



## **Request for Proposal (RFP) for a Review of the Tuberculosis Biomarkers Landscape including the Prioritisation of Biomarkers for Further Development**

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

#### **About Wellcome**

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.

#### **Background**

Tuberculosis is the leading cause of death from infectious disease and remains a major global health challenge. Ending the tuberculosis epidemic by 2030 is among the health targets of the United Nations Sustainable Development Goals. Our ambitions are to drive forward a programme of TB prevention towards the ultimate goal of elimination. While the majority of people exposed to TB clear the infection, 5-10% fail to control the infection and gradually progress to active disease. Detecting and treating at the early stage of disease is crucial for improving diagnosis, treatment, and prevention efforts. Biomarkers for distinguishing stages of disease, predicting disease progression, and assessing treatment response can enable targeted interventions and more efficient clinical trials. Despite significant efforts and advancements in biomarker discovery, the lack of clear consensus on candidates most likely to succeed in clinical evaluation hinders progress and makes informed decision-making challenging for researchers and funders.

#### **Scope and Purpose**

Wellcome are commissioning this review to gain a better understanding of:

- the biomarker landscape
- the most promising biomarkers to target treatment of early disease, preventing progression to active disease
- treatment response biomarkers.

The goals of the review are:

- To map out the landscape of TB biomarker research, including which potential biomarkers have been identified, what questions about TB status and treatment response they can answer, and their strengths and limitations, and also mapping key stakeholders, initiatives and organisations.
- To work with the research community (including industry) to identify the most critical biomarker use cases and prioritisation criteria to target treatment of early disease and prevent progression to active disease.
- To assess the identified candidate biomarkers against the use cases and prioritisation criteria and validate the conclusions with the research community.



The exact scope and parameters of the work will need to be fully defined with the successful suppliers; this includes but is not limited to assessment of the following three categories:

- Markers for Patient Stratification: Biomarkers capable of differentiating between the different disease states during asymptomatic, early disease, including latent (IGRA positive, sputum negative) and subclinical (CXR positive and sputum positive or negative) disease states.
- Markers of Disease Progression: Biomarkers that reliably predict the risk of progression to active TB.
- Markers of Response to Treatment: Biomarkers that track and predict an individual's response to TB chemotherapy.

### **Objectives**

Objective 1: Overview of the range of biomarkers in development and the stages of TB infection they may be used for (Patient Stratification, Disease Progression and/or Response to Treatment as defined above). To include details of the key researchers, institutions and consortia developing the biomarkers, the laboratory methods (e.g. sample types, timepoints, analysis techniques) required for each biomarker assay, and the stage of development of each biomarker assay.

Objective 2: Prioritisation of existing biomarkers, both pathogen and host, to identify which are the best candidates for further clinical development towards the following goals:

- Biomarkers to target treatment of early disease, preventing progression to active disease
- Treatment response biomarkers.

As part of the landscape review, we expect the supplier to convene a stakeholder meeting to consult the community on the most promising biomarkers for each use case, and the prioritisation criteria that should be used. This development of prioritisation criteria should consider the Target Product Profiles published by the World Health Organisation for biomarkers of TB disease progression and treatment monitoring and optimisation<sup>1</sup>.

Objective 3: A critical analysis of the barriers and enablers of TB biomarker development, including the challenges that have hindered the translation of promising TB biomarkers into routine clinical practice. Recommendations for key activities needed to support the development of these biomarkers for use to inform clinical practice, and recommended opportunities for future research. Identification of the key stakeholders in the TB biomarkers development landscape.

## **2. RFP Specification**

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<sup>1</sup> <https://www.who.int/publications/i/item/WHO-HTM-TB-2017.18>  
<https://www.who.int/publications/i/item/9789240081178>



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. Wellcome will be guided by the supplier as to what is a reasonable budget for this activity as we do not want limit ambition or innovation.

The review of the TB biomarker landscape should be based on a systematic review of grey and published literature, and consultation with experts. The experts should have a strong track record in the field and be currently involved in TB biomarker research or the delivery of TB treatment in lower resourced settings (including relevant health policymakers). We expect the supplier to engage with industry as well as academic experts. The report should cover Objectives 1, 2 and 3 of this landscape review as set out above.

#### *Sources of information*

Information should be gathered directly from those currently involved in TB biomarker research and TB treatment in lower-resourced settings. We propose that the supplier includes the following steps in their development of the report:

- Hold a side meeting at the Union TB conference in November 2024 for stakeholder consultation on TB biomarkers.
- A literature review should be undertaken to understand the TB biomarkers assessed to date and to identify which potential biomarkers exist (both host and pathogen focused), their presumed mechanisms of action, what questions about TB status they can answer and their strengths and limitations. Where up to date systematic reviews are not available, these should be carried out.
- A review of the grey literature to identify relevant information on biomarker development outside peer-reviewed journal articles.
- Additional stakeholder consultation as appropriate to complete the preparation of a draft report.
- Following information gathering and analysis stages and the preparation of a draft report, a second stakeholder consultation to validate the report's conclusions with a wider group of relevant stakeholders.

#### *Proposed methodology*

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

- Methodology for literature search and systematic review(s), including the framework that outlines the parameters for investigation
- Selection of stakeholders to consult and suggested consultation process
- Approach to analysis, including quantitative and qualitative approach
- Proposed changes or additions to the categories outlined above

#### *Key deliverables and outputs for the project*

1. Stakeholder meeting at Union TB conference in November 2024



2. Agreement with Wellcome how the outputs of the stakeholder meeting will inform the biomarker prioritisation criteria in the draft report
3. Production of a draft report by April 2025
4. Validation of the draft report's conclusions in a further stakeholder consultation in May 2025
5. Production of a final report in May 2025 that meets the objectives set out above and an executive summary
6. Publication of the systematic reviews completed during the project in an open-access academic journal
7. Presentation of the findings to Wellcome and other funders and selected representatives at the end of the contract

All our content should be WCAG 2.2. AAA compliant. Any documents being provided to Wellcome must pass accessibility requirements. If you are unable to produce accessible documents, budget must be set aside to employ a suitable agency to do this work.

### 3. RFP Timetable

#	Activity	Responsibility	Date
1	RFP issue to Suppliers and issued on <a href="#">Contract Opportunities</a> webpage	Wellcome	17/06/2024
2	Submission of Expression of Interest and Supplier Q&A [via form link]	Supplier	05/07/2024
3	Return of Supplier Q&A to Suppliers	Wellcome	12/07/2024
4	Submission of RFP Response	Supplier	29/07/2024
5	RFP Evaluation Period	Wellcome	29/07/2024 – 16/08/2024
6	Supplier Presentations	Supplier	02/09/2024 – 06/09/2024
7	Notification of Contract Award	Wellcome	September 2024
8	Contract Negotiation	Wellcome & Supplier	September/ October 2024
9	Contract Start Date	Wellcome & Supplier	October 2024

### 4. Response Format

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

#### Expression of Interest and Supplier Q&A

Suppliers are asked to submit a short expression of interest by e-mail to the Wellcome contact in accordance with the RFP timetable, which should contain the following information.



- Confirming whether you are an organisation or individual. We welcome applications from teams, bringing together relevant expertise on the different aspects of the landscape analysis.
- If an organisation please provide registered name, address, and registration number.
- A non-binding cost estimate as a single figure in GBP
- Any questions you have about the exercise and activity

Prior to the submission of your full proposal to the RFP, Suppliers are provided the opportunity to submit any questions they have about the exercise and the activity. 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.

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

Please note, if we have an overwhelming response, we may choose to use this EOI stage as a selective phase, this is at Wellcome's discretion.

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

### **RFP Response**

Suppliers submitting a full proposal should cover the following areas in their response:

**Responses should be a maximum of 10 pages, excluding budget and references.**

<b>#</b>	<b>Question</b>	<b>Max pages</b>
<b>1</b>	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. If you are applying as a team including members from different organisations, please outline how you will work effectively together to deliver the project.	<b>1</b>
<b>2</b>	What makes you/the team best placed to fulfil Wellcome's requirements set out in this RFP? Please comment in relation to both the analysis and report production, and the stakeholder convenings.	<b>1</b>
<b>3</b>	Your proposed approach to this work, including the proposed: <ul style="list-style-type: none"><li>• Methodology</li><li>• Timeframes</li></ul>	<b>6</b>



#	Question	Max pages
	<ul style="list-style-type: none"> <li>• Management plan, including role of team members and risk mitigation</li> <li>• Plan for engagement with Wellcome during contract</li> <li>• Plan for identifying and engaging with relevant key stakeholders throughout the project, including both planned stakeholder meetings</li> <li>• Plan for production of final report, including copy editing, formatting and graphics</li> <li>• 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).</li> <li>• How will diversity, equality and inclusion be incorporated into the delivery of the project?</li> </ul>	
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	1
6	Cost proposal detailing and justifying the proposed costs to meet our requirements including breakdown as necessary. Please include costs associated with the two stakeholder consultations.	1
7	<p>Provide details of any existing restrictions that may impact your ability to meet Wellcome's requirements. These should include (but not be limited to):</p> <ul style="list-style-type: none"> <li>• Conflicts of interest with other clients</li> <li>• Conflicts of interest with internal Wellcome staff</li> <li>• Restrictions on your licence to operate in certain jurisdictions</li> </ul>	1

#### Evaluation Criteria

Criteria	Detail	%
Methodology	<p><i>Coverage:</i> How well are the desired focus areas (as outlined in the specification) covered in the proposed methodology?</p> <p><i>Quality:</i> Is the proposed methodology aligned with our needs?</p> <p><i>Utility:</i> Will the proposed methodology deliver the desired, credible, and useful results?</p> <p><i>EDI:</i> Does the proposed methodology include appropriately diverse representation at all levels. Are diversity, equality and inclusion considerations incorporated into the delivery plan?</p>	35%
Team and Experience	<p><i>Skills and Experience:</i> Does the supplier have the relevant skills, experience, and contextual understanding to deliver this work?</p>	25%



Criteria	Detail	%
Delivery & Outputs	<i>Communication:</i> Is there a good plan for communicating with the Wellcome team? <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%
Accessibility	<i>All our content should be WCAG 2.2. AAA compliant. Any documents being provided to Wellcome must pass accessibility requirements. If you are unable to produce accessible documents, budget must be set aside to employ a suitable agency to do this work.</i>	N/A
	<b>Total:</b>	<b>100%</b>

### Contract Feedback

This section allows Suppliers to provide specific feedback to the contractual agreement which will be used should their proposal be successful. This is the suppliers' opportunity to provide negotiation points on Wellcome's terms and conditions.

We will not consider negotiations that are raised in your response to this proposal i.e. after the contract has been awarded so as not to delay the contracting process. Please ensure you engage with a relevant legal contact if applicable. 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 Wellcome's Standard 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 6 below).

### Information Governance

Wellcome is committed to upholding data protection principles and protecting your information. The [Wellcome-Privacy-Statement-2023.pdf](#) explains how, and on what legal



basis, we collect, store, and use personal information about you. This includes any information you provide in relation to this proposal.

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 will be asked to complete the [TPSRA2](#) assessment before presentation stage to assess how you handle data.

### **Supplier Presentations**

Following a submission of the proposal successful proposals will invited to a virtual meeting which will last 50 minutes in total and will be a PowerPoint presentation followed by questions and answers session.

## **5. About Wellcome**

Wellcome improves health for everyone by funding research, leading policy and advocacy campaigns, and building global partnerships. Collaborative research that involves a diverse range of people from different fields of interest is key to progress in health science – and to achieving our aim of fostering a healthier, happier, world. We're taking on the biggest health challenges facing humanity – climate and health, infectious disease, and mental health – to find urgent solutions and accelerate preventions. Find out more about Wellcome and our work at: [wellcome.org](http://wellcome.org).

## **6. 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.

## **7. Equity Diversity and 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. We want to cultivate an inclusive and diverse culture, and 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.

## **8. 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). 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.

## **9. 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.

All our content should be WCAG 2.2. AAA compliant. Any documents being provided to Wellcome must pass accessibility requirements. If you are unable to produce accessible documents, budget must be set aside to employ a suitable agency to do this work.

## **10. 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.

## **11. Funding**

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

## **12. 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.

### **13. 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.

### **14. Wellcome Contact Details**

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

Name: Alyce O'Connor  
Pronouns: She/Her  
Role: Procurement Officer  
Email: [RFP@wellcome.org](mailto:RFP@wellcome.org)