# WHO R&D Blueprint

**Public consultation on ideas for potential platforms to support development and production of health technologies for priority infectious diseases with epidemic potential**

Update March 2016

**Extension of date for submission of ideas**

In response to requests, the initial date for submission of ideas has been extended to Friday 5 February 2016.

Update 11 December 2015

**Priority pathogens for production platform ideas**

A WHO meeting held on 8-9 December in Geneva agreed the initial list of disease priorities needing urgent R&D attention. These, in alphabetical order, are:

Crimean Congo haemorrhagic fever,
Ebola virus disease and Marburg,
Lassa fever,
MERS and SARS coronavirus diseases,
Nipah
Rift Valley fever

This information is provided to guide stakeholders who plan to submit an initial, high-level proposal by the due date of Friday 15 January 2016 (updated to 5 February 2016).

This initiative excludes infections and diseases for which there are already extensive programs and/or partnerships for disease control and mechanisms in place for Research & Development. The initiative also excludes diseases and infections that are endemic so the particular issues about research preparedness and research response for sporadic outbreaks with the potential to generate a public health emergency are not applicable.

The request for ideas on production platform ideas therefore excludes the following: malaria, TB, HIV, cholera, dengue, chikungunya, other neglected tropical diseases (see http://www.who.int/neglected_diseases/diseases/en/), and pandemic influenza.

Background

The epidemic of Ebola in West Africa showed that the world is unable to develop effective interventions in a timely manner for control of severe emerging infectious diseases using current approaches to vaccine, drug and diagnostics development.

Indeed, market-driven models for R&D do not cater for medical technologies for diseases that are sporadic or unpredictable, especially when they occur in countries with low investment in health infrastructure and delivery. The challenge becomes even greater when faced with a wholly new disease such as SARS, MERS and Nipah virus infection, which are just three examples of diseases that have emerged at the human-animal interface in the last two decades.

The international community needs to invest to improve our collective ability to respond to new threats and to prepare itself with a novel R&D paradigm to address future epidemics.

The R&D Blueprint for infectious diseases with epidemic potential

An efficient and effective research response during an infectious disease epidemic requires R&D preparedness – work done between epidemics to fill knowledge gaps, identify potentially useful candidate medical products and other interventions, and to ensure the timely availability of such when an epidemic occurs. Following a request from its Member States, through the R&D Blueprint, the World Health Organization is reviewing options for a global effort to enhance R&D preparedness for future epidemics.

The World Health Organization (WHO) is inviting submission of structured ideas on how to improve R&D readiness for priority infectious disease threats. Specifically, propositions are requested for flexible development and production platform technologies. The scope of health products under consideration includes vaccines, therapeutics (drugs and blood products), and diagnostics against 5 to 10 top priority pathogens/diseases, to be defined by WHO[1]. Development and production platforms would be needed to manufacture candidate vaccines or therapeutics for evaluation up to at least Phase 1 clinical trials before any confirmed epidemic threat, as well as for Phase 2/3 clinical evaluation during a potential epidemic. For diagnostics, platforms would be needed to progress products to a point where they can reliably be validated and used in the field. Only platforms that can address at least three priority pathogens (as defined by WHO) will be considered.

[1] See 11 December 2015 update

Candidate medical products developed through such platforms and that are found to have a favourable benefit-risk profile should become available in sufficient quantity to enable larger scale testing during an outbreak and use, where appropriate, in disease control efforts through Expanded use or Emergency use approval (or listing) schemes. Therefore the submissions should go beyond preparing materials for Phase 1 clinical studies only, and include strategies to assure readiness for production at a scale sufficient to potentially contribute to epidemic control.

While infectious pathogens may affect any country, options to address affordability in low and middle income countries (LMICs) need to be addressed. Management of intellectual property (IP) rights is likely to play an important role for the viability of the platform(s). The proposals should explain how IP and potential transfer of technology issues will be managed to ensure fair and equitable access, especially for LMICs, to any product(s) developed through the proposed platform(s).

The manufacturing process must be capable of meeting general regulatory standards and WHO norms and standards, where they exist, and WHO-requirements for emergency listing of a product or, where appropriate, prequalification. Platform ideas that would facilitate strategic geographic distribution of platform production sites are especially welcomed. Localization of production in countries with oversight by a WHO-recognized National Regulatory Authority will be important.

Submissions should explain what internal resources of those submitting would be used and what additional external funding would be required to implement the platform concepts being proposed. Creative approaches are encouraged to develop options that include meaningful participation by entities in LMICs.

Consultation process

**While WHO does not intend to provide direct financial support to any proposal**, the most meritorious ideas emerging from the process – as assessed by a WHO Advisory Group - will be invited to present in a dedicated workshop where WHO Member States and relevant R&D funders will be invited to participate.

Eligibility

The public consultation on ideas is open to non-profit organizations, for-profit companies, international organizations, government agencies and academic institutions.

How to submit ideas

Platform ideas should be submitted electronically to the following email address: ebola-research@who.int

Format

The submission should clearly communicate the platform being proposed in not more than 5 pages. It should cover the following elements:

1) **Concepts and ideas**: Describe and justify the rationale for and the impact that the proposed platform would have on R&D preparedness.
2) **Proposed technical approach**: Succinctly describe the technical details of the technology platform, including any prior use or experience with other products, and scientific and technical justifications why the platform would be useful for products to address the priority pathogens. It will also be necessary to describe how the technology lends itself to rapid scaling up on demand at the time of an outbreak.
3) **Proposed collaborative approach**: Succinctly describe how meaningful participation by entities in LMICs would be achieved, and the intended strategic geographic distribution of platform production sites. Include a description of the how collaborations between partners would be structured and managed.
4) **Costs and timelines**: Include estimates of costs, per year, of the proposal. Indicate what resources the proposers would donate to the project and what external resources would be required. Indicate what deliverables, in terms of candidate products for the priority pathogens, would become available and over what timelines. Also indicate how affordability of products for LMICs developed through this proposal would be addressed.

Selection process

The process for selecting submissions to be presented at the workshop will be as follows:

1) An initial screening of submissions by the WHO secretariat to determine if they are within scope of the consultation. Submissions that are out-of-scope will be removed from further consideration, and the applicant informed.

2) Proponents of submissions that are within scope will be invited to present their platform ideas during a technical workshop convened by WHO. Grouping of complementary proposals into larger collaborative projects will be suggested when appropriate.

3) Ideas emerging as the most promising will be identified during the workshop, and proponents invited to submit more detailed and refined plans. Additional instructions will be provided at that time.

4) The refined submissions will be assessed by a WHO Advisory Group.

5) The strongest propositions emerging from the process will be presented in a dedicated workshop where WHO Member States and other organizations which fund Research and Development will be invited to participate.

Key dates

a. Submission of platform ideas by Friday 5 February 2016, 17:00 Geneva time
b. First workshop with technical experts to discuss platform ideas, by 4-6 April 2016
c. Notification of invitation by WHO to submit a phase 2 revised platform concept by 25 April 2016
d. Deadline for receipt of phase 2 revised submission (invited proposals only) by Friday 27 May 2016, 1700 Geneva time
e. Shortlisting by a WHO Advisory Group completed by end of June 2016
f. Second workshop, where proponents will be invited to present the shortlisted platform ideas, convened by WHO with Member States and other organizations which fund Research and Development by 31 July 2016