



**Request for Proposal (RFP) for**  
**Regulatory support consultancy for the use of human infection studies to**  
**accelerate coronavirus vaccine licensure**

## **1. RFP Background & Objectives**

### **Background**

Wellcome is publishing a request for proposals for consultancy services relating to the regulatory support for the use of human infection studies in coronavirus vaccine licensure. The consultant will provide support on regulatory considerations of conducting SARS-CoV-2 human challenge studies, and investigate the regulatory challenges involved by engaging with regulators and other stakeholders.

Recognising the potential roles of human infection studies in healthy adult volunteers have played in the development of certain vaccines, there have been numerous proposals and advocacy efforts for human infection studies (HIS) with virulent SARS-CoV-2. Such studies could be important for 1) down-selecting of multiple vaccine candidates; 2) understanding immune response about the novel virus; 3) providing an alternative approach to assess efficacy of vaccine candidates if field trials are no longer possible. However, given the unknowns about the virus and the fact that a reliable “rescue therapy” has not yet been identified, the consensus is that human infection studies with SARS-CoV-2 will need to be closely-monitored and performed with caution, with suitable conditions and priority goals for these studies clearly defined.

The World Health Organization has developed [an ethics guidance](#) to define key criteria for the ethical acceptability of COVID-19 human challenge studies. It has also convened a multi-disciplinary group of global experts to discuss from different perspectives the concept of volunteer challenge studies with SARS-CoV-2, and a [report](#) has been published. Among the topics discussed, regulatory considerations associated with testing and emergency use of vaccines pre-licensure and with larger-scale deployment post-licensure are raised as key challenges as enhanced coordination among stakeholders is paramount in a greatly accelerated vaccine development process.

### **Purpose of the consultancy**

This project aims to determine how SARS-CoV-2 HIS should satisfy the regulators’ demand on efficacy and safety, and to explore on the data requirement for both emergency use and licensure.

The objectives are:

- To understand whether efficacy data obtained through a COVID-19 HIS can be used by global regulators in accelerating vaccines for emergency use in a pandemic situation
- To understand more broadly the utility of human challenge data to be included as part of a vaccine licensure pathway in order to accelerate the availability of vaccines



- To understand how early researchers should engage with regulators in preparing for COVID-19 human infection studies

## 2. RFP Specification

This section sets out the specification of services for this RFP exercise. Suppliers should use this section to fully understand Wellcome's requirements and to inform their response.

### **Work to be performed (due 6 months from the contract start date)**

#### **Output 1: Alignment among regulators with regards to standards and testing requirement for HIS**

- Activity 1.1: Convene global or regional regulators/regulator platforms to discuss HIS both for emergency use (in case of COVID-19 vaccines) and the vaccine licensure pathway in general, including discussion on:
  - rescue therapy for COVID-19 human infection studies
  - standards that can be applied to determine effectiveness for different types of vaccines
- Deliverable 1.1:
  - Informed opinion on the utility of HIS efficacy data for emergency use (in case of COVID-19 vaccines) and the vaccine licensure pathway in general, and discussion of barriers in the case that the data is not usable
  - Map of what information is needed to ensure successful inclusion in documentation (or a list of product agnostic questions for official review and comment)
- Activity 1.2: Engage with regulators for the benefits to them of evaluating and accepting data from COVID-19 HIS for COVID-19 vaccine licensure.
- Activity 1.3: Review other models of accelerated approval of pandemic vaccines (e.g. influenza H1N1 vaccines, which were approved rapidly during the 2009 pandemic) to draw on lessons on how safety data of vaccines could be adequately provided and safety actively monitored.
- Deliverable 1.2:
  - Summary of other potential uses for HIS that regulators consider invaluable

#### **Output 2: Establishment of best-practice models through a collaborative process involving key stakeholders and regulatory agencies, with a view to coordinate and facilitate testing across multiple testing sites**

- Activity 2.1: Convene global stakeholders including:
  - Researchers currently working on establishing COVID-19 HIS (including both university and industry researchers in the UK/US/RoW)



- Industry with COVID-19 vaccine candidates in their pipelines
- COVAX, GAVI, CEPI, WHO etc..
- Activity 2.2: Facilitate discussion between regulators and companies on how evidence from HIS may be able to be extrapolated to the real-world situation
- Deliverable 2: Summary of all discussions with the researcher network and regulators, with a view to understand how the model development timelines relate to the overall COVID-19 vaccine development and vaccines access

### **Specific requirements of the consultant**

#### *Qualifications and Experience*

- Regulatory experience in pharmaceutical/medical industry
- Experience of direct interactions with public health and regulatory authorities [e.g. MHRA, FDA, EMA, FAMHP (Belgian regulatory authority) and other national agencies or association (e.g. ICMRA)]
- Experience with human infection studies not required but he/she should be familiar with the science and the current available guidelines
- Global experience preferred but not necessary

#### *Technical skills and knowledge*

- Knowledge of regulatory approval procedures (experience in vaccines preferred)
- Good communication skills (both oral and written English)

### **3. RFP Timetable**

#	Activity	Responsibility	Date
1	RFP issue to Suppliers	WT	24th September 2020
2	Submission of expression of interest to RFP	Supplier	5pm on 7 <sup>th</sup> October 2020
3	Submission of Supplier Q&A to Wellcome Contact	Supplier	5pm on 14 <sup>th</sup> October 2020
4	Return of Supplier Q&A to Suppliers	WT	16 <sup>th</sup> October 2020
5	Submission of RFP Response	Supplier	5pm on 23 <sup>rd</sup> October 2020
6	RFP Evaluation Period	WT	26 <sup>th</sup> Oct to 5 <sup>th</sup> Nov 2020
7	Notification of Contract Award	WT	6 <sup>th</sup> November 2020
8	Contract Negotiation	WT & Supplier	9 -13 <sup>th</sup> November 2020
9	Contract Start Date	WT & Supplier	w/c 16 <sup>th</sup> November 2020

### **4. Response Format**

The following headers support the timetable by providing further detail of the key steps.



## Expression of Interest

Suppliers are asked to submit a short expression of interest by e-mail to the Wellcome Contact in accordance with the RFP timetable.

## Supplier Q&A

Prior to the submission of your RFP response, Suppliers are provided the opportunity to submit any questions they have about the exercise. All questions are to be submitted to the Wellcome Contact by e-mail in accordance with the RFP timetable.

## RFP Proposal

Suppliers are required to submit proposals which respond to the following sections;

### Contract Feedback

This section allows Suppliers to provide specific feedback to the contractual agreement which will be used should their proposal be successful. Contract feedback is to be incorporated into your proposal as an annex and in the following format;

Clause #	Issue	Proposed Solution/Comment

Suppliers submitting proposals as a registered company should review this [document](#). Individuals submitting proposals as a sole trader (not registered) should review this [document](#).

Individuals submitting proposals through their own personal services company please highlight this to the Wellcome contact immediately (see point 7 below).

### Information Governance

Suppliers are asked to complete the [TPSRA2](#) assessment before the RFP submission deadline for Wellcome to assess how you handle data.

### RFP Questions

This section requests responses from Suppliers specific questions in relation to this RFP exercise.

#	Question	Max [Pages]
1	Describe how you propose to meet our requirements. Please detail all the stakeholders you are proposing to engage, and	4



	your plans on how best to engage with them. Provide an overview of previous engagements which you might have had. You will be scored by your understanding of our requirements.	
2	Describe the stages and timeframes in which you propose to meet our requirements.	1
3	Provide a cost proposal which details and justifies the proposed costs to meet our requirements.	1
4	Provide case studies of where you have successfully provided services similar to those described in this request for proposal.	1
5	Provide confirmation that if you were appointed by Wellcome this would not create a conflict of interest.	1
6	What makes you best placed to fulfil Wellcome's requirements set out within this request? Highlight to us any risks which you foresee with meeting Wellcome's requirements.	1

## 5. About Wellcome

Wellcome exists to improve health by helping great ideas to thrive. We support researchers, we take on big health challenges, we campaign for better science, and we help everyone get involved with science and health research. We are a politically and financially independent foundation. Find out more about Wellcome and our work: [wellcome.ac.uk](https://www.wellcome.ac.uk).

## 6. 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.

## 7. Prospective Suppliers Personnel - IR35 and Off Payroll Working Rules

Before the RFP response deadline, Prospective Suppliers must make the Wellcome Contact aware if they are intending to submit a proposal where the services will be provided by any individuals who are engaged by the Prospective Supplier via an intermediary i.e.

- Where the Prospective Supplier is an individual contracting through their own personal services company; or
- The Prospective Supplier is providing individuals engaged through intermediaries, for the purposes of the IR35 off-payroll working rules.

## 8. 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.

## 9. Funding



For the avoidance of doubt, the output of this RFP exercise will be funded as a **Contract** and not as a Grant.

## **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. Sustainability**

Wellcome is committed to procuring sustainable, ethical and responsibly sourced materials, goods and services. This means Wellcome seeks to purchase goods and services that minimise negative and enhance positive impacts on the environment and society locally, regionally and globally. To ensure Wellcome's business is conducted ethically and sustainably, we expect our suppliers, and their supply chains, to adhere to these principles in a responsible manner.

## **12. Accessibility**

Wellcome is committed to ensuring that our RFP exercises are accessible to everyone. If you have a disability or a chronic health condition, we can offer adjustments to the response format e.g. submitting your response in an alternate format. For support during the RFP exercise, contact the Wellcome Contact.

If, within the proposed outputs of this RFP exercise, specific adjustments are required by you or your team which incur additional cost then outline them clearly within your commercial response. Wellcome is committed to evaluating all proposals fairly and will ensure any proposed adjustment costs sit outside the commercial evaluation.

## **13. Diversity & Inclusion**

Embracing [diversity and inclusion](#) is fundamental to delivering our mission to improve health, and we are committed to cultivating a fair and healthy environment for the people who work here and those we work with. As we learn more about barriers that disadvantage certain groups from progressing in our workplace, we will remove them.

Wellcome takes diversity and inclusion seriously, and we want to partner with suppliers who share our commitment. We may ask you questions related to D&I as part of our RFP processes.

## **14. Wellcome Contact Details**



The single point of contact within this RFP exercise for all communications is as indicated below (Please indicate the RFP title as the subject).

Name: Shobana Balasingam  
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