



Request for Proposal (RFP) for R&D activity on mucosal immunity landscape review

About Wellcome and the Novo Nordisk Foundation

Wellcome is a politically and financially independent global charitable foundation. We support 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, climate and health and infectious diseases. In 2021, Wellcome established the Infectious Disease Health Challenge, whose vision is a world in which escalating infectious diseases are under control in communities most affected.

Established in Denmark in 1924, the Novo Nordisk Foundation is an enterprise foundation with philanthropic objectives. The vision of the Foundation is to improve people's health and the sustainability of society and the planet. The Foundation's mission is to progress research and innovation in the prevention and treatment of cardiometabolic and infectious diseases as well as to advance knowledge and solutions to support a green transformation of society.

1. RFP background and objectives

Wellcome and Novo Nordisk Foundation are co-commissioning this review on mucosal immunity to gain a better understanding of mucosal immune responses and how to harness mucosal immunity to provide protection from pathogenic infections. Many pathogens enter the body through mucosal surfaces, but mucosal immune responses are complex and currently not well understood with limited knowledge of the nature of protective immunity at mucosal surfaces, mucosal correlates of protection, lack of mucosal adjuvants and limited access to mucosal tissues for analysis of responses, especially T cell responses. The relationship between systemic and mucosal responses is also not well established for many pathogens.

Given the clear knowledge gaps in this developing area, Wellcome & NNF would like to commission a focussed analysis on the current landscape of human mucosal immunity induced by vaccines with a particular focus on the following pathogens:

Respiratory: Mycobacterium tuberculosis, Group A Streptococcus, Influenza virus, SARS-CoV-2, Measles virus

Enteric: Vibrio cholerae, Salmonella species, Rotavirus, Shigella species.

Genitourinary: HIV, HPV, Neisseria gonorrhoeae, Chlamydia trachomatis, Group B Streptococcus (GBS), Herpes Simplex Virus (HSV)

The analysis should use the above pathogens to achieve the following objectives:

Objective 1: To gain an understanding to what extent currently-licensed human vaccines given parenterally (intramuscular, subcutaneous or intradermal) for protection against respiratory enteric and genitourinary pathogens induce mucosal immunity. Including a summary of the composition and kinetics of the mucosal response and its contribution toward vaccine efficacy and long-term protection.

Objective 2: To review the pipeline of vaccines targeting protection against human mucosal pathogens (from late pre-clinical through marketed products, informed by data from human and advanced animal challenge models) in development



for respiratory, enteric and genitourinary pathogens including a comparison of their immunological and clinical outcomes and safety profile.

Objective 3: To review the pipeline of exploratory adjuvants in development for human mucosal vaccines targeting respiratory, enteric and genitourinary pathogens, including the immunological and clinical outcomes and safety profile.

Objective 4: Identify key activities needed to support the design and development of new vaccines that target and enhance optimal mucosal immune protection.

The **goals** of the report are:

- To identify current status of vaccines which induce mucosal immunity for human respiratory, enteric and genitourinary pathogens
- To identify promising areas and key gaps in knowledge to accelerate development of human vaccines to induce mucosal immunity.

2. RFP Specification

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

We are interested in understanding the landscape of vaccine development for human respiratory, enteric and genitourinary pathogens with a particular focus on induction of mucosal immunity, and the strategies and actions can be taken to support future development.

We would therefore like to commission a report based on a literature review/landscape analysis and interviews with experts. The experts should have strong track record in the field and be currently involved in mucosal immunity and vaccine development for respiratory, enteric or genitourinary pathogens.

We are interested in developing and prioritising a set of solutions, strategies and actions centred around induction of protective mucosal responses which will guide development of vaccines and maximise the impact such vaccine have in preventing infectious diseases.

Literature/Landscape Analysis

The anticipated outcome would be a comprehensive overview and analysis of the current landscape of mucosal vaccines for respiratory, enteric and genitourinary pathogens from both published and grey literature. Potential areas where funding would develop the field should be identified and mapped to the outcome from the Landscape Analysis. It would be useful to gather information directly from those currently involved in mucosal vaccine research. The review should specifically cover the following:

Systematic Review of Human Vaccines

A literature review should be undertaken to understand current human vaccines given parenterally against airway, intestinal genital tract pathogens including data available on respiratory, enteric and genitourinary immunity, mucosal responses induced, and how systemic and mucosal responses are related.

A review of mucosally delivered vaccines via airway and oral routes including data on mucosal responses detected after mucosal priming and/or boosting.

Landscape Analysis on Exploratory Adjuvants



In addition, a summary landscape analysis on exploratory adjuvants tested should be developed. This should include adjuvants tested for respiratory, enteric and genitourinary vaccines in non-human primates (NHPs) and humans, including the immunological and protection outcomes as well as safety

Actions

The report should identify the key activities likely to achieve advances in our understanding of mucosal immunity, and how to induce it in the short, medium and long term. Of interest would be the identification of specific places and/or interventions where stakeholders including Wellcome and NNF could assist and have impact.

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 (if used)
- Approach for analysis, including quantitative and qualitative approach
- Proposed changes or additions to the categories outlined above

Scope

We are interested in understanding the landscape of mucosal vaccines targeting respiratory, enteric and genitourinary pathogens. Specifically the following pathogens:

Respiratory: Mycobacterium tuberculosis, Group A Streptococcus, Influenza virus, SARS-CoV-2, Measles virus

Enteric: Vibrio cholerae, Salmonella species, Rotavirus, Shigella species.

Genitourinary: HIV, HPV, Neisseria gonorrhoeae, Chlamydia trachomatis

Out of scope: non-mucosal routes of transmission and non-human vaccines.

Deliverables

OUTPUT 1 – A final report of the analysis that will be published in an open access format. The intended audience will be vaccine manufacturers, 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):



	Deliverable	Deadline
1	Contract start date	
2	Inception meeting	
3	Presentation/"inception report" from Supplier to Wellcome with detailed plans	
4	Mid-point check in	
5	First draft of report (for comments from Wellcome)	
6	Slide deck and presentation to Wellcome	
7	Final report	
	Wellcome sign-off Publication of final report	

3. RFP Timetable

#	Activity	Responsibility	Date
1	RFP issue to Suppliers	WT	15 th January 2024
2	Submission of expression of interest to RFP via the following form	Supplier	16 th February 2024
3	Submission of Supplier Q&A to Wellcome & NNF	Supplier	16 th February 2024
4	Review of EoI's and shortlisting for full application	WT & NNF	19 th Feb – 1 st March
5	Return of Supplier Q&A to Suppliers and invitations for full applications	WT	1 st March
5	Submission of RFP Response and TPSRA2 form	Supplier	19 th March 2024
6	RFP Evaluation Period	WT & NNF	20 th March -12 th April 2024
7	Supplier Presentations	WT, NNF, Supplier	W/C 15 th April 2024
8	Notification of Contract Award	WT & NNF	Mid April 2024
9	Contract Negotiation	WT, NNF & Supplier	MidApril 2024
10	Contract Start Date	WT, NNF & Supplier	Mid April 2024

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 via this [form](#).



We will review expressions of interest to ensure that proposals fit within the scope of the RFP. Where we are satisfied of this, we will invite organisations to submit a full proposal to the RFP in accordance with the RFP timetable. Please note that you should only submit a full proposal to the RFP if you have been invited to do so.

Submitting an EOI is not a binding commitment to submit a full proposal should your organisational priorities change, you will not then be penalised for future opportunities

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 by the timeframe set out in the RFP Timetable above. All questions will be collated, anonymised, answered and returned to all Suppliers who have submitted an expression of interest in the RFP process.

Please make sure you ask all questions at this stage. Once Wellcome have responded to all questions If you have any additional questions after this deadline these will not be answered to ensure that this is a fair and equitable process.

5. RFP Proposal

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

RFP Questions

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

#	Question	Max pages
Team		
1	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/experience and their main responsibilities.	1
2	What makes you best placed to fulfil Wellcome's requirements set out in this RFP?	1
Approach		
3	Your proposed approach to this work, including the proposed: <ul style="list-style-type: none">• Methodology• Timeframes• Management plan, including role of team members• Plan for engagement with Wellcome during contract• Plan for production of final report, including copy editing, formatting and graphics• Diversity and inclusion planning (how you will ensure that: the literature reviewed, and interviews conducted will be	6



	inclusive to different groups of people and locations; your methodology does not introduce bias).	
4	Case studies of where you have successfully provided similar services to those described in this RFP	1
5	Highlight any risks you foresee in meeting the RFP requirements and any mitigation you will undertake (both related and not related to Covid-19)	1
Costs		
6	Cost proposal detailing and justifying the proposed costs to meet our requirements including breakdown as necessary	1
Other		
7	Provide details of any existing restrictions that may impact your ability to meet Wellcome's requirements. These should include (but not be limited to): <ul style="list-style-type: none"> • Conflicts of interest with other clients • Conflicts of interest with internal Wellcome staff • Restrictions on your licence to operate in certain jurisdictions 	1

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Methodology	<i>Quality:</i> Is the proposed methodology aligned with our objectives? <i>Utility:</i> Will the proposed methodology deliver the desired, credible, and useful results?	40%
Team and experience	<i>Skills and Experience:</i> Does the applicant/s have the relevant skills, experience, and contextual understanding to deliver this work?	20%
Delivery and outputs	<i>Delivery plan:</i> Is the proposed delivery plan appropriate and achievable? <i>Feasibility:</i> How feasible is the delivery plan? Are there significant risks associated with the proposed timelines, and how well are they mitigated?	30%
Budget	<i>Value for Money:</i> Is the proposed work within budget and good value for money?	10%

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 the following Terms and Conditions [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

Wellcome's Data Protection Compliance

Under [GDPR/Data Protection law](#), Wellcome must keep a record of all personal information it is processing (i.e. collecting, using and sharing). This record will be made available to the Information Commissioner's Office upon request.

This is Wellcome's record of data processing activities which meets GDPR article 30 requirements.

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

6. 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. Find out more about Wellcome and our work at: wellcome.org.

7. 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.

8. 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.



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. Funding

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

11. 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.

12. 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.

13. Disability Confident

The Wellcome Trust is proud to be a Disability Confident Employer (DC Level 2) and we encourage all our partners and suppliers to do the same. More information about this can be found on the government website [Disability Confident employer scheme and guidance - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/guidance/disability-confident-employer-scheme-and-guidance). Disability Confident is creating a movement of change, encouraging employers to think differently about disability and take action to improve how they recruit, retain and develop disabled people.

14. 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.

15. 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.

16. Wellcome Contact Details

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

Name: Alyce O'Connor
Role: Procurement Officer
Email: RFP@Wellcome.org