



Request for Proposal (RFP) for Landscape Report: Early antibiotic development

1. RFP Background & Objectives

The Wellcome Trust ('Wellcome') is the world's second highest spending global charitable foundation. It is both politically and financially independent. Wellcome supports scientists and researchers worldwide, takes on big problems, fuels imaginations, and sparks debate. Our funding supports over 14,000 people in more than 70 countries in exploring ideas, seeking solutions and improving the human condition through science, population health, medical innovation, the humanities and social sciences and public engagement. Further information about Wellcome can be found at [wellcome.org](https://www.wellcome.org) and all prospective suppliers are encouraged to visit the website to gain an insight into the organisation.

Wellcome has just launched a new [strategy](#) to solve the urgent health challenges facing everyone, including infectious diseases. We hope that the work that will result from this request for proposals will inform the infectious disease health challenge area. As part of our mission, we are already proactively tackling some of the world's biggest health challenges, including Drug-Resistant Infections (DRI) – estimated to cause 700,000 deaths per annum globally. This number will rise to 10 million per annum by 2050 if no action is takenⁱ. Wellcome has been a significant advocate to avert this growing crisis and in 2016 established a priority area in bacterial drug resistance focussing on four areas: evidence for decision makingⁱⁱ; stronger global governanceⁱⁱⁱ; faster clinical trials^{iv} and **development of new antibacterial treatments^v**.

To address this latter area of antibiotics development, Wellcome co-founded the initiative CARB-X ([Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator](#)) with the US Biomedical Advanced Research and Development Authority (BARDA)^{vi}. CARB-X supports the development of anti-bacterial drugs globally with a portfolio of more than 50 projects. To apply for CARB-X funding – for antibiotics, non-traditional therapeutics and vaccines to address priority bacterial infections – projects must be at the 'hit-to-lead' stage and can progress through preclinical development to the end of Phase 1. CARB-X successfully addressed the lack of funding at the preclinical stages of product development and is one of the main funders of antibiotics globally. Our work is not done yet as there are two key challenge areas that the antibiotic development sector is facing: 1) there is an acute need for push funding and pull incentives for later stages of antibiotics development to ensure successful market entry and 2) the need to develop / strengthen the capacity, infrastructure and capabilities of researchers in the field of antibiotic development.

Here we are focusing on the second challenge. As major pharmaceutical companies are no longer investing in antibacterial drug discovery^{vii,viii}, and the funding initiatives that have been made available to address the need for new antibiotics predominantly *do not* focus on exploratory translation and drug discovery, we are relying on the academic sector to provide new insights into all aspects of therapeutic discovery^{ix}. Yet, the barriers to starting an academic drug discovery project are significant. For example, conducting good drug discovery programmes requires access to expertise from a wide range of disciplines^x that are not routinely available to every academic researcher. Without appropriate resources and access



to these different disciplines, in combination with input from product development experts, it's therefore unlikely that research insights will be readily translated into new drugs. Providing access to expertise and infrastructure alone will not be enough either, we need to develop sustainable solutions where researchers are enabled to develop the much-needed skillsets. We know from CARB-X's experience of reviewing >1100 proposals to date (and funding 71), that even for innovators with *some* drug development experience (as applications mostly come from small and medium-sized enterprises) many of the rejected applications demonstrate a considerable lack of understanding of what it takes to design the key proof-of-concept experiments that would convince CARB-X to support an antibacterial hit-to-lead campaign^{xi}. Therefore, we must ensure that these researchers are able to access the right expertise at the right time and enable them to develop the skills needed for the long term.

2. RFP Specification

Wellcome is considering how we can enable researchers in academia and SMEs to access relevant expertise and resources at different stages of product development, access training to develop relevant skills, and raise funding for programmes of R&D, with the aim of strengthening the antibiotic drug discovery pipeline. For both groups, we are looking to support early stage researchers, those working in the pre-hit-to-lead development stages:

- DRI researchers with varying levels of experience in basic research and exploratory antibiotic discovery, including those who have never taken steps to translate their research through to experienced drug developers who may be seeking specific expertise or access to antibiotic-related infrastructure and training.
- Small and medium-sized enterprises focused on early antibiotics discovery research that are not yet competitive or experienced enough to receive funding from CARB-X.

Our aims are:

1. To strengthen the early drug discovery pipeline by improving both the *quality* of antibiotic discovery (in terms of the proportion of early-stage projects that receive further funding) and increasing the *diversity* of researchers/innovators engaging in this field.
2. To enable academics and SMEs to develop the relevant skills and expertise needed to successfully commit to early discovery and development of antibiotics.
3. To develop or support currently available infrastructure networks for academics and SMEs where they can access any relevant expertise or training.

We are seeking proposals for a landscape report to inform Wellcome's work in this area. The report should address the following themes for the two groups outlined above:



Theme 1 – Overview of capacity and capability

- Key issues identifying why antibiotic development projects are, or are not, selected to receive funding from CARB-X, Novo Repair Fund, and other funding schemes (that may include antibiotic development). This should address (but not necessarily be limited to): quality of science; strength of proof of concept and research proposal; overall grantsmanship and the expertise of the applying team.
- An assessment of the current capacity and capability-building activities that are available through CARB-X (<https://carb-x.org/>), GARDP (<https://gardp.org/>) and iCARE (www.icarecourse.org).
- Overview of the demographics of applicants and the diversity implications.
- Identification of missing expertise in the sector.
- Identification of gaps in current capacity and capability-building activities in the field of early antibiotic discovery.

Theme 2 – Overview of current barriers and incentives

- A landscape analysis of which interventions are already available (that could address any of the gaps identified in theme 1) but may need additional support to expand capacity.
- Identification of current incentives that encourage researchers to participate in early-stage anti-bacterial drug discovery and development.
- Identification of current disincentives that deter researchers from participating in early stage anti-bacterial drug discovery and development.

Report format and audience:

- Written report suitable to inform the next steps of Wellcome's work in this area. These will involve using the report findings to work with external partners to develop and implement practical short, medium, and long-term solutions to the barriers that have been identified. Partners could include, but are not limited to, research funders, universities, SMEs, pharmaceutical companies, product development partnerships (PDPs) and policy makers.
- The report should be no more than 50 pages, including an Executive Summary and relevant graphics. Any supporting data can be provided in accompanying appendices.

Timeframe:

- Final report to be delivered by **14 June 2021** and should be preceded by first and second drafts that will be reviewed by the Wellcome team.

The successful supplier will report to Wellcome on a biweekly basis, including the discussion of interim findings and data.

Work location:

Work should be carried out remotely.



Out of scope:

- Any in-depth discussion of barriers that could only be addressed at government-level or by interventions within public health systems.
- Researchers or development stages outside of the groups or development stages detailed in section 2 “Aims and Scope of work”.

3. RFP Timetable

#	Activity	Responsibility	Date
1	RFP issue to Suppliers	WT	4 Dec 2020
2	Submission of expression of interest to RFP	Supplier	16 Dec 2020
3	Submission of Supplier Q&A to Wellcome Contact	Supplier	7 Jan 2020
4	Return of Supplier Q&A to Suppliers	WT	15 Jan 2020
5	Submission of RFP Response	Supplier	17:00 20 Jan 2021
6	RFP Evaluation Period	WT	21 Jan-29 Jan 2021
7	Supplier Presentations	WT	08-10 Feb 2021
8	Notification of Contract Award	WT	12 Feb 2021
9	Contract Negotiation	WT & Supplier	15 Feb-12 Mar
10	Contract Start Date	WT & Supplier	15 Mar 2021

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 (no more than 250 words) by e-mail to the Wellcome Contact in accordance with the RFP timetable. Please include the following information:

- Experience in delivering similar landscape reports and indicative budget
- Knowledge of the field
- Personnel on the project

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 a written proposal which details to Wellcome the following requirements;

- i. A brief overview of your organisation and proposed project team, including your track record, expertise in evaluating research landscapes and editorial proficiency (max 1000 words). Please include as annexes:
 - a. PDFs or website links with examples of similar reports previously delivered.
 - b. Details of your team with CVs for each member

- ii. Your proposed approach including methodology and delivery of this work (max 4 pages), including:
 - a. Please detail all the stakeholders you propose to engage and how you propose to engage with them. Provide an overview of previous engagements which you might have had.
 - b. Provide a budget which details and justifies the proposed costs to meet our requirements and states whether the costs are inclusive of VAT.
 - c. Provide a timeline including delivery of first and second draft reports.
 - d. Provide confirmation that if you were appointed by Wellcome this would not create a conflict of interest.
 - e. Please explain 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.
 - f. Include any contract feedback (as below)

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

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.

If you intend to start collecting personal or business confidential data, you will need to speak to Wellcome's Information Governance Team and complete a [Gating Questionnaire](#). This is a high-level risk assessment checking if a new third party is used, what lawful basis is used for processing personal data and if there is risk associated with this activity. As an outcome, there might be a need to send the [TPSRA2](#) Assessment form to a new supplier. If the lawful basis for processing personal data is Legitimate interests– a Legitimate interests Assessment will also need to be complete. If at the end of Gating Questionnaire the risk is identified as high, there will be a need to complete Data Protection Impact Assessment (DPIA). This should take place ahead of starting the activity. Once activity starts and is in progress – evidence of processing should be captured within ROPA which stands for Records of Processing Activities.

[This is Wellcome's record of data processing activities which meets GDPR article 30 requirements.](#)

RFP Questions

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

#	Question

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.

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: Bethan Hughes
Role: Partner
Email: b.hughes@wellcome.org

ⁱThis figure includes deaths from AMR of any cause with *E. coli*, TB and malaria being the biggest drivers; Jim O’Neill, [Review on Antimicrobial Resistance](#) (2014)

ⁱⁱCreating a global portfolio of open research & data to help guide national & global strategies for tackling DRI.

ⁱⁱⁱDeveloping a global framework to coordinate, monitor and evaluate progress.

^{iv}Building global clinical trial networks to innovate and standardise protocols and make trials more efficient.

^vFunding the development of potential new antibiotics, diagnostics and preventative approaches.

^{vi}The funders of CARB-X have now diversified and include the Germany’s Federal Ministry of Education and Research (BMBF), the UK Government’s Global Antimicrobial Resistance Innovation Fund (UK GAMRIF) and the Bill & Melinda Gates Foundation. CARB-X projects also receive in-kind support from the US National Institute of Allergy and Infectious Diseases (NIAID).

^{vii}Power E. [Impact of antibiotic restrictions: the pharmaceutical perspective](#). *Clin. Microbiol. and Inf.* **12**, 25-34 (2006).

^{viii}WHO. [Antibacterial agents in preclinical development](#) (2019) “71% of the therapeutics in the pipeline are being developed by small and medium sized enterprises”.

^{ix}For example: bacterial virulence factors, disease mechanisms, novel therapeutic targets, the host response and microbiome, new chemistry, natural products and alternative therapeutic approaches (like use of antibodies, innate immunity stimulation and countering resistance mechanisms).

^xFor example: medicinal chemistry, synthetic chemistry, analytical chemistry, computational chemistry, biological target expertise, enzyme pharmacology, assay development and high throughput screening, biophysical screening, structural biology, cellular biology, *in vivo* animal models, drug metabolism & pharmacokinetics and clinical insight.

^{xi}Personal communication with four members of the CARB-X review committee.