Work Phase to the Partner within twenty (20) Business Days after the later of receipt of invoice and the date of signature of the Work Phase Statement, unless otherwise provided for in the relevant Work Phase Statement.
- 3.7. **Milestone Reports.** The Partner shall promptly notify FUNDER when the Partner considers that a Milestone within any Work Phase has been achieved, and it shall, as soon as reasonably practicable send to FUNDER:
 - 3.7.1. a detailed report evidencing such achievement (the “**Milestone Report**”); and
 - 3.7.2. up to date, true, complete and accurate Financial Documents.
- 3.8. **FUNDER Evaluation of Milestones.** Within twenty (20) Business Days after receipt of a Milestone Report and the Financial Documents, FUNDER shall confirm to the Partner whether:
 - 3.8.1. the Milestone has been achieved by the Milestone Date to FUNDER’s reasonable satisfaction, and that it has no objections to the Partner’s Financial Documents. In this case, FUNDER shall pay the next tranche of the FUNDER Funding (as defined in the relevant Work Phase Statement) to the Partner within twenty (20) Business Days after FUNDER’s confirmation pursuant to this Clause;
 - 3.8.2. FUNDER (acting reasonably) disagrees with the Partner that the Milestone has been achieved by the relevant Milestone Date. In this case FUNDER shall provide the Partner with reasonable details of the grounds on which it considers that the Milestone has not been met by the Milestone Date, and FUNDER shall have no obligation to make any further payments to the Partner until such failure has been cured; or

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- 3.8.3. where FUNDER (acting reasonably) has objections to the Financial Documents, FUNDER shall provide the Partner with reasonable details of its concerns, and shall have the right to request additional information and re-profile the payments of the FUNDER Funding to the Partner, provided that it informs the Partner of the revised payment schedule in writing.
- 3.9. **End of Work Phase Reporting.** At the end of each Work Phase, within twenty (20) Business Days of the last Milestone Date in that Work Phase, the Partner shall submit to FUNDER a final Milestone Report for that Work Phase and a Final Financial Summary.
- 3.10. **Payment of Retained Amount.** FUNDER shall pay the Retained Amount to the Partner within twenty (20) Business Days of FUNDER's acceptance of the final Milestone Report provided that:
- 3.10.1. the Partner has used Reasonable Efforts to achieve the final Milestone for a given Work Phase by the relevant Milestone Date,
- 3.10.2. the Partner has confirmed to FUNDER in good faith that the findings and papers supported by the FUNDER Funding are compliant with the FUNDER Transparency Policy and the FUNDER Open Access Policy; and
- 3.10.3. the Final Financial Summary does not show any FUNDER Funding is unspent following completion of the Work Phase (an "**Underspend**").
- 3.11. **Underspend.** In the event that the Final Financial Summary does show an Underspend FUNDER may:
- 3.11.1. Reduce any Retained Amount payable to the Partner by the value of the Underspend or
- 3.11.2. Where the Underspend is greater than the Retained Amount, FUNDER shall be under no obligation to pay the Retained Amount to the Partner, and the Partner shall (at FUNDER's sole choice) either: (i) repay to FUNDER such Underspend (less the Retained Amount) within twenty (20) Business Days of providing the Final Financial Summary to FUNDER or (ii) carry over the Underspend for use in a subsequent Work Phase (if any).

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- 3.12. **Payment Administration.** FUNDER shall make all payments of FUNDER Funding to the Partner in USD unless otherwise agreed in the Work Phase Statements. FUNDER shall make payments by electronic wire transfer of immediately available funds directly to the Partner's account designated below (or to any other account which the Partner may specify by written notice on headed paper and signed by an authorised signatory):

Account Name: [REDACTED]

Account No.: [REDACTED]

Bank: [REDACTED]

Sort code: [REDACTED]

SWIFT code: [REDACTED]

Branch: [REDACTED]

Account Currency USD

- 3.13. **Other Payment Conditions.** In addition to the other requirements set out at this Clause 3, FUNDER shall only make payments of FUNDER Funding to the Partner if none of the events described at Clauses 15.2 or 15.3 have occurred

- 3.14. **Third party funding or support for the Project.** In order to ensure that the Parties can achieve the FUNDER Mission, the Partner may seek other funding or support (whether in kind or otherwise) for the Project or any Work Phase, whether commercial or non-commercial but undertakes not to accept such funding without FUNDER's prior written consent. This Clause shall have no effect in the event that FUNDER informs the Partner that it is not exercising its option to fund a further Work Phase in accordance with Clause 3.5.3.

4. RECORDS AND STANDARDS

- 4.1. **Policies.** The Parties agree that the Project, the Work Phases, the Foreground Intellectual Property and Background Intellectual Property and associated matters shall be governed in accordance with this Agreement and the FUNDER Policies. If there is any conflict between the provisions of the main body of this Agreement and the FUNDER Policies, then the provisions of

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this Agreement shall prevail. If there is any conflict between the provisions of the main body of this Agreement and any Work Phase Statement, then the provisions of the Work Phase Statement shall prevail.

- 4.2. **Standards.** The Partner shall be responsible for the management, monitoring and control of all research work undertaken by it in the Project. This shall include the requirements of all applicable laws and regulatory authorities, including those governing appropriate ethical approvals and consents. Both Parties shall ensure that their respective staff observe professional standards at all times in relation to the Project.
- 4.3. **Animals in Research.** Where the Partner, its collaborators or sub-contractors undertake any research under any Work Phase of the Project that involves animals, it shall comply with both the Wellcome policy on the use of animals in research and the principles set out in the document "Responsibility in the use of animals in bioscience research: Expectations of the major research council and charitable funding bodies" (<http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTD040129.htm>). If procedures regulated under the UK Animals (Scientific Procedures) Act 1986 are to be used in any Work Phase, the research must comply with the Act, be approved by the local ethical review process and be conducted with due consideration for the 3Rs (replacement, reduction and refinement of the use of animals in research).
- 4.4. **Research involving human participants.** Where the Partner, its collaborators or sub-contractors undertake any research under any Work Phase of the Project that involves human subjects, it shall comply with the FUNDER Policies regarding such work.
- 4.5. **Clinical Trial.** For any Clinical Trial:
 - 4.5.1. The Partner shall be the sponsor of the Clinical Trial unless FUNDER otherwise agrees in writing and shall conduct the Clinical Trial in accordance with GCP.

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- 4.5.2. The Partner shall be responsible for obtaining and maintaining all Regulatory Approvals, including Ethical Committee approvals, necessary or reasonably useful for the conduct of the Clinical Trial.
- 4.5.3. The Partner shall establish a TSC which shall approve the Clinical Trial protocol and monitor the progress of the Clinical Trial, including any changes to the protocol. The TSC shall only include members who are independent of the Partner and who are not otherwise involved in the Clinical Trial.
- 4.5.4. The Partner shall communicate to FUNDER in writing any data relating to a Product of which it becomes aware which discloses a serious adverse event, promptly (and in any event within forty-eight (48) hours) and where that serious adverse event is a suspected, unexpected, serious adverse reaction or death or raised any other material safety signal, immediately.
- 4.5.5. The Partner shall inform FUNDER, in writing, of any Product recalls with twenty-four (24) hours of receiving notice of same.
- 4.5.6. The Partner shall obtain from each subject in the Clinical Trial, prior to enrolment into, and as a condition of that Clinical Trial subject's participation in, any Clinical Trial, his or her informed consent to:
 - i. Direct access to his or her medical records;
 - ii. The processing of data relating to him or her and to the movement of that data to other countries, including countries outside of the European Economic Area; and
 - iii. The transfer of such data to the Partner, FUNDER and in each case their permitted sub-licensees, and the use of those data in obtaining Regulatory Approvals.
- 4.6. **FUNDER attendance at TSC and DSMB meetings.** A FUNDER representative or nominee shall have the right (except for any matters which should remain blinded to FUNDER in the interests of the integrity of the Clinical Trial) to:
 - 4.6.1. attend meetings of the TSC and the DSMB for the Clinical Trial as an observer;

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- 4.6.2. receive all papers that a member of the TSC or DSMB would be entitled to receive ; and
- 4.6.3. attend TSC or DSMB meetings by telephone or other electronic means rather than in person.
- 4.7. **Clinical Trials Register.** The Partner shall publish details of the Clinical Trial on a publicly accessible clinical trials register prior to the commencement of patient recruitment for a Clinical Trial, and shall provide to FUNDER evidence of such publication within twenty (20) Business Days of the same.
- 4.8. **Records.** The Partner shall ensure that its staff, collaborators and sub-contractors keep full, detailed and accurate records of all of their activities and results obtained in connection with each Work Phase of the Project; in particular, the Partner shall ensure that its staff, collaborators and sub-contractors keep scientific records of all research, development and other work carried out in respect of each Work Phase of the Project and the results of such research, development and other work in accordance with GLP, GCP and GMP as applicable and in a way which is appropriate for patenting and regulatory purposes. With respect to each Clinical Trial, the Partner shall procure that the Data are complete and include all completed case report forms and all other clinical trial documentation required to be in the possession of a clinical trial sponsor by Article 15(5) of Directive 2001/20/EC, Article 16 of Directive 2005/28/EC or other relevant Applicable Law.
- 4.9. **Access to Records.** Upon FUNDER's request, the Partner shall make available (and shall procure that its collaborators and sub-contractors make available) to FUNDER all records generated in connection with any Work Phase of the Project (except for any records which at the time of the request should remain blinded to FUNDER in the interests of the integrity of the Clinical Trial).
- 4.10. **Accuracy of data.** The Partner shall ensure that the Data it maintains and reports to FUNDER and the JMAG are complete, reliable, accurate and not misleading.

- 4.11. **Audit.** The Partner shall procure that the control of expenditure of the FUNDER Funding and the Partner Contribution are governed by the normal standards, procedures and formal audit arrangements that exist in the Partner. FUNDER shall have the right to ask for confirmation from the Partner's external auditors that the external auditors have signed their opinion on the Partner's annual accounts of the Partner without qualification and the management letter from the auditors raises no matters that did or could significantly affect the administration of grants awarded by FUNDER. If the auditors have raised any such matters in their management letter, FUNDER may require the Partner to provide it with relevant extracts from the letter.
- 4.12. **Accounting records.** The Partner shall provide access to accounting and other financial records relating to the FUNDER Funding, Partner Contribution and the activities funded by the foregoing (as well as income and expenditure associated with the Project and the systems used by the Partner to administer the Project financially and otherwise) for auditors and other personnel from or appointed by FUNDER at any time if requested. Such access shall include the right to inspect any equipment or facilities acquired or funded under the FUNDER Funding or Partner Contribution. Where activities funded by the FUNDER funding or the Partner Contribution have involved a collaborator or have been sub-contracted, the Partner shall ensure that the right of access extends to the accounts and records of any such collaborator or sub-contractor.
- 4.13. **Specific cost code.** The Partner shall maintain a separate accounting cost code specific to the Project, and all costs and income properly relating to the Project (including the Partner Contribution) shall be accounted for through that cost code. The Partner shall ensure that appropriate records are kept to support the entries made on the cost code.

5. PROJECT MANAGEMENT AND OVERSIGHT

- 5.1. **Project Lead and Project Manager.** The Partner shall ensure that the Project Lead shall lead each Work Phase and shall assume the responsibilities of the Project Lead as set out in this Agreement. The Partner shall further ensure

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that the Project Lead has project management support to ensure that there is efficient co-ordination of each Work Phase on a day-to-day basis.

- 5.2. **Project Lead replacement.** If the Project Lead ceases to be involved with the Project, ceases to be employed by or provide services to the Partner, ceases to carry out research at premises controlled by the Partner, or is prevented from working on the Project through illness or injury for a period of over one (1) month, the Partner shall promptly notify FUNDER. In such a case, the Parties will seek to agree a suitable replacement Project Lead as soon as possible.
- 5.3. **Joint Monitoring and Advisory Group.** The Parties shall establish a JMAG to oversee all Work Phases as well as the Development, Manufacturing, Regulatory and Marketing Activities of any Product including:
 - 5.3.1. monitoring the performance of each Work Phase and technical content of the Work Phase against the Milestones;
 - 5.3.2. critically assessing the results of each Work Phase on an on-going basis and identifying and addressing any weaknesses or delays in any Work Phase;
 - 5.3.3. subject to Clause 5.4, reviewing and approving the Development Plan, material changes and updates to the Development Plan (including any matters pertaining to any budget for Development) and progress against the Development Plan;
 - 5.3.4. reviewing and approving the regulatory strategy for any Product in the Affected Territory, with any Approved Regulatory Authority and the Regulatory Filings with each;
 - 5.3.5. reviewing and approving the Marketing Activities Plan and any material changes thereto (including any matters pertaining to budget);
 - 5.3.6. receiving periodic updates on Outbreak System Activities, material Development activities, Outbreak Preparation Activities, Outbreak Response Activities and regulatory activities conducted or proposed to be conducted with respect to Product in the Affected Territory (including submission and prosecution of applications for Marketing Approval);

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- 5.3.7. providing a forum for discussion as to whether Development and Marketing Activities are sufficient to satisfy FUNDER's Mission and the Parties obligations to use Reasonable Efforts;
 - 5.3.8. reviewing safety and compliance reports for the Product in the Affected Territory and providing a forum for co-ordinating the Parties' responses to crises with respect to the Product, including unexpected disruptions to the supply of the Product, recalls, safety issues or withdrawals of Product;
 - 5.3.9. reviewing and approving potential sublicenses; and
 - 5.3.10. making such other decisions as may be delegated to the JMAG pursuant to this Agreement or by written agreement of the Parties.
- 5.4. **No right to approve Milestones.** The JMAG shall have no right to approve the achievement of Milestones (which right is reserved to FUNDER pursuant to Clause 3.8), to amend or vary the provisions of this Agreement, to alter the fundamental scope or objectives of the Project, or to change or enter into any Work Phase Statements which power is reserved to the Parties.
- 5.5. **JMAG Composition.** The JMAG shall be comprised of the following persons ("Members"):
- 5.5.1. the Project Lead, who shall be the chairperson of the JMAG;
 - 5.5.2. an independent expert adviser with experience which is relevant to the Project; such Member to be agreed between the Parties. The costs and expenses of the independent expert adviser shall be met out of the FUNDER Funding; and
 - 5.5.3. a FUNDER representative or nominee; FUNDER may, at its sole discretion, appoint or remove any FUNDER representative or nominee plus any accompanied expert(s) serving a FUNDER advisory capacity but who are not Members.
- 5.6. **Quorum.** The quorum for JMAG meetings shall be three (3) Members being the FUNDER Member, the Project Lead and the independent expert adviser. Decisions of the JMAG shall be made by unanimity of Members; where

consensus cannot be reached, the matter shall be escalated in accordance with Clause 17.1.

- 5.7. **Meeting Organisation.** The Project Lead shall be responsible for organising JMAG meetings, including preparing meeting papers and ensuring that minutes of meetings are produced promptly after each meeting and circulated to Members in a timely manner. The Project Lead shall convene JMAG meetings at least once every three (3) months during each Work Phase, and after the end of the Project at least once every six (6) months (or less frequently with FUNDER's consent). The Project Lead shall ensure that except in exceptional circumstances all Members are provided with at least ten (10) Business Days' written notice of the JMAG meeting (accompanied by an agenda for the meeting, and a report on the progress of the Project, a spend report setting out use of the FUNDER Funding and details of the Partner's Contribution used in the Project).
- 5.8. **Attendance.** Members may attend any JMAG meeting by telephone or other electronic means rather than in person, provided that all Members attending the meeting can hear and be heard for all parts of the meeting. Members attending a JMAG meeting by telephone or other electronic means shall have the same voting rights as a Member present in person.
- 5.9. **Expert attendees.** Each of the Parties may invite other members of their staff or consultants or other persons whose special skills or knowledge might advance the Project, the Development, Manufacturing, Regulatory and Marketing Activities of any Product or the FUNDER Mission to attend and address JMAG meetings as observers; such observers shall not be Members and shall not have a right to participate in JMAG decision-making process. With regards to notifications to JMAG of Project Inventions, JMAG shall solicit the advice of appropriate intellectual property counsel. The Project Lead shall ensure that any such observers sign confidentiality agreements in a form acceptable to both Parties.
- 5.10. **Quarterly Reports.** For any calendar quarter where there has not been a JMAG meeting and where the Partner has not submitted a Milestone Report to FUNDER, the Partner shall provide a Quarterly Technical and a Quarterly

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Financial Report to JMAG and FUNDER with updates on any matters relating to the Development Plan or otherwise within the JMAG's remit.

- 5.11. **Collaborators and Sub-Contractors.** If the Partner wishes to use a collaborator or sub-contractor to conduct any part of the Project, it shall seek the consent of the JMAG prior to entering into any agreement with such sub-contractor or collaborator unless such sub-contractor or collaborator is specified in the Work Phase Statement. The Partner shall ensure in all cases that each collaboration agreement or sub-contract shall:
- 5.11.1. be consistent with the Work Phase approach to the Project, as well as any Milestones and Milestone Dates in each Work Phase;
 - 5.11.2. be consistent with the milestone nature of the award and the termination provisions of this Agreement, and be capable of termination if this Agreement or any Work Phase terminates;
 - 5.11.3. prohibit the collaborator or sub-contractor sub-contracting its obligations;
 - 5.11.4. comply with the provisions of Clauses 10.2 and 13.2; and
 - 5.11.5. require the sub-contractor or collaborator to comply with all aspects of applicable law including GCP, GLP and GMP;
 - 5.11.6. the third party shall not have any rights to any results emerging from such work, and all such results shall as between the Parties and the third party be deemed to be Foreground Intellectual Property and owned in accordance with the provisions of this Agreement;
 - 5.11.7. the third party shall keep detailed records including scientific notebooks of all of its activities and upon request by FUNDER shall make available copies of such records and any associated data to FUNDER (such disclosure not to constitute a breach of confidentiality by the third party);
 - 5.11.8. that FUNDER will have the rights of access to the accounts and records of the third party; and
 - 5.11.9. that the third party will upon reasonable request by FUNDER make available its employees and/or consultants for discussion with FUNDER and the Site Visit Group.

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- 5.12. **Partner Affiliates.** The Partner may perform its obligations under an Agreement through an Affiliate and shall be responsible for the acts and omissions of such Affiliate as if they were the Partner's own acts and omissions.

6. DEVELOPMENT AND REGULATORY ACTIVITIES

- 6.1. **Development.** The Partner shall use Reasonable Efforts to Develop the Product before any Outbreak or an Increased Outbreak Preparation Need and all reasonable endeavours to Develop the Product for use in the Affected Territory when an Outbreak or an Increased Outbreak Preparation Need has been declared and in each case in accordance with the terms and conditions of this Agreement and the Development Plan.
- 6.2. **Development Plan.** A draft the Development Plan is attached hereto as Schedule 6. A Development Plan that specifies all the Development activities to be performed in the Development of the Product shall be finalized by the Partner and submitted to the JMAG for its approval within six (6) weeks of the Effective Date. The Development Plan is to be considered by the JMAG at its next meeting after such submission and must be approved by the JMAG as soon thereafter as is reasonable under the circumstances. It is recognised that the Development Plan will need to be amended, expanded, altered and refined over time as more information becomes available and include details relevant to the stage of the Product's development. The Partner shall update the Development Plan on an ongoing basis to ensure that this remains fit for purpose and proposed amendments to the Development Plan shall be reviewed and approved at the next JMAG meetings. The Development Plan shall set out, where appropriate:
- 6.2.1. the planned location, volume and capacity of Investigational Stockpiles of the Product and the plans for maintenance and replenishment of such Investigational Stockpiles taking account of any frameworks developed by the Medical Countermeasures Task Force, GHSI or another relevant Public Sector Agency;
- 6.2.2. resource mobilisation plans for conducting Pivotal Trials of Product in the event of an Outbreak or Increased Outbreak Preparation Need in the

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Affected Territory taking account of any frameworks developed by the Medical Countermeasures Task Force, GHSI or another relevant Public Sector Agency;

- 6.2.3. a manufacturing plan clarifying volume and capacity, including any plans to reserve capacity, to produce investigational doses of Product for use in the Field in the event of an Outbreak or Increased Outbreak Preparation Need in the Affected Territory;
 - 6.2.4. details of the Outbreak Response Activities;
 - 6.2.5. plans to engage manufacturing partners and Secondary Manufacturers if required to meet the volume and cost targets set out in Clause 8 , including any plans to reserve capacity, or to mitigate anticipated risks;
 - 6.2.6. plans to engage with Public Sector Agencies including procurement agencies for Investigational Stockpiles;
 - 6.2.7. the strategy to keep the cost of goods of investigational doses of Product as low as possible in line with the methodology to determine pricing obligations set out in FUNDER Equitable Access Policy;
 - 6.2.8. plan for engagement with Regulatory Authorities; and
 - 6.2.9. the strategy to best facilitate timely and sustainable equitable access to the Product in the Affected Territory in the event of an Outbreak or Increased Outbreak Preparation Need.
- 6.3. **Regulatory.** Subject to the provisions of Clauses 9 and 15, the Partner shall be responsible for developing the regulatory strategy for the Product for review and approval by the JMAG. Such strategy shall include the strategy with respect to any data, market or other regulatory exclusivity periods that may be applicable to Product in the Affected Territory or a territory served by an Approved Regulatory Agency. The Partner shall use Reasonable Efforts to file for, obtain and maintain IND or a CTA for the Product in both a territory served by an Approved Regulatory Agency and the Affected Territory, and Marketing Approval for the Product in the Field in such countries in the Affected Territory.

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- 6.4. **FUNDER obligations.** FUNDER will, where considered useful in FUNDER's sole discretion, engage with the Partner, applicable Regulatory Authorities and Public Sector Agencies to facilitate the obtaining and maintaining of regulatory approvals.
- 6.5. **Regulatory Filings.** The Partner will keep the JMAG updated regarding all Regulatory Filings and provide each Member with copies of the following in a timely manner:
 - 6.5.1. all submissions to Regulatory Authorities relating to the manufacture or of the Marketing Activities of any Product (other than ministerial submissions that do not involve safety or efficacy issues);
 - 6.5.2. all Regulatory Filings and any Data including or referenced therein in respect of Product in the Field;
 - 6.5.3. related documents and information exchanges between any Regulatory Authority and the Partner, including as part of regulatory planning in early stages of development; and
 - 6.5.4. upon request, the Master File.
- 6.6. The Partner shall invite a FUNDER nominee to observe all interactions between the Partner and Regulatory Authorities which relate to the Project, the Product and the development or protection of the Foreground Intellectual Property. The Partner shall promptly notify FUNDER of its receipt of information from any Regulatory Authority that raises any material concerns regarding safety or efficacy of the Product. At FUNDER's reasonable request, the Partner will request a meeting with Regulatory Authorities to deal with major unresolved issues. The Parties acknowledge and agree that FUNDER is bound by confidentiality obligations to the Partner pursuant to Clause 13 of this Agreement and therefore Regulatory Authorities' communications with the Partner should not be limited by the presence of FUNDER nominees at regulatory meetings.

7. SITE VISIT GROUP

- 7.1. **Monitoring of Project.** FUNDER may appoint a Site Visit Group made up of a small team of independent experts together with some FUNDER observers to

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consult informally with the Partner's staff working on the Project, to evaluate progress, performance and key issues and to report back to FUNDER and the JMAG on its findings. The Partner agrees that the Site Visit Group shall have reasonable access during normal working hours and at mutually agreed times to visit the premises where any Work Phase activities are being conducted; the Partner agrees to procure that these rights of access for the Site Visit Group extend to the staff and premises of any collaborators and sub-contractors.

- 7.2. **Site Visit Group Recommendations.** The Site Visit Group may recommend that FUNDER terminates any Work Phase due to a serious failure in the progress, management or conduct of the Work Phase (including a finding that the Partner will be unable to achieve the next Milestone by the relevant Milestone Date), or due to a major external scientific, technical or commercial barrier which means that the Work Phase or the Project is unlikely to succeed in its objectives.

8. ACCESS TO AND SUPPLY OF PRODUCT

- 8.1. **FUNDER Policy.** Partner acknowledges and understands the FUNDER Equitable Access Policy and agrees to comply with such policy as it applies to the Product. In accordance with that policy, Partner shall provide the following then current information to FUNDER in accordance with Clause 3.5.2:
- 8.1.1. Progress report on the scale-up of the Manufacturing process to fulfil the requirement of an Approved Regulatory Authority for the grant of Marketing Approval for the Product or plans to do that same and a good faith estimate of the number of doses of Product such scaled-up Manufacturing process will be capable of producing in each year of manufacture and by when such volume will be achieved; and
 - 8.1.2. a good faith estimate of Cost of Goods for the Product for (i) the Investigational Stockpile and (ii) additional doses of the Product together with any information that would impact the cost of the Product.
- 8.2. **Volume.** If the Partner has not developed a Manufacturing process for the Product which meets the estimated capabilities disclosed under Clause 8.1 by

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[date], (i) the Partner shall provide FUNDER with full details of the obstacles to meeting such requirement and all related Data within ten (10) Business Days after such date; (ii) FUNDER may at its sole discretion (i) grant an extension of time and require the Partner to consult with experts in the field approved by FUNDER or (b) exercise its step-in rights under Clause 9.

8.3. **Cost of Goods.** If the Partner has not developed a Manufacturing process for the Product which will maintain the Cost of Goods for the Product at a level Public Service Agencies agree is affordable for use in the Affected Territories by [date], (i) the Partner shall provide FUNDER with the Cost of Goods and supporting Data and (ii) FUNDER may in its sole discretion, (a) participate in the negotiations with the Public Services Agency(ies), (b) facilitate introductions for the Partner to third parties who may be of assistance in the establishment of a secondary manufacturing facility, (c) audit the Partner's Cost of Goods (and may use a reputable accounting firm to do so in its behalf), or (d) exercise its step-in rights under Clause 9.

8.4. **Access to Product.**

8.4.1. Within [timing] the Partner shall deliver to FUNDER a Marketing Plan which will describe the Partner's planned activities to make the Product available for stockpile in accordance with the definition of "Market" or otherwise in preparation for an Outbreak or Increased Outbreak Preparation Need.

8.4.2. Partner shall ensure that the first [w%] of doses of Product Manufactured in the first [v] years after scale-up shall be provided as directed in writing by FUNDER in accordance with the FUNDER Equitable Access Policy.

8.5. **Updates to the Marketing Plan.** The Partner shall review and, where appropriate, update the marketing plan at least once every calendar year and will deliver to FUNDER, not less than one (1) month prior to the commencement date of the revised marketing plan, the revised marketing plan together with an update on the implementation of the marketing plan.

8.6. **Commercial benefits arising from the Product.** The Parties acknowledge and agree it is unlikely that any significant commercial benefits will arise from the Development and the Marketing of the Product in the Field for use in the

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Affected Territory given the epidemiology of the disease as of the Effective Date and the provisions of this Clause 8. In the event of any commercial benefits arising from the Product to the Partner as a result of FUNDER Funding, the Partner shall promptly notify FUNDER of such benefits and shall comply with the FUNDER Shared Risks/Shared Benefits Policy. The Parties shall agree in good faith how such benefits (if any) arising are to be managed in a fair, equitable and proportionate manner, taking account of the financial contribution of each of the Parties to the Background Intellectual Property and Foreground Intellectual Property being exploited, the public and philanthropic nature of the FUNDER Funding, the public benefit derived from the proposed Development and Exploitation, and any private or ancillary benefit that may arise. Any benefits sharing shall be subject to a separate agreement that the Parties shall execute in a timely manner.

9. CONDITIONS PRECEDENT AND FUNDER STEP-IN RIGHTS

- 9.1. **FUNDER step-in rights and Conditions Precedent.** FUNDER shall not be entitled to Develop, Market or otherwise exploit Product whether itself or through third parties unless and until one or more of the events set out below occurs:
- 9.1.1. the Partner materially fails to Develop the Product in accordance with the Development Plan except where the Parties agree such failure is due to reasonable scientific, safety or regulatory issues;
 - 9.1.2. the Partner fails to use Reasonable Efforts to satisfy any Milestone by the relevant Milestone Date;
 - 9.1.3. the Partner notifies FUNDER that it has elected either not to (i) Develop the Product for use in the Field or (ii) Market Product for use in the Field in one or more countries or regions in the Affected Territory;
 - 9.1.4. the occurrence of any of the events set out in Clauses 15.2 or 15.3 (or both);
 - 9.1.5. in the event of an Outbreak or Increased Outbreak Preparation Need, and
 - i. the Partner informs FUNDER that it will not be able to manufacture or deploy the Product in appropriate timescales and quantities or at a cost appropriate to the Outbreak or Increased Outbreak Preparation Need; or

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- ii. in FUNDER's reasonable judgement, the Partner cannot or will not take all necessary steps in a timely manner to manufacture or deploy the Product in quantities and at a cost appropriate to the Outbreak or Increased Outbreak Preparation Need;

9.1.6. if FUNDER opts to exercise its step-in rights in either of the events set out in Clause 8.2 and 8.3;

(each a "**Condition Precedent**" and together, the "**Conditions Precedent**").

9.2. **Effects of the occurrence of one or more Conditions Precedent.** On the occurrence of one or more of the Conditions Precedent:

9.2.1. FUNDER shall notify the Partner in writing of the occurrence of one or more Conditions Precedent;

9.2.2. FUNDER may exercise the rights granted under the Licences;

9.2.3. FUNDER shall have the discretion to make any and all decisions in relation to the Development and Marketing of the Product in the Field for use in the Affected Territory and if so instructed by FUNDER in writing, the Partner shall cease Developing and Marketing Product.

9.2.4. The Partner shall use all reasonable endeavours to give assistance to FUNDER (or its nominees) in relation to the Development and Marketing of the Product for use in the Affected Territory including:

- i. assisting in the transfer to FUNDER or its nominee Existing Data, Data, Materials, Confidential Information and Regulatory Filings (including the Master File) necessary or desirable for the FUNDER or its nominee to conduct such Development and Marketing of the Product in the Field for use in the Affected Territory; and
- ii. executing any necessary documents.

9.2.5. FUNDER shall have the right to take all such action as it shall consider necessary or appropriate at its discretion and expense to bring or defend an action on behalf of the Partner. The Partner shall (at the Partner's cost) provide all reasonable assistance to FUNDER as FUNDER may request in

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relation to such action, including granting FUNDER the right to bring an action in the name of the Partner if necessary.

9.2.6. The Escrow Materials shall be released immediately to FUNDER or its nominee.

9.3. **Development and Use Licences.** The Partner hereby grants to FUNDER with effect from the Effective Date and for all rights, data and materials not in existence at the Effective Date, shall grant on their creation:

9.3.1. a non-exclusive, irrevocable, worldwide, royalty-free licence, under the Foreground Intellectual Property with the right to grant sub licences to (i) Develop the Product worldwide for use in the Field, (ii) Manufacture the Product worldwide for use in the Field and (iii) Market the Product in the Field for use in the Affected Territory; and

9.3.2. a non-exclusive, irrevocable, worldwide, royalty-free licence, with the right to grant sublicenses under Background Intellectual Property to (i) Develop the Product worldwide for use in the Field, (ii) Manufacture the Product worldwide for use in the Field and (iii) Market the Product in the Field for use in the Affected Territory; and

9.3.3. a non-exclusive, irrevocable, worldwide, royalty-free licence, with the right to grant sub licences to use the Existing Data, the Data, Confidential Information, Regulatory Filings, Master File and Materials to (i) Develop the Product worldwide for use in the Field, (ii) Manufacture the Product worldwide for use in the Field and (iii) Market the Product in the Field for use in the Affected Territory, and

9.3.4. where the Condition Precedent is also a breach of this Agreement by Partner, the licence granted under Clause 9.3.1 shall be an exclusive, irrevocable, worldwide, royalty-free licence;

(together, the "**Licences**"); provided however that FUNDER may not exercise the rights granted under the Licences unless and until the occurrence of one or more Conditions Precedent.

9.4. **Escrow.** The Partner shall as soon as reasonably practical after the Effective Date, establish escrow arrangements with a mutually agreed third party

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escrow agent (the “**Escrow Agent**”) upon terms which are acceptable to FUNDER (acting reasonably), pursuant to an escrow agreement entered into by the Escrow Agent, the Partner and FUNDER. Such escrow agreement shall allow FUNDER access to Confidential Information, Existing Data, Data, Materials and Regulatory Filings, including the Master File, and any supporting data for the Background Intellectual Property and Foreground Intellectual Property relating to Product in the Field for use in the Affected Territory as necessary or useful for the Development and Marketing of the Product in the Field for use in the Affected Territory by FUNDER or a third party. The escrow arrangements may extend, as necessary and appropriate to biological materials, cell-lines, software, source code for manufacturing processes, assays, most up to date pathogen samples and the like. The Partner shall make ensure that all materials required to be placed in escrow are in escrow and complete and up to date at the time Partner requests any Milestone Payment from FUNDER. FUNDER shall only be able to access the escrow with the consent of the Partner or if any of the events described in Clause 9.1 have occurred.

- 9.5. **No implied licences.** Except for the rights and licences expressly granted under this Agreement, the Partner retains all rights under its Intellectual Property and no rights shall be deemed granted by the Partner to FUNDER by implication, estoppel or otherwise.

10. INTELLECTUAL PROPERTY – OWNERSHIP AND PROTECTION

- 10.1. **Foreground Intellectual Property.** The Partner shall procure that the Project Lead monitors the work carried out under all Work Phases for material that may be the subject of Project Inventions and shall promptly notify the JMAG of any such Project Invention. The Partner shall additionally promptly disclose all Project Inventions and Foreground Intellectual Property to FUNDER in writing.
- 10.2. In the event that any Foreground Intellectual Property arises, it shall be the property of the Partner; any Project Patents shall be applied for in the name of the Partner. To this end, the Partner shall procure that:
- 10.2.1. Any Affiliate, third party collaborator, third party funder or sub-contractor shall assign all its right, title and interest in any results or Foreground Intellectual

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Property arising from work carried out under the Project promptly to the Partner and shall retain no rights in the same; and

10.2.2. it shall have in place contracts with those working on or funding all Work Phases of the Project to ensure that the Foreground Intellectual Property shall vest in the Partner and not with any members of staff individually. Where by local applicable law such rights do vest in individual members of staff, the Partner shall promptly exercise all rights to take and assignment of all right title and interest in the same. The Partner shall bear the costs of any necessary contribution to such individual or other costs of assignment.

10.3. The Partner undertakes to take responsibility for seeking and maintaining protection for Foreground Intellectual Property at its sole cost, including the filing, conduct, prosecution and maintenance of all Project Patents in consultation with FUNDER.

10.4. **Background Intellectual Property.** The Partner shall make the Background Intellectual Property available for use in all Work Phases and for the protection or exploitation of the Foreground Intellectual Property. The Partner shall retain responsibility for seeking and maintaining protection for the Background Intellectual Property at its own cost and shall not assign or otherwise convey any of its interest, right and title in the same without FUNDER's prior written consent, not to be unreasonably withheld, conditioned or delayed.

10.5. **Infringement.** The Partner shall immediately give notice to FUNDER if it becomes aware of:

10.5.1. any infringement or suspected infringement or misappropriation of the Background Intellectual Property or Foreground Intellectual Property; or

10.5.2. any claim by a third party that an action carried out under the Project infringes the Intellectual Property or other rights of any third party.

10.5.3. In such cases, the provisions of Clause 14.6 and 14.7 will apply and Partner will consult with FUNDER about what action it should take.

11. INTELLECTUAL PROPERTY – MANAGEMENT AND EXPLOITATION

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- 11.1. **Consent.** In order to ensure that any proposed exploitation is in accordance with the FUNDER's Mission, the Partner shall obtain FUNDER's prior written consent before exploiting any of the Foreground Intellectual Property or any Product. FUNDER shall only withhold its consent to exploitation:
- 11.1.1. where the proposed exploitation in the Field in the Affected Territory is inconsistent with the FUNDER Mission, the FUNDER Policies or the provisions of this Clause;
 - 11.1.2. FUNDER has material concerns about the capability, solvency or reputation of any third party who is proposed to be involved in the exploitation; or
 - 11.1.3. the Partner plans to transfer the Foreground Intellectual Property to a third party but does not also intend to transfer to the third party the Partner's obligations to FUNDER under this Agreement in such a way that FUNDER could enforce such obligations directly against such third party.
- 11.2. **Exploitation outside the Field or outside the Affected Territory.** Where any proposed exploitation by the Partner is either:
- 11.2.1. in the Field, but with Development and Marketing Activities directed outside the Affected Territory; or
 - 11.2.2. outside the Field and for Development and Marketing Activities directed outside the Affected Territory;
 - 11.2.3. FUNDER's consent shall be conditional on the following: (i) the Partner shall be the sponsor of any clinical trial of a pharmaceutical composition which infringes the Foreground Intellectual Property (a "**Similar Product**") unless FUNDER otherwise agrees in writing; (ii) the Partner shall consult with and agree the protocol for such clinical trial with FUNDER in advance and shall not proceed with any such clinical trial without FUNDER's approval, such approval not to be unreasonably withheld, conditioned or delayed; (iii) the Partner shall communicate to FUNDER in writing any data relating to a Similar Product of which it becomes aware which discloses a serious adverse event, promptly (and in any event within forty-eight (48) hours) and where that serious adverse event is a suspected, unexpected, serious adverse reaction or death or raised any other material safety signal,

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immediately; (iv) any relevant event under any pharmacovigilance activities and (v) shall grant FUNDER a right of reference to the regulatory materials relating to any and all Similar Products.

11.3. **Commercial benefits arising from the Foreground Intellectual Property.**

In the event of any commercial benefits arising from the Foreground Intellectual Property to the Partner as a result of FUNDER Funding, the Partner shall promptly notify FUNDER of such benefits and shall comply with the FUNDER Shared Risks/Share Benefits Policy. The Parties shall agree in good faith how such benefits (if any) arising are to be managed in a fair, equitable and proportionate manner, taking account of the financial contribution of each of the Parties to the Background Intellectual Property and Foreground Intellectual Property being exploited, the public and philanthropic nature of the FUNDER Funding, the public benefit derived from the proposed Development and Exploitation, and any private or ancillary benefit that may arise. Any benefits sharing shall be subject to a separate agreement that the Parties shall execute in a timely manner.

12. ANNOUNCEMENTS AND PUBLICATIONS

12.1. **Announcements.** Save as required by law or any competent regulatory authority or in compliance with this Clause, the Parties shall consult on and agree the form of all press releases, publications and public announcements concerning this Agreement, its subject matter or the FUNDER Funding. Notwithstanding the foregoing, the Parties agree that the summarised progress and outcomes of the Project, a summary of the terms and conditions of this Agreement, the name of the Partner and the Project Lead, and the amount of the FUNDER Funding, will be published or otherwise disseminated to the public in an appropriate form in accordance with the FUNDER Policies.

12.2. **Publications.** The Partner shall ensure that the Project Lead furnishes FUNDER with a copy of any proposed publication or presentation which relates to a Project Invention or Foreground Intellectual Property at least fifteen (15) Business Days in advance of the submission of such proposed publication or presentation to a journal, editor or publication.

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- 12.3. **Patent publications.** Following publication of any patent filed hereto, the Partner shall have the right to publish and reproduce any such publication freely with due acknowledgement of the sources including, where appropriate, sources of funding and the individuals and communities from whom data has been collected.
- 12.4. **Open Access.** A copy of the final manuscript of all research publications that relate to any Work Phase of the Project must be deposited into PubMed Central (or Europe PubMed Central) upon acceptance for publication, to be made freely available immediately after the journal publisher's official date of final publication.
- 12.5. **Open Data.** The Partner shall publicly share all data and results (including negative results) arising from the FUNDER Funding as close to real time as possible. The Partner shall share its data through an easily discoverable public route (website or system) which 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). The Partner should share Clinical Trial results as close to real time as possible and at any rate within twelve (12) months of study completion.

13. CONFIDENTIALITY

- 13.1. **Confidentiality Obligations.** Subject to the provisions of this Clause 13, each Party undertakes that both during the term of this Agreement and for a period of ten (10) years after its termination, it shall keep confidential and not disclose to any person any Confidential Information of the Party disclosed to or obtained by it in connection with this Agreement.
- 13.2. Each Party shall take all reasonable security precautions in relation to the Confidential Information under its control. Where the Partner engages any collaborator or sub-contractor, the Partner shall ensure that such collaborator or sub-contractor shall be bound by confidentiality obligations which are at least as onerous as those set out under in Agreement. Each Party shall ensure that all staff and third parties to whom Confidential Information of the other Party is disclosed are:

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13.2.1. informed of the provisions of Clause 13 of this Agreement; and

13.2.2. bound by confidentiality and non-use obligations at least as onerous as those herein.

13.3. **Exceptions.** Clause 13.1 shall not apply to:

13.3.1. information which is or was already known to the receiving Party at the time of disclosure under this Agreement, as shown by the receiving Party's written records, without any obligation to keep it confidential;

13.3.2. information which is independently developed by employees of the receiving Party who have not had access to the Confidential Information of the disclosing Party;

13.3.3. information which at the time of being disclosed or obtained by the receiving Party under this Agreement 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;

13.3.4. the disclosure of Confidential Information to a Party's officers, employees, staff, consultants or professional advisors and in the case of the Partner, to collaborators and contractors pursuant to Clause 13.2 whose province it is to know, and who are bound by confidentiality and non-use obligations at least as onerous as those herein;

13.3.5. the disclosure of information by either Party to the JMAG or any Site Visit Group;

13.3.6. the disclosure of information which 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;

13.3.7. the disclosure of Partner's Confidential Information by FUNDER:

13.3.8. where such disclosure is expressly provided for in the terms of this Agreement including where FUNDER has exercised the Licences pursuant to Clause 9; or

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13.3.9. to any member of the FUNDER Group.

13.4. In recognition of the FUNDER Mission, nothing in this Clause 13 shall prevent FUNDER from using the Confidential Information, or comparing the Confidential Information to information already in its possession, in each case solely to inform its assessment of other applications made to it for funding in furtherance of its objects.

14. WARRANTIES AND LIABILITY

14.1. **Warranties.** As at the Effective Date, and at the submission of each Milestone Report to FUNDER, the Partner warrants to FUNDER (subject to any matters fairly and accurately disclosed in the Disclosure Letter (if any)) that:

14.1.1. it has the requisite authority to enter into this Agreement;

14.1.2. it has full power and authority to assume all of its obligations under this Agreement; and

14.1.3. to the best of its knowledge and belief it is the legal and beneficial owner of all right, title and interest in and to the Background Intellectual Property, the Existing Data and the Material;

14.1.4. it has not granted any third party any right in respect of any Project Inventions, Data, Material or Foreground Intellectual Property (other than in accordance with the terms of this Agreement), and has not charged or encumbered any of the same;

14.1.5. save as disclosed in the Disclosure Letter, to the best of its knowledge and belief, the Background Intellectual Property and Foreground Intellectual Property are not subject to any claim, opposition, attack, assertion or other arrangements of whatever nature which may impugn upon the use, validity, enforceability or ownership of any such Intellectual Property, and there are no grounds or other circumstances which may give rise to the same;

14.1.6. it has not itself or through any of its staff, collaborators or sub-contractors, disclosed to any third party (other than under appropriate confidentiality obligations) any Confidential Information relating to the Project, nor is it obliged so to do;

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- 14.1.7. to the best of its knowledge and belief, no person has the right to call for the assignment of, grant of a licence to it of or the right to any charge or encumbrance over any Background Intellectual Property, Data, Materials or Foreground Intellectual Property under any option, grant or other agreement, nor is there any conditional or unconditional agreement or circumstance whereby such a right may arise;
- 14.1.8. 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 Background Intellectual Property, Existing Data, Data, Materials or the Foreground Intellectual Property;
- 14.1.9. all activities performed in the Development Plan/Project have been performed in accordance with all applicable laws, regulations and standards including GCP, GLP, GMP and the UK Bribery Act 2010 and FUNDER Policies where applicable;
- 14.1.10. the Partner is the sponsor of all Clinical Trials from which Data was obtained;
- 14.1.11. the Partner has disclosed to FUNDER all adverse information with respect to the safety and efficacy of the Product;
- 14.1.12. the Partner has disclosed to FUNDER all material communications with Regulatory Authorities; any Ethical Committee refusal to grant approval for a Clinical Trial, any suspension of the Clinical Trial, whether initiated by the sponsor, an Ethical Committee, a Regulatory Authority or an investigator, any action or recommendation of a data safety monitoring board to suspend the Clinical Trial, and all findings of any audit for the Clinical Trial for compliance with GCP;
- 14.1.13. none of the Partner, its Affiliates, collaborators and sub-contractors nor any officer or employee of the Partners, its Affiliates, collaborators or sub-contractors has been debarred or is subject to debarment by a Regulatory Authority anywhere;
- 14.1.14. all Escrow Materials required to be placed into escrow in accordance with Clause 9.4 have been; and

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- 14.1.15.all Financial Documents were true, complete and accurate at the date of such document.
- 14.2. Except as expressly provided in this Agreement, neither Party gives any warranties or makes any representations with respect to any of the Foreground Intellectual Property, the Background Intellectual Property or any products derived from them, or their fitness for any purpose, or that any material produced or supplied by either Party and any processes or techniques used, proposed or recommended by either Party will not infringe any patent or other Intellectual Property rights of any person in any country.
- 14.3. **Liability.** The FUNDER Group's maximum liability in aggregate to the Partner arising out of this Agreement shall not exceed the aggregate of the Total Work Phase Budget.
- 14.4. Except as provided by Clause 14.5, neither Party shall be liable to the other Party for indirect loss of profits, 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.
- 14.5. Notwithstanding the foregoing, nothing in this Agreement shall limit the liability of either Party in respect of:
- 14.5.1. personal injury or death arising out of that Party's negligence or wilful misconduct; or
- 14.5.2. fraud or fraudulent misrepresentation or wilful misconduct.
- 14.6. **Third Party Claims.** The Partner agrees to indemnify FUNDER and hold FUNDER harmless from and against any and all claims, damages, and liabilities asserted by third parties (including claims for negligence) ("**Third Party Claims**") which arise directly or indirectly from the use of the Background Intellectual Property, the Foreground Intellectual Property, the Existing Data, the Data or the Material or the Development or Marketing of the Product.
- 14.7. **Conduct of Third Party Claims.** Each of the Parties shall use reasonable endeavours to avoid, dispute, resist, appeal, compromise or defend any Third

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Party Claim brought against it and to minimise its losses, claims, liabilities, costs, charges and expenses and:

14.7.1. The indemnified party shall give the indemnifying Party prompt written notice of any Third Party Claim for which it requires indemnification under this Clause 14.7 together with copies of all relevant papers and official documents;

14.7.2. The Parties shall Confer with the indemnifying Party on how to respond to and handle the Third Party Claim in an efficient manner; and

14.7.3. The indemnified Party shall not take any material action in respect of any Third Party Claim without the consent of the indemnifying Party (such consent not to be unreasonably withheld, conditioned or delayed).

14.8. **Insurance.** The Partner will obtain and continuously maintain the following insurance on a claims arising basis with an insurance company of a credit rating of A or better:

14.8.1. During the period covered by the Development Plan, Clinical Trials Insurance as follows:

- i. if the Clinical Trial is part of a biomedical countermeasure as defined by GHSI (in accordance with the recommendation from the GHSI dated [insert date]), (i) the recipient countries of the Product will be liable for any and all personal injury claims arising from the dosing of human subjects with the Product in the Clinical Trial and will provide compensation mechanisms to those of their citizens and residents receiving the Product as part of the Clinical Trial and (ii) the Partner will obtain and maintain Clinical Trial Cover on a claims arising basis of at least [x million GBP] per claim including non-negligence cover in accordance with the conditions of the Associated British Pharmaceutical Industry agreed wording for any other recipient of the Product as part of the Clinical Trial; and
- ii. if the Clinical Trial is not part of a biomedical countermeasure as defined by GHSI, prior to the commencement of the Clinical Trial, the Partner shall obtain and maintain Clinical Trial Cover on a claims arising basis of at least [x million GBP] per claim including non-negligence cover in accordance with

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the conditions of the Associated British Pharmaceutical Industry agreed wording. Such Clinical Trial Cover to be effective from the commencement date of the Clinical Trial until at least six (6) years after the completion of the Clinical Trial or such longer period as is required by the relevant Ethical Committee.

14.8.2. From the date of the first Marketing Approval or if earlier, first sale to a Public Sector Agency, product liability insurance of at least [GBP y] per occurrence other than in Low Income Countries or Middle Income Countries covered by the WHO product liability insurance; and

14.8.3. During the term of this Agreement and for at least three (3) years afterwards, general commercial liability insurance including contractual liability of at least [GBP z] per occurrence.

14.9. The Partner shall:

14.9.1. Procure that the insurer notes FUNDER's interest on each such insurance policy;

14.9.2. Provide FUNDER with a copy of each such insurance policy and certificate and annually on renewal;

14.9.3. Notify FUNDER of any claims made under these policies relating to the Product or the subject matter of this agreement during the Term and for at least the duration of any applicable statutory period of limitation afterwards; and

14.9.4. Comply with the terms of these insurance policies during the Term and for at least the duration of any applicable statutory period of limitation afterwards.

15. TERM, TERMINATION AND EFFECTS OF TERMINATION

15.1. **Term.** This Agreement shall commence on the Effective Date and shall continue in full force and effect until terminated pursuant to this Clause 15 (the "**Term**").

15.2. **Termination.** Either Party (the "**Terminating Party**") shall have the right to terminate this Agreement forthwith at any time upon giving written notice of

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termination to other Party (the “**Defaulting Party**”), upon the occurrence of any of the following events:

- 15.2.1. the Defaulting Party commits a breach of a material obligation set out in this Agreement which is not capable of remedy;
- 15.2.2. the Defaulting Party commits a breach of a material obligation set out in this Agreement which is capable of remedy but has not been remedied within thirty (30) Business Days of the receipt by it of a notice from the Terminating Party identifying the breach and requiring its remedy;
- 15.2.3. the Defaulting Party is unable or admits inability to pay its debts as they fall due, suspends making payments on any of its debts or, by reason of actual or anticipated financial difficulties commences negotiations with one or more of its creditors with a view to rescheduling any of its indebtedness;
- 15.2.4. a proposal is made or a nominee or supervisor is appointed for a composition in satisfaction of the debts of the Defaulting Party or a scheme or voluntary arrangement of its affairs within the meaning of the relevant bankruptcy or insolvency laws, or the Defaulting Party enters into any composition or voluntary arrangement for the benefit of its creditors, or proceedings are commenced in relation to the Defaulting Party under any law, regulation or procedure relating to the re-construction, deferment or re-adjustment of all or substantially all of the Defaulting Party’s debts;
- 15.2.5. the Defaulting Party takes any action, or any legal proceedings are started whether by a third party or not, for the purpose of the winding up or dissolution of the Defaulting Party, other than for a solvent reconstruction or amalgamation;
- 15.2.6. the appointment of a liquidator, trustee, receiver, administrative receiver, receiver and manager, interim receiver, custodian, sequestrator, administrator or similar officer, in respect of all or a substantial part of the assets of the Defaulting Party;
- 15.2.7. an effective resolution being passed for the winding-up or entering into administration (whether out of court or otherwise) of the Defaulting Party;

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- 15.2.8. a distress, execution or other legal process being levied against all or substantially all of the assets of the Defaulting Party, and not being discharged or paid out in full within ten (10) Business Days of the commencement of each process; or
- 15.2.9. the occurrence in respect of the Defaulting Party of any event in any jurisdiction to which it is subject having an effect similar to that of any of the events referred to in Clauses 15.2.3 to 15.2.8.
- 15.3. In addition, FUNDER shall be entitled to terminate this Agreement with immediate effect by providing written notice to the Partner in the following circumstances:
- 15.3.1. If the Partner takes any action which would be incompatible with or which would have an adverse effect (or by omitting to take any action has or would have a similar adverse effect) on:
- i. FUNDER's Mission or reputation; or
 - ii. the Partner's ability to comply with its obligations under the Agreement;
- 15.3.2. If the Parties are unable to agree a suitable replacement Project Lead within thirty (30) Business Days of the notification referred to in Clause 5.2;
- 15.3.3. If the Site Visit Group recommends termination of any Work Phase or the Project in accordance with Clause 7;
- 15.3.4. Where Site Visit Group recommends termination of any Work Phase or the Project in accordance with Clause 7, and FUNDER (in its sole discretion) elects to allow the Partner a period of time to take corrective action to address any failings identified by the Site Visit Group (if such failings are capable of correction), if the Partner does not correct such failings within the period specified by FUNDER;
- 15.3.5. If the JMAG does not approve the Development Plan or Marketing Activities Plan;
- 15.3.6. If FUNDER, in its sole discretion, elects, or has elected, not to fund any subsequent Work Phase; or

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15.3.7. On a change of Control of the Partner without FUNDER's prior written agreement.

15.4. **Partner Obligations on Termination for Partner Default or Insolvency.** On termination of this Agreement pursuant to Clause 15.2 the Partner shall:

15.4.1. On the Termination Date cease to use the Foreground Intellectual Property for any purpose and cease to exploit the Product anywhere in the anywhere in the World;

15.4.2. Have the right to exhaust supplies of Product then in inventory in performance of its obligations under any agreement for supply with a Public Sector Agency or if no such agreement exists at the Termination Date, immediately transfer ownership of the same to FUNDER at no cost and inform any third party GMP storage facility of the same forthwith;

15.4.3. Use all reasonable endeavours to promptly transfer to FUNDER (or its nominee), at the Partner's cost, any Regulatory Approvals and applications for Regulatory Approvals relating to the Product;

15.4.4. Ship to FUNDER (or its nominee) all Materials within thirty (30) days of FUNDER requesting such Materials;

15.4.5. Provide FUNDER with copies of all sub-license, contract manufacturing agreements and other agreements and arrangement to which it is a party which relate to the Development and Marketing of the Product (the "**Contracts**"), within thirty (30) days of the Termination Date; and

15.4.6. Provided that the termination of this Agreement was not caused directly or indirectly by the sub-licensee or other party to the Contract and that sub-licensee or other party is not then in breach, use all reasonable endeavours to deal with each Contract, at FUNDER's reasonable request, in one of the following ways: (i) assign the benefit (subject to the assumption of the burden) of the Contract to FUNDER or its nominee and, where consent of a third party is required, seek to obtain such consent; (ii) novate the Contract to FUNDER or its nominee; or (iii) terminate the Contract in accordance with its terms at the Partner's cost.

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- 15.5. **Effects of Termination.** Termination of this Agreement howsoever arising shall be without prejudice to the rights and duties of either Party accrued prior to termination. The Clauses in this Agreement which expressly or impliedly have effect after or notwithstanding termination (including Clauses 4 to 16) shall continue to be enforceable notwithstanding termination. The Parties shall not enter into any further Work Phase Statements after the date of termination.
- 15.6. **Effects of Termination prior to the end of a Work Phase.** Upon termination prior to the end of a Work Phase:
- 15.6.1. FUNDER shall not be required to make any further payments to the Partner under this Agreement or any Work Phase Statement;
- 15.6.2. the Partner shall return any of the relevant Work Phase Budget received from FUNDER under this Agreement which is unspent at the date of termination (after deduction of costs and non-cancellable commitments incurred prior to the date of termination) within twenty (20) Business Days after the date of the notice of termination; and
- 15.6.3. where termination is by reason of Clause 15.2, or FUNDER terminates pursuant to Clause 15.3 for reasons other than scientific failure, efficacy failure or safety failure, the Partner will return a sum equal to the full FUNDER Funding that FUNDER has paid to it as at the date of notice of termination (less the unspent funds, which are to be handled in accordance with Clause 15.6.2) to FUNDER within forty (40) Business Days of the notice of termination.
- 15.7. **Clinical Trial Wind-down.** In the event of termination pursuant to Clause 15 where at the date of termination there is an on-going Clinical Trial, unless agreed otherwise by the Parties in writing, the Partner shall procure that no further trial subjects are entered into the Clinical Trial, and the JMAG and TSC shall work together to plan a wind-down of Development activities in an orderly fashion, with due regard for patient safety and the rights of any subjects that are participants in Clinical Trial and in consultation with any relevant Ethical Committee.

16. GENERAL

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- 16.1. **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 authorised representative of that Party. In particular, no delay or failure of either Party in exercising or enforcing any of its rights or remedies under this Agreement shall operate as a waiver of those rights or remedies nor shall any single or partial exercise or enforcement of any right or remedy by a Party preclude or impair any other exercise or enforcement of that right or remedy by that Party.
- 16.2. **Entire Agreement.** This Agreement, including its Schedules attached hereto, together with the Application, and the Work Phase Statements constitutes the entire agreement and understanding between the Parties relating to the subject matter hereof and together they supersede and replace all prior drafts, previous understandings, arrangements, representations or agreements, whether in writing or oral, between the Parties relating to the subject matter of this Agreement. Each Work Phase Statement shall be part of this Agreement and shall not form a separate contract to it.
- 16.3. **Variation.** No variation, amendment, modification or supplement to this Agreement shall be valid unless and until it is made in writing and signed by a duly authorised representative of each Party. Once a Work Phase Statement has been signed by both Parties, no amendment shall be made to it except if the amendment is in writing, has been approved by the JMAG and has been signed by a duly authorised representative of each Party.
- 16.4. **Assignment.** Neither Party shall 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 hereunder to any third party, EXCEPT THAT FUNDER may transfer its rights and obligations to either Wellcome or Gates or an organisation of equivalent charitable mission, if FUNDER considers (in good faith) that FUNDER will not be in a position to fulfil its obligations or exercise its rights in the future.
- 16.5. **Severance of Terms.** If the whole or any part of this Agreement is or becomes or is declared illegal, invalid or unenforceable in any jurisdiction for

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any reason (including both by reason of the provisions of any legislation and also by reason of any court or competent authority which either has jurisdiction over this Agreement or has jurisdiction over either Party):

16.5.1. in the case of the illegality, invalidity or un-enforceability of the whole of this Agreement it shall terminate only in relation to the jurisdiction in question; or

16.5.2. in the case of the illegality, invalidity or un-enforceability of part of this Agreement that part shall be severed from this Agreement in the jurisdiction in question and that illegality, invalidity or un-enforceability shall not in any way whatsoever prejudice or affect the remaining parts of this Agreement, which shall continue in full force and effect.

If in the reasonable opinion of any Party any severance under this Clause materially affects the commercial basis of this Agreement, the Parties shall discuss, in good faith, ways to eliminate the material effect.

16.6. **Costs.** Each Party shall bear its own legal costs, legal fees and other expenses incurred in the preparation, negotiation and execution of this Agreement, the Licences and any Work Phase Statements.

16.7. **Further Assurances.** Each Party shall perform such acts and execute such documents as may be reasonably required for securing to or vesting in the other Party the rights agreed to be granted to it under or pursuant to this Agreement.

16.8. **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 set out below or such other address as a Party may from time to time designate by written notice to the other Party:

Address of the Partner: [INSERT PARTNER ADDRESS]

For the attention of: [NAME OR TITLE]

Address of FUNDER: [XX]

For the attention of: [NAME OR TITLE]

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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.

- 16.9. **Partnership.** Nothing in this Agreement shall be taken to constitute a partnership between the Parties. Except as specifically provided in this Agreement, neither Party shall by reason of this Agreement be empowered to act as agent for the other Party nor to pledge the credit of the other Party nor shall either Party be held liable for or incur liability in respect of the acts or defaults of the other Party to this Agreement.
- 16.10. **Counterparts.** This Agreement may be executed in any number of counterparts and by the Parties on separate counterparts, but shall not be effective until each Party has executed at least one counterpart. Each counterpart shall constitute an original of this Agreement, but all the counterparts shall together constitute one and the same instrument.
- 16.11. **Rights of Third Parties.** Other than Wellcome or Gates, a person who is not a Party has no right under the Contracts (Rights of Third Parties) Act 1999 to enforce or to enjoy the benefit of any term of this Agreement.

17. DISPUTE RESOLUTION, GOVERNING LAW AND JURISDICTION

- 17.1. **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 FUNDER and [Name, Title] of the Partner (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 sixty (60) days of such dispute being escalated to the Senior Officers, then in respect of any dispute, controversy or claim other than those that concern:

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17.1.1. the validity or infringement of Intellectual Property;

17.1.2. anti-trust, anti-monopoly or competition law or regulation; and

17.1.3. breach or threatened breach of Clauses 9, 10, 11 and 13,

the Parties irrevocably submit to arbitration in accordance with Clause 17.2. In respect of disputes relating to Clauses 17.1.1 to 17.1.3, (inclusive), the Parties irrevocably submit to the exclusive jurisdiction of the Courts of England and Wales.

17.2. **Arbitration.** Any disputes to be resolved by binding arbitration pursuant to Clause 17.1 (including any question regarding its existence, validity or termination or this Agreement), shall be referred to and finally resolved by arbitration under the LCIA Rules, 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.

17.3. **Governing Law.** This Agreement (and any dispute, controversy, proceedings or claim of whatever nature arising out of this Agreement or its formation) shall be governed by and construed in accordance with the laws of

_____.

IN WITNESS whereof the Parties through their duly authorised representatives have executed this Agreement.

Signed for and on behalf of [THE PARTNER] by its duly authorised signatory:

Signature:

Name:

Title:

Date:

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DATE:

Signed for and on behalf of **FUNDER** by its duly authorised signatory:

Signature:

Name:

Title:

Date:

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SCHEDULE 1: TEMPLATE WORK PHASE STATEMENT

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DATE:

SCHEDULE 2: PARTNER CONTRIBUTION

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SUBJECT TO CONTRACT

DRAFT:

DATE:

SCHEDULE 3: APPLICATION

SUBJECT TO CONTRACT

DRAFT:

DATE:

SCHEDULE 4: BACKGROUND INTELLECTUAL PROPERTY

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DATE:

SCHEDULE 5: PRE-CLINICAL WORK PHASE STATEMENT

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DATE:

SCHEDULE 6: DRAFT DEVELOPMENT PLAN