

# Process for prioritization of candidate therapeutics for the evaluation in clinical trials

Dr Marco Cavaleri  
EMA



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## 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!**

As of Aug 02, 2023 there were 4634 <sup>2</sup> randomized trials of COVID-19 treatments



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## A WHO Global Committee for prioritization of candidate treatments for evaluation during outbreaks

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Established in early 2020

Independent experts, transparent, data-driven, with a priori defined criteria

Pathogen	Number of products reviewed	Type of product
COVID-19	Over 20	<ul style="list-style-type: none"> <li>• Antiviral</li> <li>• Immunomodulators</li> <li>• Antimalarials</li> </ul>
Sudan ebola virus	7	<ul style="list-style-type: none"> <li>• MABs cocktail and MAb</li> <li>• Antiviral</li> <li>• Therapeutic to target host response</li> </ul>
Marburg	3	<ul style="list-style-type: none"> <li>• MABs cocktail and MAb</li> <li>• Antiviral</li> </ul>



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Technical Advisory Group on Therapeutics Prioritization  
January 2026

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WHO R&D Blueprint

WHO Technical Advisory Group on Therapeutics  
Prioritization



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## Members

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Marco Cavaleri, chair, Head of Public Health Threats, European Medicines Agency.

Ashish Bavdekar, Director, Department of Paediatrics, KEM Hospital Research Centre, Pune, India.

Sanjay Bhagani, Royal Free London NHS Trust and UCL, London, UK.

Gavin Harris, Emory University Hospital, Atlanta, USA

Elizabeth Higgs, Global Health Science Advisor, Division of Clinical Research, National Institute of Allergy & Infectious Diseases (NIAID), USA

Andre Machado Siqueira, Infectious Diseases Physician and Clinical Researcher, Oswaldo Cruz Foundation, Rio De Janeiro, Brazil.

Julia Tree, Senior Project Team Leader, Antivirals/Technology Development Group, UK Health Security Agency (UKHSA), UK.

Thomas Geisbert, University of Texas Medical Branch, Texas, USA



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## Function

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To review the evidence of the current armamentarium of therapeutic medical countermeasures used during previous outbreaks or under development for a given disease. The review will cover treatment modalities for all stages of the disease, including prophylaxis or post-exposure prophylaxis as needed, except vaccines.

To make preliminary recommendations on whether the therapeutics should be prioritized to be included in the clinical trials.

*The consultation will focus on all new or repurposed drugs to be immediately included in phase II/III efficacy evaluations.*

*The evaluation of potential therapies takes into account the possibility of combination therapies and/or treatment modalities with different pharmacological properties, e.g. antiviral and anti-inflammatory agents*



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# Operations

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TAG meetings may be held in open and/or closed session, as decided by the Chairperson in consultation with WHO.

Open sessions: Open sessions shall be convened for the sole purpose of the exchange of non-confidential information and views, and may be attended by Observers

Closed sessions: The sessions dealing with the formulation of recommendations and/or advice to WHO shall be restricted to the members of the TAG and essential WHO Secretariat staff.

Information and documentation to which members may gain access in performing TAG related activities shall be considered as confidential and proprietary to WHO and/or parties collaborating with WHO.



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# Evidence to be gathered

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Table 1. Overview of candidate therapeutics

Type of treatment	Treatment description	Developer	Current stage of clinical evaluation/regulatory status	Target Pathogen(s) Strain(s) aimed to protect against	Summary of Preclinical Evaluation (in vitro and in vivo data)	Summary of available clinical evidence (including any efficacy data)	Clinical Safety data	PK/PD including potential for DDI	Mechanism of action (host, target directed)	Availability of clinical material supply	Plans for clinical evaluation including target population (including vulnerable population) and endpoints	Route of administration	Current presentation and schedule	Storage	Manufacturing Capacity

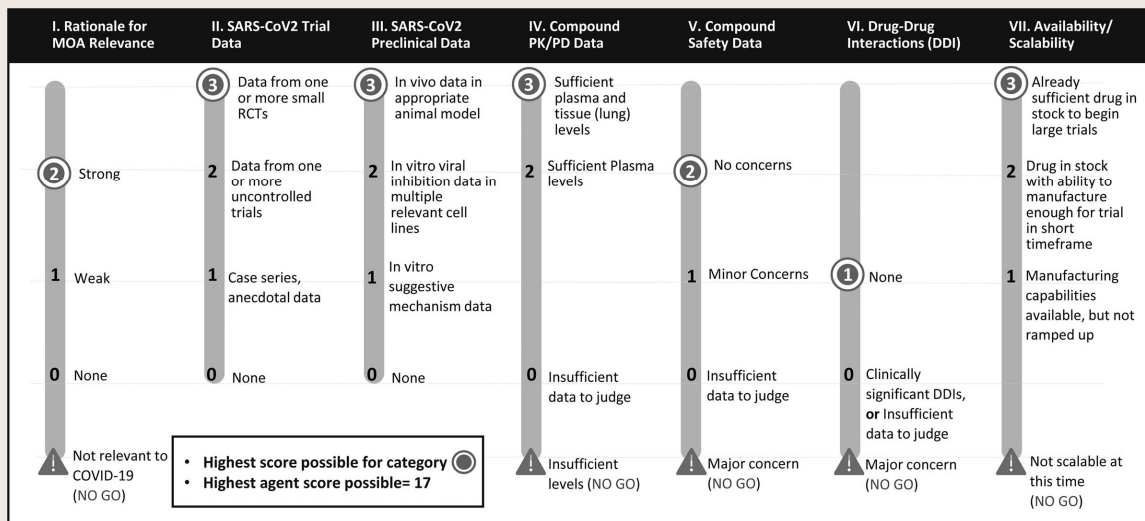


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## Ranking scores under considerations based on ACTIV experience

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### Critical Care Medicine



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## Viral families and priority areas

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- Interactions with CORCs are essential to ensure proper coordination and awareness and CORCs coordinators/ reps could be added as observers at the TAG meetings
- The TAG needs full visibility of candidate products and ongoing or planned clinical/preclinical investigations
- Essential to have information on clinical trial design and potential indication of use, e.g. PEP vs treatment and/or specific populations
- Initial priorities tentatively identified for RVF, filoviruses and influenza, but would be refined based on input from CORCs

**LOOK FORWARD TO ENGAGING WITH ALL OF YOU!!**



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# Thank you



World Health Organization



R&D Blueprint

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