



# novel Coronavirus

## Call for nominations for experts

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

**13 July 2020, Geneva**



**R&DBlueprint**

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## **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.

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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 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 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

## Timeline for submission of nominations

Proposals for nominations should be sent by email to the email: **covid19@who.int** with a Curriculum Vitae, indicating area of expertise, years of experience and current involvement, if any, in COVID vaccines development and evaluation.

All nominations submitted will be considered by an independent panel. Only complete nominations received by Wednesday, 22 July 2020, 23:59 CET will be considered.

## 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 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.