Contract Opportunity:

Project Adviser, Regulatory Pathways and Systems for Snakebite Treatments

Summary

We are seeking to engage an external expert to provide thought leadership and advisory support for a project focused on investigating regulatory pathways and systems for developing snakebite treatments. This time-limited project will contribute towards advancing Wellcome's Snakebite programme.

Position: Up to 2 days per week (flexible to remote, in-person, or hybrid), for a total of no more than 104 full working days (based on a 7-hour workday), with an estimated duration of up to 12 months. The position offers a fixed fee of £700 per day.

Background

Wellcome, as a global charitable foundation, is dedicated to ensuring that everyone benefits from the transformative potential of science to enhance health and save lives. Our mission involves funding ground-breaking research, leading policy initiatives, advocating for change, and forging global partnerships. Over the next decade, we are committing £16 billion to drive scientific discovery and address the world's most pressing health challenges.

Launched in 2019, our Snakebite programme is a pioneering initiative committed to revolutionising the research, development, and delivery of snakebite treatments. Rooted in the vision of making these treatments safe, effective, and accessible to all, our programme aims to have a lasting impact on the landscape of snakebite envenoming and neglected tropical diseases.

Understanding regulatory pathways and systems is crucial to achieve this aim for several reasons. Snakebites, prevalent in tropical and subtropical regions, pose a substantial health risk, affecting millions annually with high morbidity and mortality rates. Despite this, the research, development, and accessibility of safe and effective antivenoms have been limited. Furthermore, the technology behind current treatments often predates the establishment of modern regulatory pathways and systems, resulting in substandard and ineffective products flooding global markets. Enhancing our understanding of regulatory pathways and enabling environments ensures that innovative snakebite treatments undergo rigorous evaluation and adhere to safety, efficacy, and manufacturing quality standards before reaching the market.

In exploring the regulatory landscape, Wellcome seeks to better understand how to support the evaluation and supervision processes for medical products, enabling faster access to affordable, quality life-saving interventions not only for snakebite but also other interventions to address global health priorities. Crucially, a deeper understanding of the applicable regulatory ecosystem including their critical pathways and fundamental requirements, enables efficiency and improved planning of the development pipeline for these interventions. Ultimately, delving into this area informs Wellcome's growing regulatory portfolio and our future role in strengthening regulatory pathways and systems for complex and innovative medical products in low and middle-income countries (LMICs) for the longer term.

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Objective

Wellcome is looking for an external expert to collaborate with the Snakebite team and provide thought leadership and advisory support for a project focused on investigating regulatory pathways and systems for developing snakebite treatments. The purpose of this call is to identify individuals with relevant experience who can lead the provision of ongoing guidance for Wellcome as we navigate the intricate regulatory landscape associated with snakebite treatments, spanning global (including WHO prequalification and the WHO treatment guideline processes), regional, and national levels. Emphasis will be placed on addressing the specific challenges and nuances within LMICs and high-burden nations.

Scope of work

The selected external expert will be expected to provide ongoing thought leadership and advisory support to Wellcome in the following areas:

1. Characterise and document current and new regulatory pathways for snakebite treatments at the global, regional, and national levels, including regulatory requirements (including safety, efficacy, and manufacturing quality) for clinical trials and marketing authorisation.
2. Guide on the development of cost-effective and efficient regulatory strategies for snakebite treatments, encompassing advice on translation of preclinical to clinical studies, as well as suitable regulatory submissions and interactions with regulatory agencies at both the clinical trials stage and at the marketing authorisation stage. Emphasis will be placed on addressing the requirements and unique challenges within low and middle-income countries (LMICs) and high-burden countries.
3. Monitor and track changes in the regulatory landscape for snakebite treatments, providing timely updates to Wellcome on relevant developments.
4. Develop a public-facing report on the regulatory landscape for snakebite treatments. This report is expected to include an overview of regulatory pathways, regulatory requirements, challenges and potential solutions associated with bringing snakebite treatments to market, including the interface between regulatory authorisation by specific pathways and eligibility for procurement tenders by major procurers of snake antivenoms at the global and national levels. A special emphasis should be placed on LMICs and high-burden countries.
5. Advise on strategic opportunities for Wellcome within the realms of regulatory convergence, harmonisation, reliance, work sharing, and recognition, at the global, continental, and regional levels. This includes exploring collaborative frameworks in diverse directions, such as north-south, south-south, and south-north partnerships, and collaborations with other regulatory authorities recognised by the WHO as either “stringent regulatory authorities” or “WHO listed authorities”.

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Deliverables

We are seeking an external expert who can contribute their in-depth knowledge and insights throughout this project and lead the creation of a final report that will contribute significantly to advancing our understanding and navigation of regulatory pathways and systems for snakebite treatments worldwide. The desired final deliverable for this collaboration is a comprehensive, report that will be published openly, intended to serve as a valuable resource for a diverse range of key stakeholders, including researchers, government bodies, industry partners, non-governmental organisations (NGOs), and Wellcome.

Engagement with Wellcome

The external expert will undertake these activities in collaboration with the Wellcome Snakebite team and internal and external stakeholders to ensure that the final deliverable meets project expectations.

The activities are anticipated to take no more than 104 full working days (based on a 7-hour workday) in total, with work expected to begin by September 2024 and to be completed no later than September 2025.

During this period, we anticipate engagement throughout the entire project, with an estimated duration of up to 12 months, including advice and guidance on regulatory pathways, updates, and strategic opportunities and considerations. In practice, this could involve a couple of days a week dedicated to ongoing consultations, staying responsive to emerging developments, and adapting strategies accordingly. The expert is expected to provide regular updates throughout the project to monitor progress.

Wellcome is open to in-person, hybrid, or remote work arrangements, in accordance with Wellcome's policy and the availability of the selected external expert. Occasional work travel may be required, but not on a regular basis.

Payments will be disbursed in instalments upon the completion of pre-agreed objectives, with a fixed fee of £700 per day (based on a 7-hour workday).

Proposal requirements

External experts interested in leading on this project should submit a proposal that includes the following:

1. A brief overview of the expert's experience in regulatory affairs for medical products, particularly biologics and small molecules (preferably with experience in the development of snakebite treatments).
2. A brief overview of the expert's experience in collaborating with regulatory agencies at the global, regional, and national levels (preferably relevant to WHO prequalification and

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treatment guideline processes and to LMICs), as well as regulatory work-sharing platforms in LMICs.
3. A proposed strategy outlining how the expert will address the requirements outlined for this project.
4. A comprehensive project plan detailing timelines, milestones, and additional resources that may be required to achieve the objective of this project.

Selection criteria

External experts interested in leading on this project should meet the following criteria:

1. Possess a minimum of 10 years of experience in regulatory affairs related to medical products, particularly biologics and small molecules. While direct experience in regulatory affairs specifically related to snakebite products is not obligatory, preference will be given to candidates with expertise in this area.
2. Demonstrate experience in collaborating with regulatory agencies and the WHO prequalification and treatment guideline processes at the global, regional, and national levels. While direct experience in regulatory affairs within LMICs and high-burden countries is not obligatory, it is highly preferred.
3. Exhibit a proven track record of leading and delivering high-quality regulatory support, including briefings, reports, and public presentations, to a variety of audiences.
4. Bring a well-established global network of regulatory experts experienced in medical products, spanning diverse levels within the regulatory landscape, from technical specialists to executive leaders, including among regulatory authorities recognised by WHO as either “stringent regulatory authorities” or “WHO listed authorities”.

External experts possessing any of the following criteria will not be considered for this project:

1. Existence of conflicts of interest that may compromise the objectivity of the work.
2. A history of non-compliance with regulatory agencies or ethical standards.
3. Involvement in any ongoing legal disputes with regulatory agencies or regulatory actions directed against the candidate themselves.

We encourage proposals from a diverse range of candidates, including those from LMICs and high-burden countries.

Application process

If you are interested, please submit a proposal outlining your suitability for this opportunity, addressing the requirements outlined above. This should be sent by email to Diogo Martins at d.martins@wellcome.org (Research Lead, Snakebite – Translation & Portfolio Integration) by midnight London time (BST) on Friday the 21st of June 2024. The selection process will take place in July 2024, and you may be invited to a 45-minute online meeting with two Wellcome team members to discuss the opportunity and your skills and experience.

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Timelines

1. **Deadline for Submission of Proposals:** 21st of June 2024
2. **Shortlisting of Experts:** Week of 24th of June 2024
3. **Expert Presentations:** Week of 1st of July 2024
4. **Selection of Expert:** Week of 8th of July 2024
5. **Estimated Project Start Date:** September 2024
6. **Estimated Project End Date:** September 2025

Important notice

Please view Wellcome's standard Terms and Conditions document which we would contract this work under.

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.

Diversity and inclusion

Diversity and inclusion are central to our strategy. We want to make sure everything we do – and everyone who works with us – upholds these principles. Our intention is to work with kindness and consideration and to value the wellbeing of everyone involved in the collaboration. If you require any reasonable adjustments during the process, please contact us at d.martins@wellcome.org.

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