R&DBlueprint

Powering research
to prevent epidemics

Research integrated into outbreak response

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Some definitions

Investigational Product | A product form of an active substance (or placebo or used as a reference) being tested in a clinical trial.

Candidate Product (Vaccine or Therapeutic) | A product developed, manufactured and/or tested that has not yet received regulatory authorization for commercial distribution other than in connection with pre-clinical or clinical trials.

Licensed Product (Vaccine or Therapeutic) | A product that has received regulatory approval (marketing authorization) for commercial distribution and use in humans for specific indications. It has completed testing in clinical trials, and there is scientific proof that it is safe and effective for treating a particular disease or condition

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AIM

- To contribute to the **rapid start randomized trials to access candidate products integrated into initial outbreak response.**

- If existing or emerging evidence indicated that the candidate product(s) are efficacious, they could be **rapidly deployed as part of an expanded access /compassionate use protocol**, with appropriate monitoring and data collection.

Candidate vaccines selection conducted by on the evidence (agnostic of funder) and informed by their public health suitability as defined by a WHO Target Product Profile (TPP).

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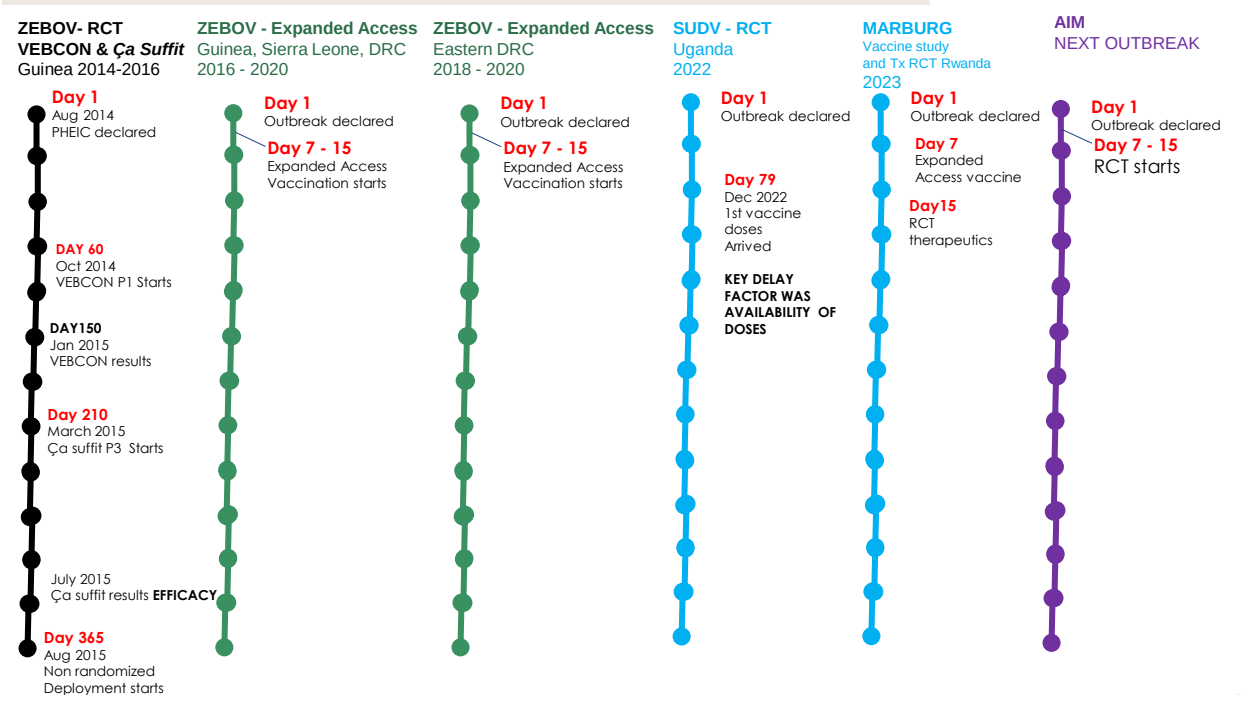

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FAST TRACK RANDOMIZED ASSESSMENT OF CANDIDATE PRODUCTS AND SUPPORT PANDEMIC PREVENTION AND CONTROL

1 Prioritization

Independent expert process to prioritize candidate vaccines

Prior agreement on a process for prioritization of candidate vaccines by an independent the WHO Technical Advisory Group on candidate vaccine prioritization (TAG-CVP), including ongoing review of emerging information.

2 Availability

Agreement on availability and access to candidate vaccines

Decisions will be informed by outcomes of the prioritization process; consensus on minimum number of candidate doses required for research during outbreaks and that need to be available at any time point.

3 Clinical trials*

Standardized platforms to scale clinical trials equitably
** includes expanded access*

This will emerge from a collaborative multilateral approach in which the Ministries of Health are at the core of all research efforts.

4 Agreements

Prior agreement on legal collaboration, insurance, indemnity and liability

This depends on having in place partnership models and signed agreements with Ministries of Health, independent prioritization system and on insurance and liability arrangements.

5 Funding

Access to readily available funding through committed financing mechanism

This depends on signed agreements with contributors; and on a simple approval process for release of funds and financial reporting. .

6. To foster an open flexible mechanism that allows a variety of contributors (pathogen / outbreak) to contribute and to help adjust this blueprint as needed

Next steps include further consultation with interested stakeholders

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Previously agreed prioritization of candidate products	**1. Data** on safety and immunogenicity 2. Independent WHO **expert group prioritization**
Funded investigational candidate products already in internationally transferable vials	1. Inputs from prioritization process 2. Agree **how many doses** 3. Funds for GMP vaccine into vials 4. **"Mechanism"** to monitor and access investigational doses
Agreed trial platforms and CORE protocols PIs and research teams nominated by the MOHs in 17 countries	**1. CORE** protocols discussions for RCT 2. NRAS and Ethics from **at risk countries pre-approval** **3. Network** of networks of local researchers 4. Logistics and supplies **ready**
Agreed LEGAL collaboration, insurance and liability framework	**1. Signed agreements** with prioritized developers 2. Insurance & liability arrangements
Agreed funding	1. Signed agreements with contributors 2. Simple process for access to funds

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AIM

INVESTIGATIONAL PRODUCTS*

Rapid start of studies integrated into initial outbreak response

Rapid deployment (as expanded access) if efficacy data available

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