



**World Health
Organization**

WHO COVID-19 vaccines research

Can booster doses contribute to control this pandemic: what research is needed?

13 August 2021

13:00 – 18:00 Central European Time CET

DRAFT Agenda

Version 3.0



R&D Blueprint

Powering research
to prevent epidemics

OBJECTIVES OF THE MEETING

In continuation to the scientific discussions on COVID-19 vaccines research, WHO R&D Blueprint is organizing a consultation on the state of the art and best research methods to evaluate existing, modified, and new COVID-19 vaccines.

The objectives of this forthcoming consultation will be to review the available evidence and plans for collecting evidence on the efficacy and effectiveness of vaccines being deployed in terms of:

- Emerging variants effect on protection levels
- Duration of protection
- Safety of booster vaccines
- Research to evaluate various delivery strategies

During the consultation, experts will debate the methodological strength and limitations of existing data and the potential designs to generate additional data leading to evidence-based decisions.

Chairperson: Philip Krause

Time	Topic	Proposed Speakers
13:00 - 13:10	Welcome address	WHO
	Objectives of the meeting	Philip Krause Center for Biologics Evaluation & Research, FDA, USA Chairperson of the WHO COVID-19 vaccines research expert group
13:10– 13:20	Overview of current COVID-19 epidemiological situation	Maria van Kerkhove Technical lead- COVID-19, WHO
13:20 - 13:30	COVID-19 vaccines as an additional tool to control COVID-19 pandemic: a public health research perspective	Peter Figueroa University of the West Indies, Mona, Jamaica Chair of PAHO's Technical Advisory Group (TAG) on Immunization
Session 1. What do we know and what additional evidence is needed to inform decisions on booster doses?		
13:30 - 13:40	Current understanding of mechanisms of vaccine-induced protection	Florian Krammer Icahn School of Medicine and Mount Sinai, New York, USA
13:40 - 13:50	Animal studies evidence on SARS-CoV-2 Delta variant pathogenesis and host response	Pragya Yadav Indian Council of Medical Research-National Institute of Virology, Pune, India
13:50 – 14:00	Vaccines and variants: What randomized evidence is available?	Anna Chaimani Institute of Health and Medical Research (Inserm), Paris, France
14:00 - 14:10	Vaccines and variants: what immunological data is available?	Dan Barouch Center for Virology and Vaccine Research, Harvard University, USA
14:10 – 14:20	Vaccines and variants: Methodological issues in using non-randomized studies to estimate vaccine effectiveness	Jonathan Sterne Bristol Population Health Science Institute, University of Bristol, UK
14:20 – 14:50	Emerging evidence from ongoing studies: a zoom on the Delta variant	<u>Brief updates by:</u> Aziz Sheikh ; Usher Institute, University of Edinburgh, UK & Chris Robertson Public Health Scotland, UK Nick Andrews ; Public Health England, UK Sharifa Nasreen ; Dalla Lana School of Public Health, University of Toronto, Canada Linda-Gail Bekker ; Institute of Infectious Disease & Molecular Medicine, University of Cape Town, South Africa Jesús Frías (TBC); Hospital Universitario La Paz, IdiPAZ, Universidad Autónoma de Madrid, Madrid, Spain Galia Rahav (TBC); Sheba Medical Center, and Sackler Faculty of Medicine, Tel-Aviv, Israel
14:50 – 15:20	Additional evidence on booster doses: developers' perspective	<u>Panel Discussion</u> TBC (moderator)

		<u>Invited developers</u> Rachael Ella – Bharat Biotech Allen Lien - Medigen Gregory Glenn – Novavax Philip R. Dormitzer - Pfizer Randy Hyer – Moderna Representative of J&J (TBC)– Johnson & Johnson Other developers anticipated to participate
Time	Topic	Proposed Speakers
15:20 – 15:50	How much safety data are needed to support benefit-risk assessment of booster doses?	<u>Panel Discussion</u> Marco Cavaleri (moderator); Biological Health Threats and Vaccines Strategy, EMA Rita Helfand ; Centers for Disease Control and Prevention, USA; Chair of the WHO Global Advisory Committee on Vaccine Safety Dror Mevorach ; Department of Internal Medicine, Jerusalem's Hadassah Medical Center, Israel Raina MacIntyre ; Biosecurity Program, Kirby Institute, University of New South Wales, Australia
15:50 – 16:00	What should a booster dose achieve from the public health perspective and what data is needed?	Alejandro Cravioto Faculty of Medicine of the Universidad Nacional Autónoma de México, Mexico Chairperson of the WHO Strategic Advisory Group of Experts on Immunization
16:00 – 16:30	What additional research is needed to support informed regulatory decision-making about the benefits and risks of booster doses?	<u>Panel Discussion</u> Philip Krause (moderator) Marie-Christine Bielsky ; Medicines and Healthcare products, Regulatory Agency (MHRA), UK Tumi (Boitumelo) Semete-Makokotlela ; South African Health Products Regulatory Authority, South Africa Peter Marks ; Center for Biologics Evaluation and Research (CBER), FDA, USA Representative of NMPA , China And the Moderators of previous panels: Helen Rees ; Wits RHI David Montefiori (TBC) & Marco Cavaleri
Session 2. How can research contribute to optimize the use of available doses of COVID-19 vaccines?		
16:30 – 16:40	What research is needed to evaluate Adjusted/Fractional doses and regimens in the context of primary vaccination and booster doses?	Benjamin Cowling School of Public Health, The University of Hong Kong
16:40 – 16:50	What complementary vaccine delivery strategies should be considered (in which context?)	Larry Brilliant Pandefense Advisory and Advisory Board of the NGO Ending Pandemics, USA
16:50 – 17:00	What research is needed to evaluate complementary vaccine strategies?	Ira Longini Department of Biostatistics, College of Public Health, University of Florida, USA

17:00 – 17:30	What research is needed to assess the potential impact of complementary vaccine delivery strategies?	<p><u>Panel discussion</u></p> <p>Larry Brilliant (moderator) Pandefense Advisory and Advisory Board of the NGO Ending Pandemics, USA</p> <p>Benjamin Cowling; School of Public Health, The University of Hong Kong</p> <p>Ira Longini; Department of Biostatistics, College of Public Health, University of Florida, USA</p> <p>John Clemens; International Vaccine Institute, Seoul, Korea</p> <p>Peter Figueroa</p> <p>Alejandro Cravioto</p>
17:30 – 17:50	Conclusions	<p>Philip Krause</p> <p>Chairperson of the WHO COVID vaccines research expert group</p>
17:50 – 18:00	Next Steps	WHO
18:00	END OF MEETING	