



Request for Proposal (RFP) for Analysis: vaccines regulatory system

1. RFP Background & Objectives

The Wellcome Trust (the 'Trust', 'Wellcome') is the world's second highest spending global charitable foundation. In 2017, Wellcome established the [Vaccines Priority Area](#).

Wellcome's Vaccine Priority Area aims to ensure that the world benefits from new and improved vaccines, and better use of vaccines, in the decades to come. In order for this to happen, we need a sustainable vaccines ecosystem which supports the development, licensure and initial use of vaccines, where they can be shown to be safe and effective. We have identified regulation as a key area where changes could support a more sustainable ecosystem.

We have a particular interest in: 1) vaccines which may be deployed in the event of, or to prevent disease outbreaks and epidemics; and 2) vaccines access for lower income settings, including those without a dual-market (i.e. for diseases which do not have a significant high income country market).

We see particular promise in exploring three elements of regulatory systems to improve the sustainability of the vaccine innovation ecosystem.

1. Strengthened capacity of National Regulatory Agencies (NRAs) in lower resource settings to regulate effectively, particularly looking at complex products
2. Increased information sharing, harmonisation of regulatory standards, and reliance between NRAs, looking at global and regional approaches
3. Embedding innovation and continuous improvement into the regulatory system through regulatory science approaches

Our concern is that the current vaccine ecosystem may not be fit for purpose in enabling new and improved vaccines to come through late stage development to early use (i.e. with the product registered and on the market equitably across geographies).

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:

- **Output 1:** Analysis of existing regulatory programs and initiatives, including: what works well and why; what underperformed or stalled and why; where improvements could be made; and what could be transferred to other contexts (e.g. a regional initiative that could transfer to another geography). The analysis should cover programs which target:
 - Strengthened capacity of NRAs in lower resource settings
 - Information sharing, harmonisation and reliance
 - Regulatory science



- **Output 2:** Cost-benefit analysis of impact to countries (particularly low- and middle-income countries) of increased regulatory information sharing, harmonisation and reliance. This should include both direct impacts (e.g. speed of access to the product for the country's population, use of regulator human capital) as well as indirect impacts and externalities.

For both outputs, as well as an overall view, we would like the analysis done of the region-by-region situation.

Output 1 will be used to improve internal understanding, so our preference is for this to be conducted quickly (first draft within 1 month), acknowledging that the findings may therefore not be fully comprehensive. Output 2 may be used to form the basis of advocacy materials, so we would require this to be more robust. We envisage that suppliers will be able to gather much of the necessary information through desk research.

Both outputs should be delivered as word document reports, with accompanying slide decks of summary findings and access provided to the underlying data/assumptions used in the analysis.

Under Wellcome's [strategy](#), the Vaccines Priority Area will be subsumed into the new Challenge Area of Infectious Disease. As such, while vaccines are the lead focus of this project, we would welcome insights that go beyond the vaccines regulatory system. We also recognise the opportunity the COVID-19 pandemic has created to establish a 'new normal' and encourage suppliers to consider this as part of the analysis.

3. RFP Timetable

#	Activity	Responsibility	Date
1	RFP issue to Suppliers	WT	15 th Jan
2	Submission of expression of interest to RFP	Supplier	09:00 on 20 th Jan
3	Submission of Supplier Q&A to Wellcome Contact	Supplier	09:00 on 22 nd Jan
4	Return of Supplier Q&A to Suppliers	WT	26 th Jan
5	Submission of RFP Response	Supplier	09:00 on 1 st Feb
6	RFP Evaluation Period	WT	1 st to 12 th Feb
7	Notification of Contract Award	WT	w/c 8 th Feb
8	Contract Negotiation	WT & Supplier	w/c 12 th Feb
9	Contract Start Date	WT & Supplier	w/c 12 th Feb

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).

RFP Questions

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

#	Question	Max [pages]
1	A brief overview of your organisation, including your track record and expertise relevant to analysis of the type outlined in this RFP.	1
2	Your proposed approach to this analysis, including the proposed methodology, timeframes, team, how you would engage with Wellcome, etc.	6
3	Cost proposal which details and justifies the proposed costs to meet our requirements	1
4	Case studies of where you have successfully provided services similar to those described in this RFP	1
5	What makes you best placed to fulfil Wellcome's requirements set out in this RFP? Highlight any risks you foresee in meeting these 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;

Name: Freya Hopper
Role: Policy Advisor
Email: f.hopper@wellcome.ac.uk