



**World Health  
Organization**

# **Solidarity Trial Vaccines**

**Prioritization of candidate vaccines for international support for further evaluation including Phase IIb/3 randomized clinical trials**

**13 September 2022, Geneva**



**R&DBlueprint**

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## Table of Contents

TABLE OF CONTENTS .....	2
CONTEXT .....	3
OBJECTIVES .....	4
EXPERTISE REQUIRED .....	4
EVIDENCE REVIEW PROCESS .....	4
COMPOSITION .....	5

## Context

In December 2019 a novel coronavirus (SARS-CoV-2) emerged in Wuhan, China, resulting in a rapidly spreading outbreak of coronavirus disease (COVID-19).

On Jan 30, 2020, the World Health Organization (WHO) declared COVID-19 a public health emergency of international concern (PHEIC), and by 12 March 2020, due to its rapid global spread, the outbreak was declared a pandemic.

The need for a vaccine has therefore become more pressing than ever, as the prospect of containment with non-pharmaceutical interventions has become less feasible.

As most promising candidate vaccines advance, practical realities will require a process that focuses global efforts on a small handful of candidates that may have the highest impact.

More than 160 vaccine candidates are now in development, with more than 21 candidates in Phase 1, Phase 2 or Phase 3 human clinical trials.

An independent group of experts has developed the proposed attributes and criteria for the evidence based and independent evaluation of all vaccine candidates.

The proposed attributes and criteria provide considerations for the evaluation and prioritization of COVID-19 candidate vaccines to be considered for further development by WHO<sup>1</sup>.

These attributes and criteria lay out some of the considerations that structure WHO's case-by-case assessments of COVID-19 vaccines, with emphasis on prioritization for Phase IIb/III evaluation. WHO independent expert group also developed a scoring guide to promote consistency and predictability of evaluation.

**Note:** On September 2022, following the outbreak of Sudan ebolavirus in Uganda, the Working Group on vaccine prioritization was asked to expand the assessment and suitability of candidate vaccines that could enter WHO sponsored trials, e.g. the ring vaccination trial in Uganda.

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<sup>1</sup> <https://www.who.int/teams/blueprint/covid-19>

## Objectives

The candidate vaccine prioritization working group will be set up with the aim of establishing an independent process to advise WHO on the selection of candidate vaccine(s) against COVID-19 and other pathogens that should be evaluated first.

The working group is established with a program of work to:

- (1) Review the data and information on all candidate vaccines under development against COVID-19 and other pathogens using the *a priori* defined attributes and criteria;
- (2) Provide an individual score for each candidate vaccine and a recommendation on the pertinence of prioritizing one or more given candidates for support and further evaluation;
- (3) Provide continuous review (monthly) of the emerging information and evidence on all candidate vaccines;

WHO will consider the recommendations of this Working Group and consult with other pertinent advisory bodies to inform their opinion.

## Expertise required

The Working Group will be composed by 10- 15 experts. Independent expertise in the following areas is sought:

- Coronavirus vaccines and/or COVID-19 vaccines
- Animal models and assays for vaccine evaluation
- Clinical evaluation of vaccines
- Regulatory expertise in vaccine evaluation
- Vaccine manufacturing and GMP issues
- Epidemiology/public health expertise, with particular experience on vaccine evaluation in large randomised clinical trials.
- Ethics of vaccination and vaccine programmes.
- Expertise in Immunization programmes and service delivery
- Social anthropology and vaccine risk communication
- Vaccine safety evaluation and monitoring

## Evidence review process

1. **Request of information from developers.** Using an *a priori* defined format, all developers will be invited to provide information that will allow the Working Group members to attribute points to each candidate vaccine in each of the domains

## Call for nominations for experts

### Prioritization of COVID candidate vaccines

covered by the set forth criteria. The information provided can include public and confidential information. Appendix X.

2. **Review of evidence.** While undergoing the review of information, the Working Group members will use a scoring guide developed by the WHO independent expert group. This will help ensure and promote consistency and predictability of evaluation. Each member will individually conduct a review of the evidence and submit it to the Chairperson in writing.
3. **Quorum for decision making and consensus.** At least two thirds of the Working Group members should participate by providing their writing evaluation. The final decision will be made by consensus.
4. **Reporting of outcomes.** The high-level summary of the reviews will be publicly announced but not the detailed information provided to the Working Group by each individual developer.
5. **Timing of the reviews.** The reviews will be updated at regular times (monthly) and the updated summaries will be posted.
6. **Decision making and communication of outcomes of the review.** It is anticipated that the review outcomes can inform and encourage investment by third parties.

## Composition

### Working Group Chair:

Myron M. Levine, MD, DTPH,  
Simon & Bessie Grollman Distinguished Professor, and  
Associate Dean for Global Health, Vaccinology & Infectious Diseases  
Center for Vaccine Development & Global Health,  
University of Maryland School of Medicine,  
Baltimore, MD, USA

### Working Group Rapporteur:

Elizabeth Miller, OBE, FMedSci, PhD  
Professor, Department of Infectious Disease Epidemiology  
London School of Hygiene & Tropical Medicine  
London, UK

## Call for nominations for experts

### Prioritization of COVID candidate vaccines

#### **Voting Members**

Dr. Rebecca E. Chandler Uppsala Monitoring Centre, Sweden

Dr. Sudhanshu Vratl Reg Ctr for Biotechnology, India Virology;

Dr. Junzhi Wang Nat. Inst. for Food & Drug Control, China

Dr. Sue-Nie Park Korea Univ.

Dr. Sergio de Andrade Nishioka Fundação Oswaldo Cruz (Fiocruz), Brasil

Dr Subhash Kapre InventVax & Inventprise, USA Vaccine manufacturing; vaccine formulations

Prof Dani Cohen School of Public Health, Tel Aviv Univ, Israel

Dr Collins Tabu Expanded Programme of Immunization, Kenya

#### **Former members**

Prof Gavin Churchyard Aurum Institute, South Africa Infectious disease

Dr. Silvia Sanchez-Ramón Univ Hosp Clin San Carlos, Spain

#### **Observers**

Prof. César Muñoz-Fontela German Ctr for Infect. Res. Germany

Dr Simon Funnell Public Health England, UK Animal models of COVID-19;