Request for Proposal – Evaluation of Reagents and Standards for Epidemic Diseases

Issued: 1st November 2019

1. Introduction

The Wellcome Trust (the 'Trust', 'Wellcome') is the world's second highest spending global charitable foundation, and a unique scientific and cultural institution of global significance, scale and achievement. It is both politically and financially independent. Wellcome supports researchers, takes on big problems and sparks debate to improve health on a global level. Our funding supports over 14,000 people in more than 70 countries in exploring ideas, seeking solutions and improving the human condition through science, population health, medical innovation, the humanities and social sciences and public engagement. Further information on Wellcome can be found at www.wellcome.ac.uk. All prospective suppliers are encouraged to visit the website to gain an insight into the organisation, particularly our epidemics hub: https://wellcome.ac.uk/hubs/epidemics.

As part of our mission, we are working proactively to tackle some of the world's biggest health challenges. We are building on experience gained from funding research responses in recent epidemics (Ebola - 2014-16 in West Africa and 2018-19 in DRC, Zika – 2015-16 in Brazil and ongoing Lassa outbreaks in Nigeria), and efforts to coordinate R&D for medical countermeasures against these diseases (WHO R&D Roadmaps for Ebola/ Marburg, Lassa and Nipah) to develop a suite of epidemic preparedness activities to support global preparedness efforts.

2. RfP Specification and Research questions

In recent years, Wellcome has focussed heavily on supporting research responses during outbreaks, whilst also continuing to support the development of new medical countermeasures for diseases, such as vaccines and therapeutics. However, Wellcome recognises that there are aspects of the epidemics ecosystem which can act as a barrier to these efforts, with the lack of reagents and standards for epidemic diseases posing one such hurdle.[1] Reagents and standards, such as antibodies, antigens, and PCR reagents, are needed to develop new or improved vaccines, therapeutics and diagnostics and strengthen disease surveillance.

The lack of, and levels of variation (E.g. type, quality etc) between, reagents and standards for many epidemic-prone diseases currently represents a significant barrier to preparedness efforts and the development of new tools to combat diseases. Wellcome is considering how it can best act in this area to facilitate the provision of reagents and standards for diseases of epidemic potential. **To inform this process, we seek to better understand the availability and quality of existing reagents and standards, and factors (drivers, barriers and gaps) affecting generation of these materials.**

[1] https://wwwnc.cdc.gov/eid/article/25/2/18-0798_article

Specification

We are asking the supplier to systematically evaluate the availability and generation of reagents and standards for epidemic-prone diseases (Appendix 1). The supplier should identify and define the different types (E.g. antigen, antibodies, nucleic acids) and tiers (Degree of development and characterisation, E.g. primary/ international reference/ working/ secondary etc) of reagents and standards available for each of the diseases in Appendix 1. We are also asking the supplier to examine systemic factors which affect the development, generation and use of these materials. We have outlined research themes below which the supplier should use as guidance when conducting the evaluation.

Methods:

- Review available literature and existing product specifications including the types and tiers of reagents and standards currently available
- Key informant interviews with experts from WHO group on biologics Technology Standards and Norms, as well as the WHO Collaborating Centres for Biological Standardisation[2] (E.g. NIBSC, CBER, PEI etc), National Control Laboratories (eg NIFDC (China), NIFDS (Republic of Korea), TGA (Australia), NIID (Japan), BGTD (Canada) etc, vaccine, diagnostics or therapeutics manufacturers, and other key fields
- Evaluate the availability and quality of existing materials for Appendix 1 diseases according to the research themes listed below
- Review the systemic issues that may affect the production of, and access to, these reagents and standards.

Output: The project findings should form a report which is of use to the global public health and research communities by outlining which materials are available to support the development of vaccines, therapeutics or diagnostics for each of the diseases listed in Appendix 1, and identifying any gaps or materials which would accelerate R&D of these medical countermeasures. We would expect the findings to be adapted for publication in peer-reviewed scientific journals.

Research themes:

a. **Availability, Quality and Use:**
   Of the diseases listed in Appendix 1,
   i. Which have reagents and standards available, which are currently under development or qualification, and which still require generation? (Availability)
   ii. Identify and describe ongoing work or upcoming plans to develop reagents and standards where these are not yet available.
   iii. How extensively have the available materials been characterised and endorsed? Is their identity, purity and potency well-defined? (Quality)
   iv. What tier (working or secondary – international) of reagents and standards are available for each disease and type of material? This should include a breakdown of the different types of materials as appropriate (Antibody, Antigen, Nucleic acids etc)

[2] https://www.who.int/biologicals/collaborating_centers/en/

v. What are the sources (i.e. blood, serum, cells etc) / who are the main providers of these materials?
vi. When available, are reagents and standards used? What factors affect their use?

b. **Value to research & development of medical countermeasures:**
   i. How does the availability, quality and level of characterisation of materials affect the development of medial countermeasures? How does the absence of these materials impact R&D? Are shared reagents and standards always necessary for the development of medical countermeasures?
   ii. What assays are used in the vaccines/ therapeutics/ diagnostics development pathway and which reagents and standards are needed for these?
   iii. Are there instances where creation of a reference hinders R&D of different medical countermeasures from competing manufacturers?

c. **Coordination, drivers and barriers**:
   i. How is the development and endorsement of reagents and standards coordinated? This should look at existing structures and organisations involved in this space (WHO, WHO Norms & Standards department, ECBS, IABS, NIBSC, others), in addition to funding organisations and systems (CEPI, BMGF, Wellcome, others)
   ii. What networks or processes exist to support the sharing and use reagents and standards? Who coordinates this?
   iii. What are the drivers behind, and barriers to, the generation of reagents and standards for epidemic diseases? E.g. coordination of stakeholders and processes, acquisition of source material or clinical samples, ethics, ownership and benefits sharing, operational issues etc.
   iv. Is, or could, the development of reagents and standards be integrated into vaccine/ therapeutic/ diagnostic development programs?

d. **Disease X:**
   i. What systems and processes are in place now to ensure reagents and standards can be rapidly generated in the event that an unknown disease emerges? Are these sufficient for a response to an emerging epidemic or are better policies, regulatory systems or processes for the development of reference standards required?

Proof of Concept: Source material or Clinical Sample Acquisition Study for reagents/ standards generation

e. **Proof of concept:**
   i. What would a model process for the acquisition of clinical/ microbiological samples and generation of reagents and standards be? Using the learnings from the themes and issues identified above, particularly the findings on coordination, drivers and barriers and benefit sharing issues, develop and propose a proof of concept source material (SMAS), or clinical sample, acquisition study (CSAS) which would provide a model for the acquisition of

clinical/ microbiological samples and pathway to the generation of reagents and standards for epidemic diseases.

3. Governance

The successful supplier will be supported to work in different locations if required (E.g. at WHO in Geneva etc) and depending upon what is most convenient. The successful supplier will report to Peter Hart (Wellcome Epidemics Project Officer) on a day-to-day basis and will ultimately be accountable to the below panel who will provide guidance and direction throughout the project.

Steering panel

- Josie Golding – Programme Manager, Epidemics (Wellcome)
- Peter Hart – Project Officer, Epidemics (Wellcome)
- Cathy Roth – Senior research fellow, Department for International Development (UK Government)
- Jennifer Stuart – Head of the Vaccines Project, Department of Health and Social Care (UK Government)
- Paul Kristiansen – Head of Biological standards and assays (CEPI)
- Stacey Efstathiou – Affiliate Lecturer (University of Cambridge)

Wellcome will provide the successful supplier with the following sources of information and relevant stakeholder connections where feasible for the duration of the review and evaluation, to help them complete the project;

- A top-line briefing on the history to the project including details of discussions with relevant parties and sources of information
- A list of networks, stakeholders and meetings relevant to epidemics and the planned project
- Access to panel for input requests and/or project guidance

4. Deliverables

A. An **inception report**, which will confirm:

- The detailed scope of work;
- The final list of research themes/ topics/ questions to be pursued;
- The proposed methodology for answering these questions;
- The supplier's proposals for collecting, managing, analysing and reporting on data;
- The milestones within the study, between the completion of the inception report and the delivery of the draft final report.

We will communicate with the successful supplier to help them develop the inception report.

B. A **full report** that addresses the project specification outlined above and an executive summary. We are open to discussions with suppliers on appropriate timeframes for this work. The full report will be delivered in two stages:

   i. A **draft final report**, which will be shared with the panel and Wellcome in advance of the end date to allow Wellcome staff and panel members time to discuss feedback, raise questions, and make recommendations for further improvement.

   ii. A **final report**: a clean and final copy which will be delivered two weeks after the receipt of feedback from Wellcome. This final report will contain recommendations, based on the research conducted against the specified questions and sub-questions, for Wellcome's consideration.

C. A **presentation of the findings** to the steering panel (detailed above)

We expect that no more than 1-2 Full-Time Equivalents (FTEs) are required in order to produce these.

5. Response Format

Candidate suppliers should note that there is a degree of flexibility in the RfP Scope (I.e. research areas or diseases of focus), timelines and the number of FTEs. Wellcome is open to further discussion on these, in order to ensure the project is able to deliver a meaningful and high-quality piece of work.

RfP Documents

We advise potential suppliers to note/ read the following documentation to guide their response to this RfP:

- Response Template (Appendix 2)
- Contractual agreement (Appendix 3): draft contractual agreement to be used with the successful supplier. For information only.
- Contract feedback sheet (Appendix 4): For suppliers to provide a response to the proposed contractual agreement as part of their response to the RfP.
- Third Party Security Risk Assessment (Sent separately): To assess how the supplier manages and protect data. Wellcome's Information Governance team will send this document separately via email.

Expression of interest, and referees

All suppliers are asked to submit an initial expression of interest (in the form of a short email), declare any potential conflicts of interest, and provide two referees who Wellcome can contact as part of the RfP process, to Peter Hart (contact details below) by the date listed in the timeline below.

When providing referees, please notify them in advance and include their contact name, organisation, brief overview of work provided, email address & telephone number (including

country code) to Wellcome. Please see the Wellcome Privacy Statement for more on our commitment to safeguarding personal information in accordance with data protection law.

Written Proposal

After submitting the expression of interest and referees, and following invitation from Wellcome, suppliers are required to submit a written proposal using the response template (Appendix 2) which details to Wellcome the following five elements;

1) A brief overview of your organisation, including your track record and expertise relevant to this RfP. We are particularly looking for experience and knowledge in fields of reagents/ standards development or coordination, clinical research, epidemics, health policy and/or health research. (max 350 words)
2) A brief overview of your organisation's track record in this area, with an emphasis on the evaluation of research and research impact. (max 350 words)
3) Your proposed approach to this evaluation (max 750 words)
4) Your team roster and CV for each member, to help us assess their individual track records and expertise as relevant to this evaluation. Please see the Wellcome Privacy Statement for more on our commitment to safeguarding your personal information in accordance with data protection law.
5) A breakdown of costs associated with the project, in Excel format, which detail and justify the proposed costs. This should include details of the hourly rate and number of hours to be contributed by each member of the evaluation team.

6. Assessment and selection criteria

Suppliers' responses will be assessed, along with the references received by panel. They will use a balanced scorecard which includes the following criteria:

- Evidence of expertise in health policy and/or health research, particularly in reagents and standards and the development of medical countermeasures such as vaccines and therapeutics for epidemic diseases, both on the part of the supplier organisation and the individual members of the supplier's proposed evaluation team (30% weighting);
- Evidence of a strong track record as demonstrated by similar work, both on the part of the supplier organisation and the individual members of the supplier's proposed evaluation team (20% weighting);
- The strength of the proposed approach to this evaluation, including an understanding of the central aims and purpose of the project, and selection of appropriate and consultative methodology (35% weighting);
- The justification and value for money for the proposed costs (15%).

7. Timetable

The timelines for this RfP exercise, including deadlines for suppliers, are detailed below. These timelines are subject to change but provided to give the supplier an indication of the various stages of the project.

#	**Activity**	**Responsibility**	**Target Date (2019)** Provisional dates only - these may be subject to change
1	Issue RfP to suppliers RfP document circulated to Supplier representatives for review.	Wellcome	1st Nov 2019
2	Supplier declares intention to respond to RfP to the Wellcome contact. Suppliers will indicate their intention to respond to the RfP along with queries regarding the RfP process. Wellcome contact will also be available to discuss via phone if needed.	Supplier	10th Nov 2019
3	Response to suppliers & invitation to submit a written proposal Wellcome to answer questions submitted by suppliers and invite suitable suppliers to submit written proposal for consideration.	Wellcome	13th Nov 2019
4	Submission of written proposal Supplier submits full written proposal using response template in Appendix 2, including cost breakdown. Supplier also to submit contract queries using contract feedback template (Appendix 4.)	Supplier	27th Dec 2019
5	Notification of shortlisted suppliers & invitation to present proposal Wellcome will notify Suppliers of whether they have been shortlisted to present to the RASE panel. At this stage dates and times of presentations will be agreed with shortlisted suppliers.	Wellcome	TBC
6	Interviews Shortlisted suppliers will present to the RASE panel via remote/ in person interviews.	Supplier	TBC
7	Notification of Contract Award to successful supplier Wellcome will notify Suppliers of their outcome from the RfP process and agree next steps.	Wellcome	TBC
8	Contract Negotiation This stage sees the contract negotiated and finalised.	Both	TBC
9	Proposed Contract Start Date Follows agreement of contract; initial meeting to discuss inception report	Both	TBC
10	Inception report completion and approval date	Supplier	
11	Mid-point check-in	Both	TBC
12	Draft final report Submission Date	Supplier	TBC

13	Wellcome response to draft final report	Wellcome	TBC
14	Final report Submission Date, with any amendments	Supplier	TBC
15	Presentation to Wellcome by the supplier	Supplier	TBC
16	Proposed Contract End Date	Both	TBC

8. Non-Disclosure and Confidentiality

Prospective suppliers should be aware that inappropriate publicity could have a serious effect upon Wellcome's business. The information contained within this document or subsequently made available to prospective suppliers is deemed confidential and must not be disclosed without the prior written consent of Wellcome unless required by law.

9. Independent Proposal

By submission of a proposal, prospective suppliers warrant that the prices in the proposal have been arrived at independently, without consultation, communication, agreement or understanding for the purpose of restricting competition, as to any matter relating to such prices, with any other potential supplier or with any competitor.

10. Costs Incurred by Prospective Suppliers

It should be noted that this document relates to a Request for Proposal only and not a firm commitment from Wellcome to enter into a contractual agreement. In addition, Wellcome will not be held responsible for any costs associated with the production of a response to this Request for Proposal.

11. Wellcome Contact Details

The single point of contact within this RfP exercise for all communications is as indicated below;

Name: Peter Hart
Role: Project Officer, Epidemics
Email: epidemics@wellcome.ac.uk

Appendix 1.
List of pathogens/ disease for evaluation

Ebola/ Marburg virus disease
Lassa fever
Middle East and Severe Acute respiratory syndromes (MERS-CoV and SARS)
Nipah and Hendra viruses
Rift Valley Fever
Crimean Congo Haemorrhagic Fever (CCHF)
Chikungunya
Severe Fever with Thrombocytopenia Syndrome (SFTS)
Zika
Disease X

Appendix 2.
Response Template

Question	Response
Section 1: Contact information. Please see the Wellcome Privacy Statement for more on our commitment to safeguarding your personal information in accordance with data protection law.	
Please provide contact details for the main point of contact for this consultancy assignment:	
Name of company:	
Named contact:	
Position:	
Address:	
Email:	
Telephone:	
Section 2: Relevant experience and skills	
Brief overview of your organisation, including track record and expertise relevant to this RfP. We are particularly looking for experience and knowledge in fields of epidemics, clinical research, health policy and/or health research. (max 350 words)	
Brief overview of your organisation's past record on similar work, with an emphasis	

on the evaluation of research and research impact. (max 350 words)	
Section 3: Approach	
Please provide an outline of your proposed approach to this evaluation (max 750 words)	
Section 4: People	
Please provide a short summary of the people who would be assigned to this piece of work and their key skills, including CVs (either in the field to the right, or as a separate file).	

Appendix 3.
Wellcome General Terms and Conditions

Wellcome General Terms and Conditions

1. **APPLICATION AND INTERPRETATION OF GENERAL TERMS AND CONDITIONS**

1.1 **These General Terms and Conditions shall apply to any contract or agreement to which they are stated to apply, including the Agreement. They shall apply to the entire exclusion of all other terms and conditions except those which are expressly referred to in the Agreement.**

1.2 **Any terms or conditions contained in the Supplier's quotation, acknowledgment or acceptance of order, specification or proposed by the Supplier in any other way shall not form part of the Agreement and the Supplier agrees that it shall not rely on such terms and conditions.**

1.3 In these General Terms and Conditions, references to any statute or statutory provision shall, unless the context otherwise requires, be construed as a reference to that statute or provision as from time to time amended, consolidated, extended, re-enacted or replaced, and shall include all subordinate legislation made under that statute or statutory provision. The headings in these General Terms and Conditions do not affect their interpretation.

1.4 The Agreement shall be read and interpreted according to the following descending order of priority: (i) the Order (ii) any Supplementary Terms and Conditions (iii) the General Terms and Conditions.

2. **COMMENCEMENT AND DURATION**

The Agreement shall commence on the date when it has been entered into by both Parties (**Commencement Date**) and shall continue, unless terminated earlier in accordance with Clause 14, until both Parties have discharged their obligations under the Agreement when it shall terminate automatically without notice.

3. **PERFORMANCE**

3.1 Any services supplied under the Agreement shall: (i) be carried out with reasonable skill, care and diligence and otherwise in accordance with the standards reasonably to be expected of a competent service provider and best industry practice by appropriately skilled and qualified personnel; (ii) be carried out by the personnel stated in the Order (where applicable); iii) be carried out at the times and on the dates (where applicable) and within the time frame specified in the Agreement; and (iv) conform to the description, specification and any other particulars stated in the Agreement.

3.2 Any goods supplied under the Agreement shall: (i) conform to the description, specification and quantity stated in the Agreement; (ii) comply with all statutory requirements that are in force at the time of delivery of the goods; and (iii) be delivered in accordance with the requirements for delivery set out in the Order.

3.3 If the Deliverables are not delivered on the due date then, without prejudice to any other rights which it may have, Wellcome may:

i) agree to delivery of the Deliverables on an alternative delivery date;

ii) cancel the Order in whole or in part;

iii) refuse to accept any subsequent delivery, or further performance or execution of the Deliverables which the Supplier attempts to make;

iv) recover from the Supplier any expenditure reasonably incurred by Wellcome in obtaining deliverables in substitution from another supplier;

v) claim damages for any reasonable additional costs, loss or expenses incurred by Wellcome which are in any way attributable to the Supplier's failure to deliver, execute or perform the Deliverables on the due date.

4. **RISK, PROPERTY, ACCEPTANCE AND REJECTION**

4.1 Risk in any Deliverables that are goods shall, without prejudice to any other rights or remedies of Wellcome, pass to Wellcome at the time of acceptance of the delivery of the goods at Wellcome. Title shall pass to Wellcome upon payment in full of the Charges.

4.2 Wellcome shall not be taken to have accepted any Deliverables until it has had ten (10) Business Days after delivery to inspect them. During this period and without prejudice to any other rights Wellcome may have under the Agreement, any goods supplied under the Agreement that are damaged or have suffered damage during manufacture which could not reasonably be discerned from inspection on delivery, or which are otherwise not in accordance with the Agreement, shall be returnable to the Supplier, whereupon Wellcome shall have the option to either accept a replacement or terminate the Agreement in accordance with Clause 14.1 i).

4.3 Following the period stated in Clause 4.2, and without prejudice to any other rights Wellcome may have under the Agreement, where any Deliverables fail to conform to the description and/or specification stated in the Agreement, or are otherwise in breach of the Agreement, Wellcome may by written notice to the Supplier reject all or any of the Deliverables and the Supplier shall at Wellcome's option either repair or replace Deliverables that are goods or rectify Deliverables that are services or works rejected by Wellcome with goods, services or works (as the case may be) which in all material respects conform to the Agreement, or otherwise promptly credit Wellcome with the invoiced price of the non-confirming Deliverables.

5. **PRICE AND PAYMENT**

5.1 The Charges shall remain firm for the duration of the Agreement.

5.2 On completion of delivery of the Deliverables or as otherwise set out in the Order, the Supplier shall invoice Wellcome for the Charges. Wellcome shall pay the Supplier the total amount of Value Added Tax (VAT) properly chargeable on the supply of the Deliverables upon receipt of a tax invoice in accordance with Regulations 13-14 of the VAT Regulations 1995.

5.3 If the invoice is one which, under the Agreement, the Supplier was entitled to submit and it is a valid and correct invoice and the Deliverables have been provided to the satisfaction of Wellcome, the final date for payment of an invoice by Wellcome shall be twenty (20) Business Days from receipt by Wellcome of that invoice.

5.4 If a Party fails to make any payment due to the other Party under this Agreement by the due date for payment, then without limiting the other Party's remedies, the defaulting Party shall pay interest on the overdue amount at the rate of 4% per annum above the Bank of England's base rate from time to time. Such interest shall accrue on a daily basis from the due date until actual payment of the overdue amount, whether before or after judgment. The defaulting Party shall pay the interest together with the overdue amount.

6. **RIGHTS OF SET-OFF**

Wellcome may set off against, or deduct from, any payment due by Wellcome to the Supplier any sums that the Supplier owes to Wellcome.

7. **DATA PROTECTION**

7.1 Each Party shall, and shall procure that its personnel, comply with any notification requirements under the Data Protection Act 1998 (**DPA**) and both Parties will observe all their obligations under the DPA which arise in connection with the Agreement.

7.2 Where either Party is processing Personal Data (as defined in the DPA) which is provided by or on behalf of the other Party, the processing Party shall only process such data for the purposes of the Agreement and shall implement appropriate technical, organisational and contractual measures to protect against: (i) unauthorised or unlawful processing of the Personal Data; and (ii) accidental loss or destruction of, or damage to, the Personal Data, as required under the DPA's Seventh Data Protection Principle. Each Party shall promptly notify the other of any breach of this Clause 7 or any request or complaint it receives relating to the other Party's Personal Data.

7.3 The Supplier shall permit Wellcome to carry out checks on the Supplier's information security arrangements on reasonable notice and shall provide such information as Wellcome may at any time reasonably request to confirm that the Supplier is in compliance with the DPA.

8. **CONFIDENTIALITY**

8.1 Each Party undertakes that it shall not at any time during the Agreement, and for a period of two (2) years after termination of the Agreement, disclose to any person any Confidential Information of the other Party or of any member of the group of companies to which the other Party belongs, except as permitted by Clause 8.2.

8.2 Each Party may disclose the other Party's Confidential Information: (i) to its employees, officers, representatives or advisers who need to know such information for the purposes of carrying out the Party's obligations under the Agreement. Each Party shall procure that its employees, officers, representatives or advisers to whom it discloses the other Party's Confidential Information comply with this Clause 8; and (ii) as may be required by law, a court of competent jurisdiction or any governmental or regulatory authority; and (iii) with the prior written consent of the other Party.

8.3 Neither Party shall use the other Party's Confidential Information for any purpose other than to perform its obligations under the Agreement.

9. **INTELLECTUAL PROPERTY**

9.1 The Background Intellectual Property belonging to each Party shall remain vested in the Party owning it.

9.2 Each Party shall grant, or shall use reasonable endeavours to procure the grant of, all such licences to the other Party to use its Background Intellectual Property as are necessary to allow that other Party to use the Foreground Intellectual Property.

9.3 All Foreground Intellectual Property shall become the property of Wellcome on its creation and the Supplier irrevocably assigns, and shall procure the assignment of, any existing and future Foreground Intellectual Property Rights to Wellcome with full title guarantee and free from third party rights or encumbrances. The Supplier waives any and all of its moral rights in relation to the Foreground Intellectual Property.

9.4 Wellcome grants a licence to the Supplier to use the Foreground Intellectual Property free of charge and royalty and on a non-exclusive, worldwide basis to the extent necessary for the Supplier to perform its obligations or exercise its rights under the Agreement. The licence granted under this Clause 9.4 will automatically terminate on the termination or expiry of the Agreement.

9.5 Neither Party shall use the name, logo, trademarks or other brand collateral of the other Party without the owning Party's prior written consent.

9.6 The Supplier warrants and undertakes to Wellcome that:

i) the manufacture, creation, supply and use of the Deliverables will not in any way constitute an infringement or other violation of any IP Rights of any third party;

ii) it owns or has obtained valid licences of all IP Rights which are necessary to the performance of any of its obligations under the Agreement;

iii) the IP Rights in the Deliverables created by the Supplier are and will be original and have not and will not be licensed or assigned to any third party, save as requested or approved by Wellcome in writing; and

iv) it shall assign or grant a licence to use, as the case may be, to Wellcome upon request, all such rights as it may have under any third party agreement (where applicable) as may be necessary for Wellcome's use of the Deliverables.

10. **INDEMNITY**

Unless otherwise stated in the Order, the Supplier shall indemnify, keep indemnified and hold harmless, Wellcome in respect of any and all damages, costs, claims, liabilities, expenses, losses (excluding indirect or consequential loss) and demands incurred by Wellcome, as a result of the Supplier's breach of Clause 9.6 i) of this Agreement or as a result of personal injury or death caused by the Supplier's negligence.

11. **INSURANCE**

The Supplier warrants and undertakes to Wellcome that it has obtained and shall maintain in force for the term of the Agreement and for the period of 12 months after its termination, all relevant policies of insurance necessary or prudent for it to obtain in providing the Deliverables. The Supplier shall provide Wellcome with evidence of such policies of insurance on reasonable request.

12. **SUPPORTING INFORMATION**

Wellcome (and its authorised representatives) may request copies of the Supplier's records relevant to this Agreement at any time on reasonable prior written notice for purposes of assessing the Supplier's performance under the Agreement.

13. **HEALTH, SAFETY AND ENVIRONMENT**

When on Wellcome premises, the Supplier agrees to comply with Wellcome's health and safety and environment policies and associated guidance including Wellcome Health, Safety and Environment: Information and Guidelines for Contractors, which shall be provided by Wellcome, where applicable.

14. **TERMINATION**

14.1 Without affecting any other right or remedy available to the Parties, the Agreement may be terminated with immediate effect:

i) by either Party on written notice to the other Party where the other Party commits a breach of warranty or any other material breach of any term of the Agreement and (if such breach is remediable) fails to remedy that breach within twenty (20) Business Days of being notified to do so;

ii) by Wellcome on written notice to the Supplier where the Supplier repeatedly breaches any of the terms of the Agreement in a way that reasonably suggests it has no intention of giving effect to the terms of the Agreement;

iii) by Wellcome on written notice to the Supplier where the Supplier (a) suspends or ceases, or threatens to suspend or cease, carrying on all or a substantial part of its business; (b) is unable to pay its debts as they fall due; (c) enters liquidation or winding up except for the purpose of a bona fide merger acquisition, reconstruction or amalgamation; or (d) circumstances arise which entitle a court or a creditor to appoint a receiver, a manager or administrator over the Supplier or over any or all of the Supplier's business or which entitle a court to make a winding-up order (except for the purpose of a bona fide merger, acquisition, reconstruction or amalgamation).

14.2 Without affecting any other right or remedy available to it, Wellcome may terminate the Agreement for convenience on giving not less than ten (10) Business Days' written notice to the Supplier provided that Wellcome shall pay the Supplier for all Deliverables delivered or completed in accordance with the Agreement (but not already paid for) at the termination date; or if not due to be delivered or completed at the termination date, a fair and reasonable sum in respect of the progress made by the Supplier on the Deliverables as at the termination date.

15. **CONSEQUENCES OF TERMINATION**

15.1 On termination of the Agreement:

i) the Supplier shall immediately cease all work and return all Wellcome property, including all Wellcome Data which the Supplier shall (at Wellcome's option) either return or delete;

ii) Wellcome may reject all or any part of the Deliverables and where possible return them to the Supplier at the risk and cost of the Supplier on the basis that a full refund for the Deliverables so returned shall be paid forthwith by the Supplier; and

iii) the Supplier shall within twenty (20) Business Days of the date of termination refund to Wellcome all prepaid Charges for Deliverables yet to be provided under the Order.

15.2 On termination or expiry of the Agreement Clauses 7, 8, 9, 10, 11, 14.2, 15, 16 and Clauses 19-24 inclusive shall continue in force.

16. **APPLICABLE LAW AND POLICY**

In obtaining the Agreement, the Supplier warrants that neither it nor any Supplier personnel has done, and in performing its obligations under the Agreement, shall not do, any act or thing that contravenes any Wellcome policy, standards or guidelines or any applicable laws and/or regulations, including but not limited to the Bribery Act 2010.

17. **FORCE MAJEURE**

Neither Party shall be in breach of the Agreement nor liable for delay in performing, or failure to perform, any of its obligations under the Agreement if such delay or failure results from a Force Majeure Event. In such circumstances the affected Party shall be entitled to a reasonable extension of the time for performing such obligations. If the period of delay or non-performance continues for ten (10) Business Days, the Party not affected may terminate the Agreement by giving five (5) Business Days written notice to the affected Party.

18. **ASSIGNMENT AND OTHER DEALINGS**

18.1 The Supplier shall not assign, transfer, sub-contract or similarly deal with any of its rights and obligations under the Agreement without Wellcome's prior written consent (which Wellcome may withhold in its absolute discretion).

18.2 If the Supplier is permitted to assign or subcontract any of its obligations under the Agreement the assignment or subcontract shall not relieve the Supplier of its obligations to Wellcome under the Agreement.

18.3 Wellcome may assign or transfer any of its rights or obligations under the Agreement to another company within the Wellcome group and may subcontract any of its rights or obligations under the Agreement.

19. **ANNOUNCEMENTS AND PUBLICITY**

Unless otherwise provided for in this Agreement, the Supplier shall not make, or permit any person to make, any public announcement concerning the Agreement or the Deliverables without the prior written consent of Wellcome.

20. **NOTICES**

20.1 Any notice given to a Party under or in connection with the Agreement shall be in writing addressed to the Party representative named in the Order and shall be delivered by hand or by pre-paid first-class post or other next working day delivery service at its registered office or its principal place of business (where the organisation is not a limited company), or sent by email including text in the subject line of the e-mail identifying the contents of the email as a formal notice given under the Agreement. Notice of any proceedings or other documents in any legal action may not be served by way of email.

20.2 The contact names and addresses for service of a notice (which may be amended by notice from time to time) are set out in the Order.

20.3 Any notice shall be deemed to have been received (i) if delivered by hand, on signature of a delivery receipt or (ii) if sent by pre-paid first-class post or other next working day delivery service, at 9.00 am on the second Business Day after posting or (iii) if sent by email, on the Business Day of sending the notice to the correct email address (as provided by the intended recipient Party) if sent between 09.00 and 17.00 on a Business Day or on the following Business day if sent after 17.00.

21. **ENTIRE AGREEMENT**

21.1 The Agreement constitutes the entire agreement between the Parties and supersedes and extinguishes all previous agreements, promises, assurances, warranties, representations and understandings between them, whether written or oral, relating to its subject matter.

21.2 Each Party acknowledges to the other that it has not been induced to enter into this Agreement by any representation, warranty or undertaking by or on behalf of the other Party or any other person save for those contained in the Agreement.

22. **GENERAL**

22.1 No variation of the Agreement shall be effective unless it is in writing and signed by the Parties' authorised representatives.

22.2 No failure or delay by a Party to exercise any right or remedy provided under the Agreement or by law shall constitute a waiver of that or any other right or remedy, nor shall it prevent or restrict the further exercise of that or any other right or remedy.

22.3 If any provision or part-provision of the Agreement is or becomes invalid, illegal or unenforceable, it shall be deemed modified to the minimum extent necessary to make it valid, legal and enforceable. If such modification is not possible, the relevant provision or part-provision shall be deemed deleted. Any modification to or deletion of a provision or part-provision under this Clause shall not affect the validity and enforceability of the rest of the Agreement.

22.4 Each right or remedy of Wellcome under the Agreement is in addition and without prejudice to any other right or remedy of Wellcome, whether under the Agreement or at common law or under statute, and in no way limits these other rights.

22.5 Nothing in the Agreement is intended to, or shall be deemed to, establish any partnership or joint venture between the Parties, constitute any Party the agent, worker or employee of another Party, or authorise any Party to make or enter into any commitments for or on behalf of any other Party and neither Party shall hold itself out as such.

22.6 No term of the Agreement may be enforced by a third party solely by virtue of the Contracts (Rights of Third Parties) Act 1999.

23. **DISPUTE RESOLUTION**

The Parties shall attempt in good faith to resolve any dispute arising out of this Agreement, within ten (10) Business Days of a Party giving notice of such a dispute to the other Party, through negotiations between the Parties' representatives as referred to in the Order. If the dispute is not resolved within that time, the dispute shall be referred to a more senior officer from each Party who shall have a further ten (10) Business Days within which to resolve the dispute. If the dispute still remains unresolved ten (10) Business Days after referral to senior officers, the dispute shall be resolved in accordance with Clause 24.

24. **GOVERNING LAW AND JURISDICTION**

The construction, validity and performance of this Agreement shall be exclusively governed by the laws of England and Wales and the Parties submit to the exclusive jurisdiction of the Courts of England and Wales.

DEFINITIONS

Agreement: together, these General Terms and Conditions, an Order, any amendments to these General Terms and Conditions and any Supplementary Conditions set out in the relevant Order, and any annexes attached to the relevant Order.

Background Intellectual Property: any Intellectual Property, other than Foreground Intellectual Property, owned by a Party or over which a Party has rights, which is expressly made available by Wellcome or the Supplier under the Agreement.

Business Day: a day other than a Saturday, Sunday or public holiday in England when banks in London are closed for business, excluding days nominated by Wellcome on reasonable notice for planned closure of its offices.

Charges: the charges for the Deliverables set out in the Order.

Confidential Information: the content of the Agreement and any information, including Wellcome Data, in whatever form (including in written, oral, visual or electronic form or on any magnetic or optical disk or memory and wherever located) relating to the business, suppliers, products, affairs and finances, business proposals of either Party for the time being confidential to a Party and trade secrets or commercially-sensitive information including technical data and know-how relating to a Party's business or any of their suppliers, customers, agents, distributors, shareholders, management or business contacts and including information that the Supplier creates, develops, receives or obtains in connection with the Agreement, whether or not such information (if in anything other than oral form) is marked confidential.

Deliverables: the goods and/or services to be supplied, or the work(s) to be undertaken, by the Supplier described in the Order, as applicable.

Force Majeure Event: any circumstances beyond the reasonable control of either Party and which occur after the date of the Order (or, if earlier, the date on which the Supplier commenced providing the Deliverables) and whose effects are not capable of being overcome without causing unreasonable expense or loss to the Party affected. Force Majeure will include but not be limited to: war and other hostilities, riots, fire, flood, earthquake or other natural disaster or act of God, civil disturbance, terrorist activity, interruption or failure of utility service, disease epidemic or pandemic. A Force Majeure Event will not include any industrial action occurring within the Supplier's (or any sub-contractor of the Supplier) organisation.

Foreground Intellectual Property: any and all Intellectual Property arising from, made, conceived, generated, developed or first reduced to practice (in whole or in part) by Wellcome or the Supplier in connection with the Agreement.

IP Rights: patents, rights to inventions, copyright and related rights, moral rights, trademarks and service marks, business names and domain names, rights in get-up, goodwill and the right to sue for passing off, rights in designs, rights in computer software, database rights, rights to use, and protect the confidentiality of confidential information (including know-how and trade secrets) and all other intellectual property rights, in each case whether registered or unregistered and including all applications and rights to apply for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world and the term "**Intellectual Property**" shall be construed accordingly.

Order: either the Order for Procurement of Deliverables or the purchase order, as applicable.

Order for Procurement of Deliverables: any front sheet to these General Terms and Conditions entitled "Order for Procurement of Deliverables".

Party: either of Wellcome and the Supplier and in the plural both of them.

Supplementary Terms and Conditions: means any supplementary terms and conditions referred to in the Order.

Supplier: means the organisation, firm or company named as the Supplier in the Order who is to supply the Deliverables to Wellcome

Wellcome Data: means any and all data in any format (including Personal Data) which is provided by or on behalf of Wellcome to the Supplier or which is made available to the Supplier or to which the Supplier obtains access in the course of providing the Deliverables.

Wellcome: The Wellcome Trust Limited, a company registered in England and Wales (no. 2711000), as trustee of the Wellcome Trust, a charity registered in England and Wales (no. 210183), whose registered office is at Gibbs Building, 215 Euston Road, London NW1 2BE, UK.

Appendix 4.
Contract Feedback Sheet

Clause #	Issue	Proposed Solution/Comment