



Major inter/national stakeholders in COVID-19 vaccines benefit-risk monitoring

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Introduction

- Landscape Summary of major inter/national stakeholders in COVID-19 vaccines benefit-risk monitoring
- Stakeholders with key activities in
 - Vaccine development and manufacturing
 - Regulatory review and approval
 - Immunization related policy making
 - Vaccine procurement and delivery
 - Surveillance of infectious diseases and the impact of immunization programmes thereon
 - Scientific advisory groups



Vaccine developers, manufacturers and marketing authorisation holders

- **Vaccine developer:** responsible for the discovery and clinical development of the vaccine
- **Manufacturer:** producing and testing the vaccine compliant with the manufacturing process
- **Marketing authorisation holder (MAH):** responsible for the quality, efficacy and safety of the product
 - Pharmacovigilance activities
 - Development/implementation of the risk management plan (RMP)
 - Communication with regulatory authorities

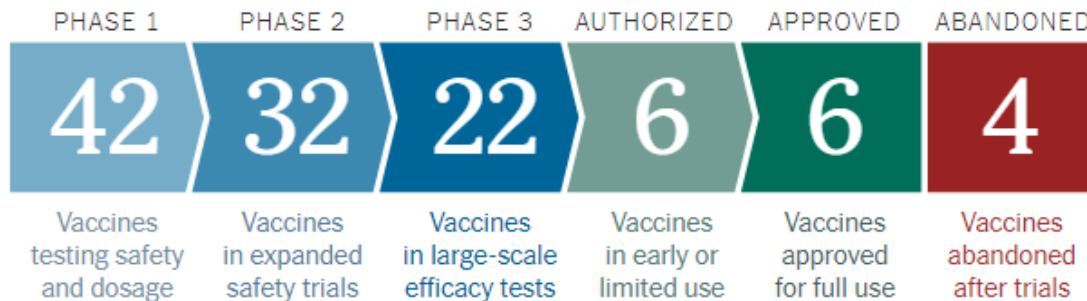


COVID-19 Vaccine Development

- Many developers across the world, incl. large multi-nationals w/o vaccine experience, biotech and academia
- Currently, 76 COVID-19 vaccines being tested

Coronavirus Vaccine Tracker

By [Carl Zimmer](#), [Jonathan Corum](#) and [Sui-Lee Wee](#) Updated March 12, 2021



From: New York Times



COVID-19 Vaccine Development

Leading vaccines

Developer	How It Works	Phase	Status
 Pfizer-BioNTech	mRNA	2 3	Approved in several countries. Emergency use in U.S., E.U., other countries.
 Moderna	mRNA	3	Approved in Switzerland. Emergency use in U.S., U.K., E.U., others.
 Gamaleya	Ad26, Ad5	3	Early use in Russia. Emergency use in other countries.
 Oxford-AstraZeneca	ChAdOx1	2 3	Emergency use in U.K., E.U., other countries.
 CanSino	Ad5	3	Approved in China. Emergency use in Mexico, Pakistan.
 Johnson & Johnson	Ad26	3	Emergency use in U.S., E.U., Bahrain.
 Vector Institute	Protein	3	Early use in Russia.
 Novavax	Protein	3	
 Sinopharm	Inactivated	3	Approved in China, U.A.E., Bahrain. Emergency use in other countries.
 Sinovac	Inactivated	3	Approved in China. Emergency use in other countries.
 Sinopharm-Wuhan	Inactivated	3	Approved in China. Limited use in U.A.E.
 Bharat Biotech	Inactivated	3	Emergency use in India, Iran, Zimbabwe.

From: New York Times



Lots of collaboration in COVID-19 vaccine development!

- Partners working together for **discovery** and **clinical development**, examples
 - Academic – industry: AZD1222 (Oxford-AstraZeneca)
 - Biotech - industry: Comirnaty® (Pfizer-BioNTech)
- Partners working together for **manufacturing**, example
 - Merck manufacturing Johnson & Johnson's COVID-19 vaccine
 - Sanofi to support the manufacturing of Pfizer and Johnson & Johnsons COVID-19 vaccines



CEPI supports Vaccine Development

- Vaccines are expensive (billions of dollars) and time-consuming (~10yrs) to develop with a high chance of failure (94%)
- CEPI: Coalition for Epidemic Preparedness Innovations
 - <https://cepi.net/>
 - *Launched in **2017**, funding from national governments, Bill & Melinda Gates Foundation, Wellcome, and the World Economic Forum*
 - **Mission:** *to develop vaccines to stop future epidemics and enable equitable access to vaccines, especially in cases in which market incentives alone are insufficient*
 - **Priority diseases (2017):** *MERS, Lassa, Nipah, Rift Valley fever, Chikungunya, Ebola, Disease X*
- *CEPI's response to COVID-19: **COVAX***

CEPI



Regulatory Authorities

- Main responsibilities in
 - *Guiding policy makers in developing and implementing immunization policies*
 - *Pharmacovigilance*
 - *Regulatory inspection*
 - *Marketing authorisation*
- Main tasks include
 - *Verify submission of Risk Management Plans*
 - *Can mandate vaccine safety studies from the MAHs*
 - *Can independently investigate potential safety signals*



(Inter)national Regulatory Authorities

- National, example
 - *MHRA (UK): Medicines and Healthcare products Regulatory Agency*
 - *PEI (Germany): Paul-Ehrlich Institut*
- International, examples
 - *EMA (Europe): European Medicines Agency*
 - *FDA (US): Food and Drug Administration*
 - *AVAREF: African Vaccine Regulatory Forum*



AVAREF





ICMRA provides a global regulatory forum

- *Global forum to support enhanced communication, information sharing, crisis response and address regulatory science issues*
- <http://www.icmra.info/drupal/en/home>
- *COVID-19*
 - *Alignment on policy approaches and regulatory flexibility during COVID-19*
 - *Requirements for COVID-19 trials, real-world evidence generation, ...*





National immunization programmes and technical advisory groups

- **National Immunization Programmes (NIPs):** organisation within the Ministries of Health (MoH) charged with preventing disease, disability and death from vaccine preventable diseases in children and adults. NIPs are responsible for storage, handling, delivery and administration of vaccines.
- **Expanded Programme on Immunization (EPI):** interchangeably used with NIP, initially used for children
- **National immunization technical advisory groups (NITAGs):** group of experts making evidence-based recommendations on immunization for policy-makers to develop immunization strategies and supporting NIPs/EPIs



National NITAGs go by different names

- Examples
 - *ACIP (US, CDC): Advisory Committee on Immunization Practices*
 - *JCVI (UK): Joint Committee on Vaccination and Immunization*
 - *STIKO (Germany)*
 - *NTAGI (India): National Technical Advisory Group on Immunisation India*



NITAG RESOURCE CENTRE (NRC) provides a platform for NITAG members worldwide



- *Information sharing for NITAG members (training, document sharing)*
- <https://www.nitag-resource.org/>
- *COVID-19*
 - *COVID-19 vaccine introduction toolbox*
 - *Sharing recommendations on COVID-19 vaccines from NITAGs worldwide*



Vaccine procurement and delivery

- **GAVI, the vaccine alliance**



- <https://www.gavi.org/>
- **Mission:** *to increase access to vaccines in developing countries, negotiate better prices for poorest countries*
- *Founded in 2000, funding from national governments, Bill & Melinda Gates Foundation, WHO, Unicef, World Bank, vaccine industry*

- **UNICEF, United Nations Children's Fund**

- <https://www.unicef.org/>
- **Mission:** *promote policies and expand access to services to protect all children*
- *Founded in 1946, funding from (inter)national governments*

- **COVAX:** GAVI and UNICEF's response to COVID-19





Public Health Authorities

- Main responsibilities in
 - Detecting and responding to new and emerging health treats
 - Prevent disease and promote healthy behaviours
- Main tasks include
 - Disease surveillance, including infectious and vaccine preventable diseases
 - Evaluation of public health programmes, including immunization programmes



(Inter)national Public Health Authorities

- National, example
 - PHE (UK): Public Health England
 - RIVM (the Netherlands)
- International, examples
 - ECDC (Europe): European Centre for Disease Prevention and Control
 - CDC (US): Centers for Disease Control and Prevention





World Health Organisation (WHO)

- Specialized agency of the United Nations responsible for international public health
- Main vaccine-related groups:
 - **WHO prequalification (PQ)** team: assesses whether a vaccine meets requirements of quality, safety and efficacy for use in immunization programmes, potentially via Emergency Use Listing (EUL) procedure
 - **Global Advisory Committee on Vaccine Safety (GACVS):** provides independent scientific advice to WHO on vaccine safety issues
 - **Strategic Advisory Group of Experts (SAGE):** advisory group to the WHO for immunization related policy





Scientific advisory groups

- **Brighton Collaboration (BC)**



- <https://brightoncollaboration.us/>
- Develops case definitions for adverse events, and guidelines for pharmaco-epidemiological studies
- COVID-19: BC partnered with CEPI via its Safety Platform for Emergency Vaccines Project (**SPEAC**), developing a list of possible Adverse Events of Special Interest (AESI) and case definitions,

- **CIOMS**: Council for International Organizations of Medical Sciences

- <https://cioms.ch/>
- To advance public health through guidance on health research and policy





COVAX – all working together

- **ACT (Access to COVID-19 Tools) Accelerator** is a global collaboration to accelerate the development, production and equitable access to COVID-19 tests, treatments and vaccines
- **COVAX** is the ‘vaccine’ pillar of ACT Accelerator
 - Co-led by CEPI, Gavi and WHO, alongside key delivery partner UNICEF
 - Speeding up the development of vaccines, building manufacturing capabilities, and ensuring fair and equitable distribution of vaccines through a global risk-sharing mechanism for pooled procurement



Take home messages

- Many different roles (hence stakeholders) involved in immunization:
 - Discovery and vaccine development
 - Regulatory approval
 - Immunization policy
 - Vaccine procurement and delivery
 - Infectious disease surveillance and measuring the effect of immunization programmes
- COVID-19: intensive collaboration within and between stakeholder groups



Want to read more?

- WHO COVID-19 vaccines: safety surveillance manual
 - <https://www.who.int/publications/i/item/10665338400>
 - Many interesting chapters, also one on stakeholders



Q&A
