Request for Proposals

Analysis of the Factors Enabling the Rapid Development of Covid-19 Vaccines

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1. RFP Background and Objectives

Wellcome is a politically and financially independent global charitable foundation. It supports science to solve the urgent health challenges facing everyone. Wellcome supports discovery research into life, health and wellbeing, and is taking on three worldwide health challenges: mental health, global heating and infectious diseases.

Since 2017, Wellcome focused and expanded its work on vaccines by establishing a Vaccines Priority Area. The aims of the Priority Area are: (1) to support the development of new and improved vaccines; and (2), to enable better and broader use of the vaccines that already exist.

In order to support the development of new vaccines, a sustainable market for vaccine Research and Development (R&D) is needed. Historically, vaccines have been developed where there are strong commercial incentives (e.g. high-volume markets in high-income countries); however, to achieve public health goals, we also need to stimulate vaccine R&D for diseases where incentives for development / commercial markets are unclear. We also know that vaccine candidates face significant barriers during development through the late stage clinical testing and licensure pathway, and developers face significant financial risks during this phase.

Wellcome and partners have carried out scoping research to identify and quantify critical barriers in the vaccine ecosystem. Based on that research, one of the key priorities for Wellcome is to further understand the impact and potential of innovation in clinical trials. A key barrier in achieving public health goals with vaccines is the length of time it typically takes to produce a new vaccine. However, the extraordinary speed at which safe and effective vaccines have been developed for Covid-19 has caused the community to question this paradigm. We are therefore interested in answering the following question:

   What factors and innovations enabled the development, testing and approval of Covid-19 vaccines to happen so quickly?

We would like to commission an analysis on the factors that enabled the rapid development of vaccines for Covid-19, examining the impact of each factor, as well as any missed opportunities or negative impacts.

2. RFP Specification

We are interested in understanding how various factors influenced the efficient and rapid development, clinical testing and approval of Covid-19 vaccines. We would therefore like to commission a report based on a literature review and interviews with experts. The experts should offer diverse viewpoints through recruitment from different sectors (including academia, industry, NGOs, developers, regulators, funders, government organisations and the WHO) and locations. The factors include, but are not limited to:

1. The nature and impact of the pandemic
2. Financial investment
3. The value of previous work on coronaviruses and vaccine technology
4. The behaviour of regulatory authorities and ethics review committees in relation to clinical trials and authorisation for use
5. The design and conduct of the clinical trials
6. The openness and sharing of research outputs
7. Any other factors
We are interested in the following key research questions:

- How, if at all, and to what extent did each of the factors identified contribute to the speed of development, testing and use (up to licensure stage) of Covid-19 vaccines?
  - Are there further factors that contributed which are not outlined above?
  - Which innovations had the most impact on the speed of vaccine development? We would like a quantitative analysis here.
  - How sustainable are these factors for broader vaccine development?
- What were the sources of financial investment? How were they distributed? What impact did they have?
- Which of the factors identified, if any, did not rely on unprecedented financial investment?
- Which of the completed and ongoing clinical trials for Covid-19 vaccines do these factors apply to? Can any insights be drawn from comparison between different trials?
- Are there examples of other positive impacts of these approaches (e.g. non-promising candidates were identified more quickly) or negative impacts (e.g. less-promising candidates allowed to progress further than under usual circumstances)?
- Is there anything that could have aided, accelerated or improved the vaccine development and the clinical trial processes which were not available or used (e.g. alternative clinical pathways)?
  - Suppliers may find it illustrative to draw out comparisons with factors / innovations in clinical trials for other modalities such as monoclonal antibodies or small molecules

**Proposed methodology**

As part of your response, we are interested in your proposed methodology, particularly:

- Methodology for literature search
- Selection of interviewees and suggested interview process (see also section 13 on Diversity and Inclusion)
- Approach for analysis, including quantitative approach
- Proposed changes or additions to the categories or key research questions outlined above

Please see Section 4 for further details of the requirements for your response.

**Scope**

We are interested in the vaccine development process from early development, through clinical testing up to the point of regulatory approval and are particularly interested in the clinical trial stages.

Out of scope: Distribution, mass manufacturing for distribution, and access and uptake.

Under Wellcome’s new strategy, the Vaccines Priority Area will be grouped together with other work tackling Infectious Diseases. Therefore, although vaccines should be the focus of this work, we would welcome insights that go beyond vaccines and are applicable to clinical trial design in general. Other biologics may be particularly relevant, such as monoclonal antibodies.

Wellcome will share insights from other work that may be relevant to this project to be included in the analysis, for example from the Good Clinical Trials Collaborative and our analysis on sustainable markets for vaccines.
Please note that there is also potential for a follow-up analysis on how these insights can be applied to future trials, which would be issued as a separate contract.

**Deliverables**

OUTPUT 1 – A final report of the analysis that will be published on the Wellcome website. The intended audience will be vaccine developers, researchers, regulators, and funders, but the report should also include an executive summary accessible to a non-expert audience. Suppliers should include in their response to this RFP how they will create an informative, accessible and clear (including graphics) final report.

OUTPUT 2 – Slide deck summarising report findings including graphics and high-level summary.

Deliverables timetable (please note that these dates may be subject to change):

<table>
<thead>
<tr>
<th>Deliverable</th>
<th>Deadline</th>
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<tbody>
<tr>
<td>1. Contract start date</td>
<td>29.04.21</td>
</tr>
<tr>
<td>2. Inception meeting</td>
<td>During 03.05.21-14.05.21</td>
</tr>
<tr>
<td>3. Presentation / “inception report” from Supplier to Wellcome with detailed plans</td>
<td>Week of 24.05.21</td>
</tr>
<tr>
<td>4. First draft of report (for comments from Wellcome)</td>
<td>26.08.21</td>
</tr>
<tr>
<td>5. Slide deck and presentation to Wellcome</td>
<td>17.09.21</td>
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<tr>
<td>6. Final report</td>
<td>01.10.21</td>
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<tr>
<td>Wellcome sign-off</td>
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<tr>
<td>Publication of final report</td>
<td>29.10.21</td>
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</table>

We also expect regular engagement with Wellcome, to be agreed during the inception meeting.

3. **RFP Timetable**

| Activity                                                        | Responsibility             | Date               |
|                                                               |                               |                    |
| 1. RFP issued to suppliers                                     | Wellcome                     | 01.03.21           |
| 2. Deadline for submission of expression of interest to RFP     | Supplier                     | 15.03.21 (5pm)     |
| 3. Submission of Supplier Q&A to Wellcome                      | Supplier                     | 18.03.21 (9am)     |
| 4. Return of Supplier Q&A to Suppliers                         | Wellcome                     | 22.03.21           |
| 5. Submission of RFP Response                                  | Supplier                     | 07.04.21 (9am)     |
| 6. RFP Evaluation Period                                       | Wellcome                     | 07.04.21 – 14.04.21|
| 7. Possible Supplier Interviews                                | Wellcome / Supplier          | 15.04.21 – 19.04.21|
| 8. Notification of Contract Award                              | Wellcome                     | 20.04.21           |
| 10. Contract start date                                        | Wellcome / Supplier          | 29.04.21           |
4. Response Format

The following information supports the above timetable with further details.

We would welcome conversations with potential applicants in advance of receiving proposals if they wish.

Expression of Interest

Suppliers are asked to submit a short expression of interest by e-mail to the Wellcome Contact (see section 14) 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. Each Supplier will receive the written answers to all the questions received (with any questions that reveal the identity of the questioning party redacted).

RFP Proposal

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

1. 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:

<table>
<thead>
<tr>
<th>Clause #</th>
<th>Issue</th>
<th>Proposed Solution / comment</th>
</tr>
</thead>
</table>

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 TPRSA2 assessment before the RFP submission deadline for Wellcome to assess how you handle data.
2. **RFP Questions**

The following are responses Wellcome requests from the Supplier to specific questions in relation to this RFP exercise. Maximum number of pages: 12.

<table>
<thead>
<tr>
<th>#</th>
<th>Question</th>
<th>Max pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Team</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>A brief overview of your organisation, including your track record and expertise relevant to analysis of the type outlined in this RFP. Please also include a brief description of who would be involved in the project team, their qualifications and their main responsibilities.</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>What makes you best placed to fulfil Wellcome’s requirements set out in this RFP?</td>
<td>1</td>
</tr>
<tr>
<td>Approach</td>
<td></td>
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<tr>
<td>3</td>
<td>Your proposed approach to this work, including the proposed:</td>
<td>6</td>
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<tr>
<td></td>
<td>- Methodology (for particular questions around methodology, see section 2, RFP Specification)</td>
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<td></td>
<td>- Timeframes</td>
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<td></td>
<td>- Management plan, including role of team members</td>
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<td></td>
<td>- Plan for engagement with Wellcome during contract</td>
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<td></td>
<td>- Plan for production of final report, including copy editing, formatting and graphics</td>
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<td></td>
<td>- Diversity and inclusion planning (how you will ensure that: the literature reviewed, and interviews conducted will be inclusive to different groups of people and locations; your methodology does not introduce bias). See also section 13.</td>
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<tr>
<td>4</td>
<td>Case studies of where you have successfully provided similar services to those described in this RFP</td>
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<td>5</td>
<td>Highlight any risks you foresee in meeting the RFP requirements and any mitigation you will undertake (both related and not related to Covid-19)</td>
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<tr>
<td>Costs</td>
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<tr>
<td>6</td>
<td>Cost proposal detailing and justifying the proposed costs to meet our requirements</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td></td>
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<tr>
<td>7</td>
<td>Provide details of any existing restrictions that may impact your ability to meet Wellcome’s requirements. These should include (but not be limited to):</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>- Conflicts of interest with other clients</td>
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<td></td>
<td>- Conflicts of interest with internal Wellcome staff</td>
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<tr>
<td></td>
<td>- Restrictions on your licence to operate in certain jurisdictions</td>
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</tbody>
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5. **About Wellcome**

Wellcome supports science to solve the urgent health challenges facing everyone. We support discovery research into life, health and wellbeing, and we’re taking on three worldwide health challenges: mental health, global heating and infectious diseases. We are a politically and financially independent foundation. Find out more about Wellcome and our work on wellcome.org.
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:

Name: Debbie King
Role: Vaccines Research Lead
Email: d.king@wellcome.org

15. Wellcome Evaluation Panel

The evaluation panel for this RFP exercise will consist of the following individuals:

Debbie King  Vaccines Research Lead
Freya Hopper  Policy Advisor, Vaccines
Lindsay Keir  Partner, Innovations
Elena Netsi  Portfolio Manager, Population Health
Zoe Adler  Graduate, Vaccines