Building Resilience Against Outbreaks & Pandemics

Research to identify sustainable solutions

The 3rd Global Research and Innovation Forum
Critical research to ensure equitable and fast access to high-quality and affordable therapeutics while ensuring people’s trust

Update and priorities

Dr. Marco Cavaleri
EMA
Only a handful of platform trials were informative

Most trials were not informative and some were too small to be able to answer confidently key public health questions.

Some of the treatments evaluated maybe should have not been prioritised

Improvements are needed in the South and in the North!
Regarding access to candidate therapeutics during outbreaks and pandemics, some have emphasized the importance of **speed** and sometimes **cost** in responding to future pandemics.

It is equally important to take a broader view that recognizes the primary importance of **quality**, **equity** in availability, and **trust** in the products safety and efficacy.
Being prepared to integrate research during outbreaks

Data-driven decisions by open collaborative scientific networks

MOH in the driving seat
designates researchers

Support of local research capacity

Local researches contribute to the process

Landscapes of candidates

Target Product Profiles

Independent process for prioritization

A virtual process to ensure therapeutics are available for outbreak evaluation

Pre-outbreak trial design

Pre-approved CORE protocol

Legal, regulatory and insurance framework

Support of local research capacity

Research and innovation priorities for other areas

World Health Organization

R&D Blueprint

Classified as internal/staff & contractors by the European Medicines Agency
Inter-epidemic research for Filovirus family

An example, leading toward a Viral family approach
Outbreaks research for Filovirus family

An example, leading toward a Viral family approach
A WHO Global Committee for prioritization of candidate treatments for evaluation during outbreaks

Established in early 2020
Independent experts, transparent, data-driven, with a priori defined criteria

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Number of products reviewed</th>
<th>Type of product</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19</td>
<td>Over 20</td>
<td>• Antiviral&lt;br&gt;• Immunomodulators&lt;br&gt;• Antimalarials</td>
</tr>
<tr>
<td>Sudan ebola virus</td>
<td>7</td>
<td>• MAbs cocktail and MAb&lt;br&gt;• Antiviral&lt;br&gt;• Therapeutic to target host response</td>
</tr>
<tr>
<td>Marburg</td>
<td>3</td>
<td>• MAbs cocktail and MAb&lt;br&gt;• Antiviral</td>
</tr>
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8 consultations on candidate treatments were held between Aug-Nov 2022
Approx 50 scientists per meeting (and 500+ for global consultations)
- clinicians/researchers from the Uganda MOH, ETCs,
- filovirus experts, clinical trial experts, developers

Topics discussed included
1. Evidence regarding different investigational therapeutic agents
2. Study design and opportunities for implementation of a clinical trial.
3. Proposed CORE protocol based on the prioritized trial design options.
An existing open collaborative scientific network (MARVAC) was triggered immediately after Marburg outbreak declaration.

4 consultations on candidate treatments were held between Feb – Jul 23

Approx 30-50 participants and 500+ for global consultations

Items discussed included
- Review of available vaccines and therapeutics, status, and availability
- Review a CORE trial protocol

With special thanks to Peter Horby, Amanda Rojek, Martin Landray, and colleagues at the Univ of Oxford for developing the full protocol based on the outputs of the global consultations.
Being prepared to integrate research during outbreaks

The planned objectives of the future scientific workshops are to:

- **Continue to foster collaboration** for evaluating candidate therapeutics within outbreak responses, led by clinical trial networks and research teams.

- **Give the opportunity to national researchers and authorities to contribute to design of trial protocols** for candidate vaccines and therapeutics towards final consensus on key trial design attributes.

- **Develop an action plan per pathogens for collaborative network** of designated researchers in “at risk” countries via engagement in a framework for clinical research preparedness to ensure clinical research is promptly integrated into future outbreak responses.
Maximizing our research efforts to inform strategic actions is critical to control outbreaks and prevent future pandemics.

“A systematic approach that studies treatments against representative pathogens from families with known pandemic potential to be better prepared vs. emerging or reemerging pathogens”.

Innovative approaches and emerging technologies, e.g. Mab platforms, broad-spectrum antivirals or host-therapies, can help select among available candidate treatments for prototype pathogens.
Thank you