CEPI

CEPI: New vaccines for a safer world

May 2021

CEPI: A global coalition to tackle epidemics

A global partnership

Vision

A world in which epidemics and pandemics are no longer a threat to humanity.

Mission

To accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need.



CEPI's vaccine portfolio



CEPI's plan to end pandemics

"We are not only experiencing a period of catastrophe but this era in history will also be remembered for the incredible advances in vaccine technology and medicine more generally."



CEPI CEO, Richard Hatchett

Rapid progress in vaccine innovation



Data source: Our World in Data

\$3.5 billion needed to...

Prepare

- 1. Strengthen our defences against COVID-19 and reducing the risk of future coronavirus pandemics
- 2. Develop vaccines for known threats

Transform

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- 3. Produce a library of vaccines and other biological interventions
- 4. Work to compress vaccine development timelines to 100 days

Connect

3

- 5. Establish global networks for lab capacity, assays, and preclinical models
- 6. Support the efforts of LMICs to take full ownership of their national health security

Speed is of the essence in outbreak response

With COVID-19 it took about 314 days from virus characterisation to submission of phase 3 data. CEPI's aspiration is reduce this time to 100 days for future outbreaks.



With COVID-19 it took about **300 days** from virus characterisation to submission of phase 3 data.

CEPI's aspiration is reduce this time to **100 days** for future outbreaks.

Harmonising assessment of COVID-19 vaccine data

Global network of seven labs using same tests ("assays") and protocols to reliably assess and compare immunological responses of COVID-19 vaccines

Minimise variation from individual lab testing

Support in identifying reliable correlates of protection





COVAX SWAT Teams & Regulatory Advisory Group

Description

COVAX supports vaccine developers on general matters related to vaccine development.

COVAX SWAT teams have been established to support vaccine developers for challenges on COVID-19 vaccine development on:

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- Manufacturing (<u>https://epi.tghn.org/covax-overview/manufacturing/</u>),
- Clinical development and operations (<u>https://epi.tghn.org/covax-overview/clinical-science/</u>), and
- Enabling sciences



The SWAT teams have members from various stakeholders such as BMGF, WHO, GAVI and industry organizations (IFPMA and DCVMN).

Regulatory Advisory Group (RAG)



The RAG was set up to give feedback on regulatory science questions of an agnostic nature raised by the COVAX SWAT teams to support and promote ongoing regulatory development among COVID-19 vaccine developers to ensure access when scientifically appropriate.

The RAG has members from Regulatory Agencies covering all WHO regions, including Argentina, Australia, Brazil, Canada, Europe (EMA & EDQM), AVAREF, India, Japan, Korea, Singapore, and USA.



PAHO, Gavi and UNICEF participate as observers



It is co-lead by CEPI Regulatory and WHO

Regulatory Advisory Group (RAG)

Feedback from the RAG is be communicated directly back to the COVAX SWAT teams, as well as published in the format of Technical Briefs on WHO's web site for the benefit of all COVID-19 vaccine developers.

Meeting proceedings can be found <u>https://epi.tghn.org/covax-overview/regulatory-advisory-group</u>

Technical Briefs can be found (<u>https://www.who.int/publications/m/item/annex-1st-technical-brief-regulation-of-covid-19-vaccines</u>) is also intended to inform the wider community of Regulatory Authorities of questions and challenges vaccine developers are facing in the development of COVID-19 vaccines.

SWAT TEAM Workshops in 2021

SWAT TEAM Manufacturing:

- Multivalent COVID-19 vaccines to help address emergence of variants: CMC and Clinical implications,
- Best practices for post approval changes,
- Best practices for tech transfer workshop

SWAT TEAM Clinical Development and Operations:

- Booster and Mix & Match COVID-19 Vaccine Strategies Planning Ahead in an Environment of Increasing Complexity,
- Multivalent COVID-19 vaccines to help address emergence of variants: CMC and Clinical implications,
- SARS-CoV-2 variants Practical considerations for accelerated clinical development in light of current regulatory guidance,
- Immune Correlates, SARS-CoV-2 variants and 'mix & match': How vaccine developer approaches might be impacted by emerging data,
- Emerging Challenges to the Development of COVID-19 Vaccines

Examples of Q&A for the Regulatory Advisory Group (RAG)

May RAG meeting

- 1. Immunobridging within same vaccine (same platform, dosing schedule, manufacturing process): Clarification on endpoints and trial populations to support immunologic noninferiority.
- 2. Immunobridging to populations / age groups not included in Phase 3 vaccine efficacy trials / for which vaccine efficacy had not been established separately (including e.g. paediatric populations, older adults). (No questions posed to the RAG at this time).
- 3. Immunobridging across vaccines (similar / different platforms) to support authorization of new vaccines for which clinical vaccine efficacy / effectiveness will be established post rollout. (Separate discussion- this was not to be recorded or captured in minutes).



https://media.tghn.org/medialibrary/2021/06/Q and As from May 2021 RAG Mtg.pdf

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