



**World Health  
Organization**

# **WHO R&D Blueprint novel Coronavirus**

**WHO Working Group –**

**Core Protocol for therapeutics against COVID-  
19**

© World Health Organization 2020. All rights reserved.



**R&D Blueprint**

Powering research  
to prevent epidemics



## Table of Contents

<b>TABLE OF CONTENTS</b> .....	<b>2</b>
<b>TERMS OF REFERENCE</b> .....	<b>3</b>
<b>OBJECTIVE</b> .....	<b>3</b>
<b>ACTIVITIES TO BE PERFORMED BY THE MEMBERS:</b> .....	<b>3</b>
<b>COMPOSITION</b> .....	<b>4</b>
EXPERTS .....	4
WHO SECRETARIAT .....	4



## Terms of Reference

WHO recommends researchers around the world to systemically evaluate experimental therapeutics in randomized control trials as a gold standard. Multiple small trials with different methodologies may not provide enough strong evidence about which treatment will be most effective.

WHO is convening a group of experts to design a clinical trial that could be implemented in several countries with similar methodology, primary and secondary outcomes that could be comparable.

The overall goal is a large international study designed to generate robust data to rapidly demonstrate which treatments are the most effective.

The core protocol should provide simplified procedures to enable even hospitals that have been overloaded to participate.

Recognizing the critical importance to the public health of COVID-19 pandemic the rapid availability and deployment of an effective treatment against COVID-19, the Working Group on the core protocol for therapeutics against COVID-19 is requested to provide a phase 3 protocol that will enable a rapid evaluation of the benefits and risks of each treatment.

## Objective

To develop a Core protocol to engage multiple sites/ countries, multi-arm randomized controlled trial to rapid provide reliable evidence about the efficacy and safety for each experimental arm and dosage against standard of-care control arm.

## Activities to be performed by the members:

1. Outline the key aims of the protocol
2. Outline the key benefits of the protocol
3. Develop a protocol synopsis.
4. Develop a core protocol for phase 3 efficacy trials for treatments against COVID-19, severe hospitalized cases
5. Prepare and be available for the regular working group calls.
6. Provide technical advice and support the WHO Secretariat through comments and or feedback from stakeholders.



## Composition

### Experts

#### Chair:

Peter Smith

#### Members:

Y. Arabi, J. Beigel, C. Bin, M. Cavaleri, J. Edmunds, S. Ellenberg, J. Farley, T. Fleming, V. de Gruttola, F. Hayden, L. Higgs, M. Jasseh, Y. Kim, A. Ko, Y. Leo, B. Lina, I. Longini, D. Lye, R. Peto, B. Poissy, M. Nason, Y. Shen, S. Van der Werf, D. Vaughn, Y. Wang, Y. Yazdanpanah

### WHO Secretariat

Ana Maria Henao-Restrepo, Pierre Gsell, Ximena Riveros, Severine Danmadji