

Innovate UK



Department
of Health



New vaccines for global epidemics: development and manufacture

Competition for development contracts

Register by 27 April 2016



Government challenges.
Ideas from business.
Innovative solutions.

The Department of Health is to invest up to £10 million in two competition streams in line with the priorities identified by the UK Vaccine Network.

This SBRI competition aims to stimulate the development of:

- vaccine for priority infectious diseases
- vaccine platform technology
- manufacturing technologies that would allow for the rapid manufacture of vaccines in low-income settings

The competition will be in 2 streams.

In stream 1 up to £6 million is available for exploring scientific and technical feasibility. This stream is mainly aimed at the development of vaccines and vaccine technology that is still some way from being ready to be used in phase I human trials. Individual contracts will be for up to £500,000, to be spent within 12 months of contract award. Depending on the success of projects from this stream, the Department of Health will consider further major awards to progress product development.

In stream 2 up to £4 million is available to projects at a more advanced stage of development. This stream is mainly aimed at candidate vaccines that are now, or will soon be, ready for phase I human trials and manufacturing technology that could potentially be commercially viable in the near future. Individual contracts for this stream will be for £500,000 to £1 million, to be spent within 18 months of contract award. Projects with higher or lower costs will also be considered on a case-by-case basis.

The competition is open to all organisations that can demonstrate that their product or work has a realistic route to market, whether in the short or long term. Successful organisations will attract a 100% funded development contract.

This competition is wholly funded by Official Development Assistance

(ODA). This means that while work on projects can be carried out in high-income countries, there must be a clear explanation of how the research/project will benefit those in low-income countries.

The Department of Health recognises that there is no time to lose in the development of candidate vaccines, vaccine platform technology and vaccine manufacturing technology to combat priority infectious diseases. As such, there is particular interest in projects that can begin rapidly and have the potential to spend significant amounts of the contract award in calendar year 2016.

The competition opens on **29 February 2016**. The deadline for registration is at noon on **27 April 2016**, and the deadline for applications is at noon on **4 May 2016**. A briefing event will be held on **11 March 2016**.

Background >

Infectious disease outbreaks are widely recognised as a key global threat. In 2014 to 2015, some 27,000 cases of Ebola in Guinea, Liberia and Sierra Leone resulted in more than 11,130 reported deaths, making it one of the worst pandemics in modern times. A more virulent disease in future would have a much more devastating impact. In June 2015, the Prime Minister established the UK Vaccine Network to ensure that the UK was at the forefront of the global fight against future disease outbreaks.

Vaccines are among the most cost-effective medical countermeasure for confronting epidemics or pandemics. Their effectiveness in preventing disease outbreaks has been far-reaching, and their availability could significantly reduce fatalities. Rapid manufacture, deployment and delivery of these vaccines in resource-poor settings are key to containing the spread of disease.

This competition is aimed at supporting the development of vaccine candidates, vaccine platform technology and vaccine manufacturing technology. These new products must have the potential

for use in low- and middle-income countries to target a range of human diseases with epidemic potential, as identified by the UK Vaccine Network.

Scope >

This competition will support projects seeking to develop vaccines, vaccine platform technologies and manufacturing technologies that will enable an effective, rapid response during future outbreaks of the following pathogens: Chikungunya, Crimean-Congo Haemorrhagic Fever, Dengue Virus, Ebola, Hantavirus, Lassa, Marburg, Middle East Respiratory Syndrome, Nipah, Plague, Q Fever, Rift Valley Fever and Zika.

We will support all aspects of existing vaccine candidate development up to phase I clinical trials, but are particularly interested in preclinical and clinical development.

Particular attention should be given to aspects such as:

- the ease and speed of manufacture
- potential delivery in resource-poor settings
- temperature stability
- the need for single immunisation or low number of boosts
- durability of protection
- the existence of a serologic marker of efficacy
- the existence of biomarkers or correlates of vaccine safety (low reactogenicity)

Development of animal vaccines will only be supported if significant impact on preventing or managing disease outbreaks in humans can be demonstrated.

We will support the development of vaccine platform technologies that:

- improve the efficacy of existing strategies such as (and not limited to) new and improved adjuvants, or methodologies to stratify patient populations to elicit improved responses



- improve candidate antigen identification
- develop vaccine formulations that can withstand temperature oscillations/do not require a cold chain, and may thus be more easily deployable in resource-poor settings

We will support the development of vaccine manufacturing technologies that:

- are flexible, fast and scalable
- allow rapid switching and manufacture of different vaccination products
- are deployable and usable in low-income settings, in particular taking into account: robustness of machinery; ease of use and repair; potential ability to operate in tropical conditions, with the potential for only intermittent power supply

The competition will have 2 streams.

Stream 1

Stream 1 is aimed at projects in early development. Funding is for an initial period of up to 12 months. It will enable projects to assess the efficacy potential of the proposed product, generate preliminary performance or validation data and develop a detailed product development plan. Projects are expected to cost in the range of £300,000 to £500,000, but projects with lower costs will be considered.

Projects that can demonstrate real progress over the contract period may, on completion, be able to access further Department of Health funding.

Stream 2

Stream 2 will look to support the development of products further along the development pipeline. Funding will be for up to 18 months and will enable projects to generate suitable evidence to begin the process towards regulatory approval. Projects are expected to be in the range of £500,000 to £1 million, although projects with higher or lower costs will be considered if suitable evidence can be provided to demonstrate why this is required.

Project proposals for both streams >

In both streams, applicants must describe the candidate vaccine, vaccine platform technology or manufacturing technology being developed, its relevance to global epidemic disease threats, the anticipated clinical application and an estimation of the anticipated medical benefit and value.

In the case of novel manufacturing technologies, applicants will be expected to set out how their proposal would realistically have a substantive impact on current manufacturing practices, including their potential to be deployed in low-income settings.

Project proposals must demonstrate strict compliance with all necessary regulatory requirements. Projects should demonstrate that the vaccine candidates, vaccine platform technologies and vaccine manufacturing technology could feasibly be used and have a substantive impact in low-income

What is SBRI?

The SBRI programme enables public sector bodies to connect with innovative ideas and technology businesses to provide innovative solutions to specific public sector challenges and needs.

The public sector is able to find innovative solutions by reaching out to organisations from different sectors, including universities and small and emerging businesses. New technical solutions are created through accelerated technology development, whilst risk is reduced through a phased development programme. SBRI also provides applicants with a transparent, competitive and reliable source of early stage funding.

SBRI competitions are open to all organisations that can demonstrate the feasibility and a potential route to market for their solution.

Developments are 100% funded and focus on specific identified needs, increasing the chance of exploitation. Suppliers for each project will be selected by an open competition process and retain the intellectual property generated from the project, with certain rights of use retained by the contracting authority. This is an excellent opportunity to establish an early customer for a new technology and to fund its development.

and middle-income settings. Applicants should provide a project plan of the work required to demonstrate this. They should describe how the product or capability would be used, where and by whom, with evidence that the technologies and models are appropriate and fit for purpose.

Out of scope

In this competition we are not funding projects covering:

- new agents/technologies not related to the diseases listed above
- discovery of wholly new immunisation agents
- development of agents for animal disease that cannot demonstrate a clear impact on human health

Funding allocation >

In this competition, we will use the SBRI mechanism to reach out to companies. In stream 1, we will invest up to £6 million in stream 1 projects that meet the challenge outlined in the scope. We expect the value of contracts to be between £300,000 and £500,000 each. Projects should last up to 12 months. Depending on the success of work funded at stream 1, the Department of Health will consider making further significant funding available for further development.

In stream 2, we will invest up to £4 million in projects meeting the challenge outlined in the scope. We expect the value of contracts to be between £500,000 and £1 million each. Projects should last up to 18 months. See the *Guidance for Applicants* for further information. All costs should include VAT.

Key dates >

Competition opens	29 February 2016
Briefing event	11 March 2016
Registration deadline	27 April 2016 noon
Deadline for applications	4 May 2016 noon
Contracts awarded	September 2016

Application process >

This competition opens for applicants on **29 February 2016**. The deadline for registration is at noon on **27 April 2016**, and the deadline for applications is at noon on **4 May 2016**. Contracts will be issued by **September 2016**.

A briefing for applicants will be held on **11 March 2016** to highlight the main features of the competition and explain the application process.

Applicants are strongly recommended to attend this event.

Applicants should register for this event at <https://innovateuk.webex.com/innovateuk/onstage/g.php?MTID=ef2e2ef03d7f528b6aa8e2db19bfaf40>

Note: All deadlines are at noon.

Applications will be reviewed by a panel of experts. Finalists may be requested to attend an interview.

More information >

For more information and all the documents you need to read before you apply, including the *Guidance for Applicants*, go to the web page for this competition at <https://interact.innovateuk.org/> or watch our video at <https://www.youtube.com/watch?v=S-rnSpIMiPc>

To apply you must first register with us through the competition page on the website. Registration opens when the competition opens and closes a week before the deadline for applications.

Get help to understand the future market for your innovation before you apply at

<http://horizons.innovateuk.org>

Competition helpline:
0300 321 4357

Email: support@innovateuk.gov.uk

Publicity >

As part of the application process all applicants are asked to submit a public description of the project. This should adequately describe the project but not disclose any information that may impact on intellectual property, is confidential or commercially sensitive. The titles of successful projects, names of organisations, amounts awarded and the public description will be published once the decision to offer an award has been communicated to applicants by email. Information about unsuccessful project applications will remain confidential and will not be made public. Email pressoffice@innovateuk.gov.uk with any queries.

Innovate UK is the UK's innovation agency. Innovate UK works with people, companies and partner organisations to find and drive the science and technology innovations that will grow the UK economy – delivering productivity, new jobs and exports. Our aim at Innovate UK is to keep the UK globally competitive in the race for future prosperity.

Innovate UK is the trading name of the Technology Strategy Board, which is an executive non-departmental public body sponsored by the Department for Business, Innovation and Skills, and incorporated by Royal Charter in England and Wales with company number RC000818. Registered office: North Star House, North Star Avenue, Swindon SN2 1UE.

Telephone: 01793 442 700
Email: support@innovateuk.gov.uk
www.innovateuk.gov.uk

Follow us on