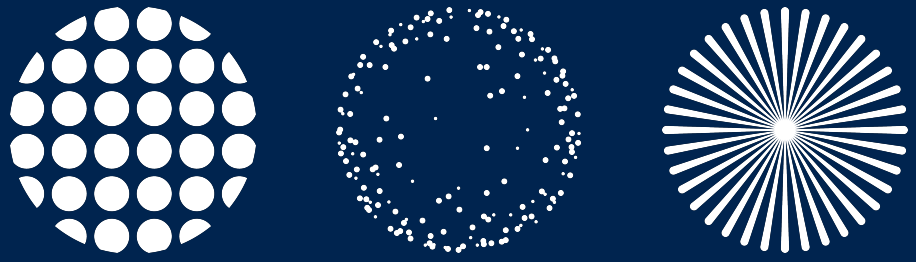
Regulatory challenges for COVID-19 Vaccine Development

CEPI

Dr. Melanie Saville

5th November 2020



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Access to COVID-19 tools (ACT) accelerator

CEPI is pursuing a range of approaches to help overcome these challenges and increase global access to any future COVID-19 vaccine

We are founding partners of the ACT (Access to Covid-19 Tools) accelerator, a global coalition to accelerate the development, production of and equitable access to new Covid-19 diagnostics, therapeutics and vaccines

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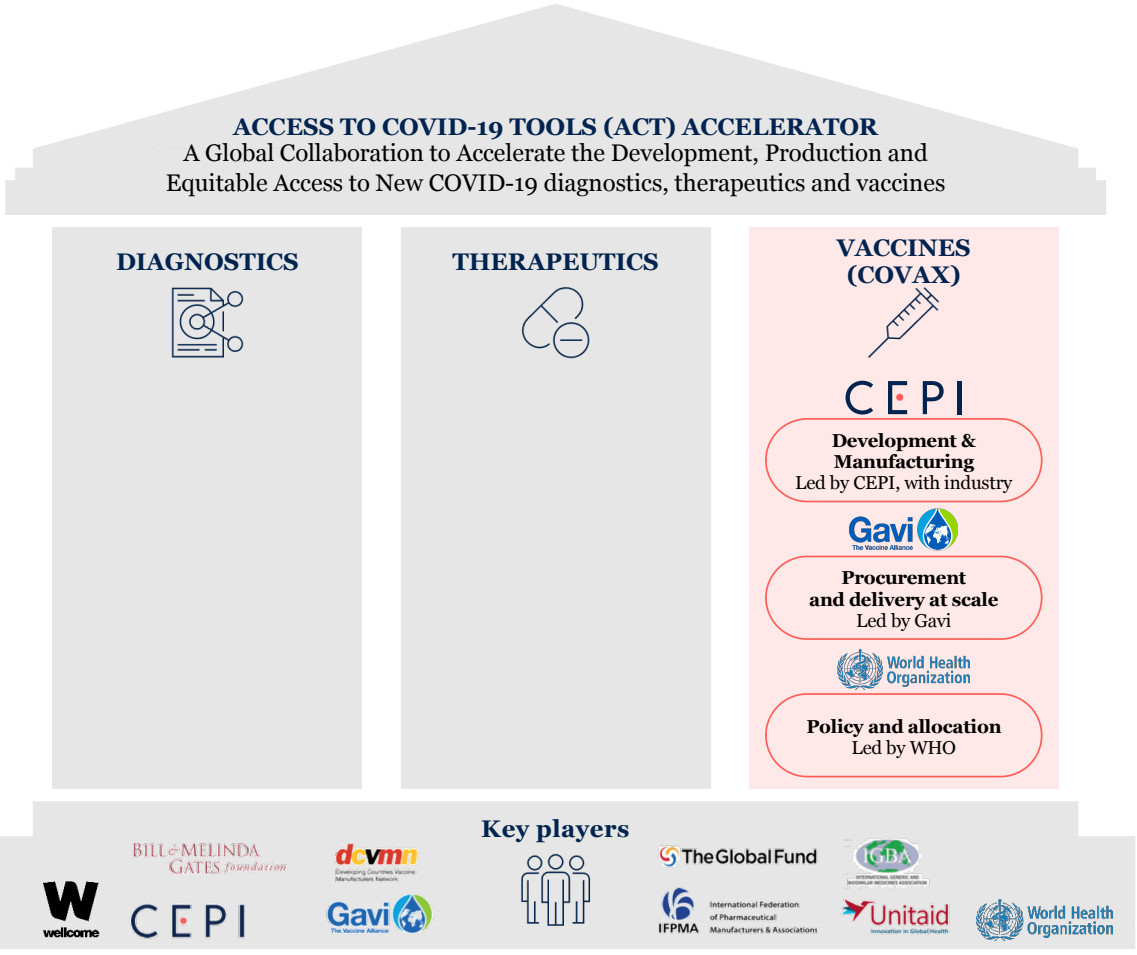
SOURCE: (ACT) ACCELERATOR Commitment and Call to Action 24th April 2020



COVAX goals

- To develop the largest and most diverse actively managed portfolio of vaccine candidates so that the best vaccines are made available and the world has access to the best science

- To deliver 2 billion doses by end of 2021

- To guarantee fair and equitable access to COVID-19 vaccines for every country in the world

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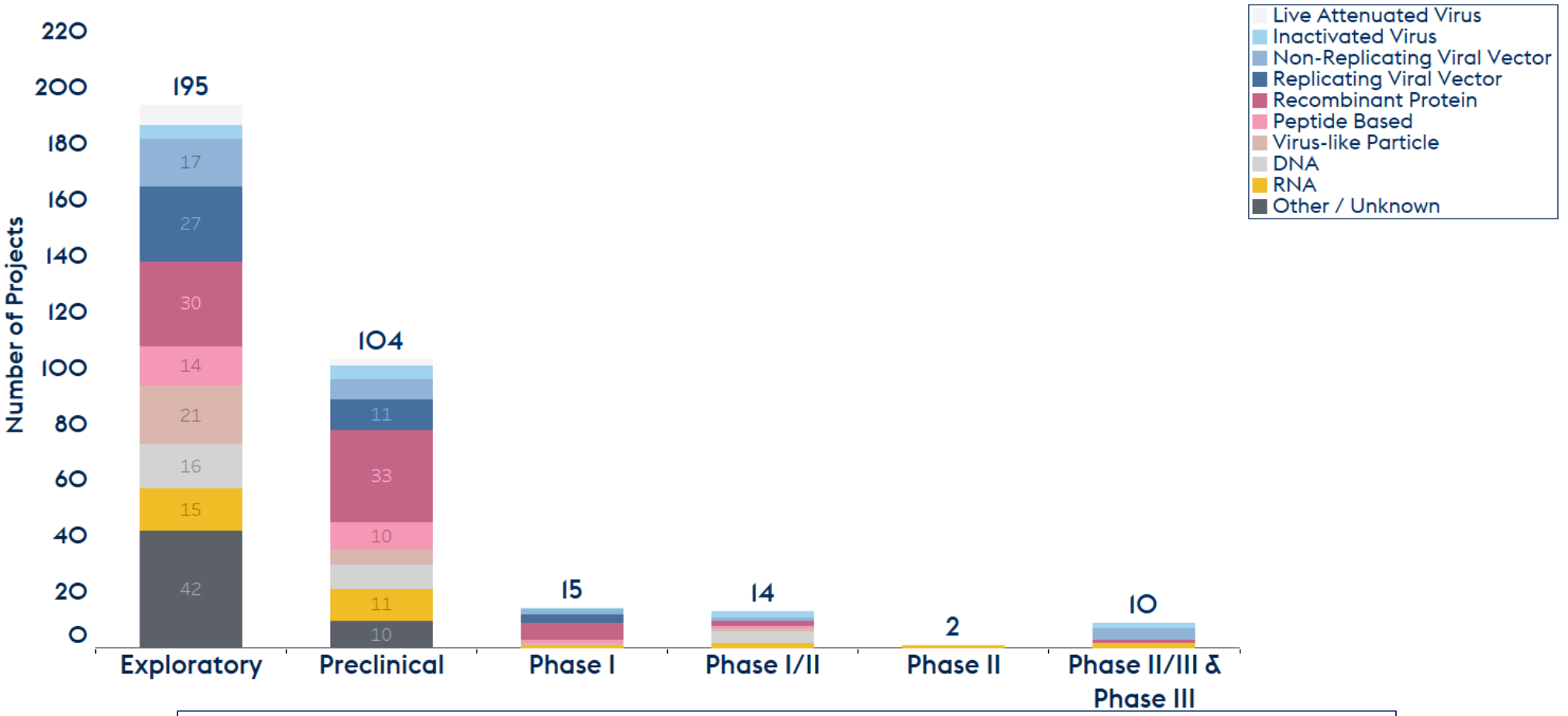
Date: 21 October 2020

An ongoing COVID-19 landscape assessment is maintained to keep abreast of vaccine candidates – by development phase and platform type



- **Exploratory:** project has not started with in-vivo testing
- **Preclinical:** project started to test in-vivo / manufacture CTM but not yet started with testing on human
- Start of **clinical phases** is defined as first subject dosed

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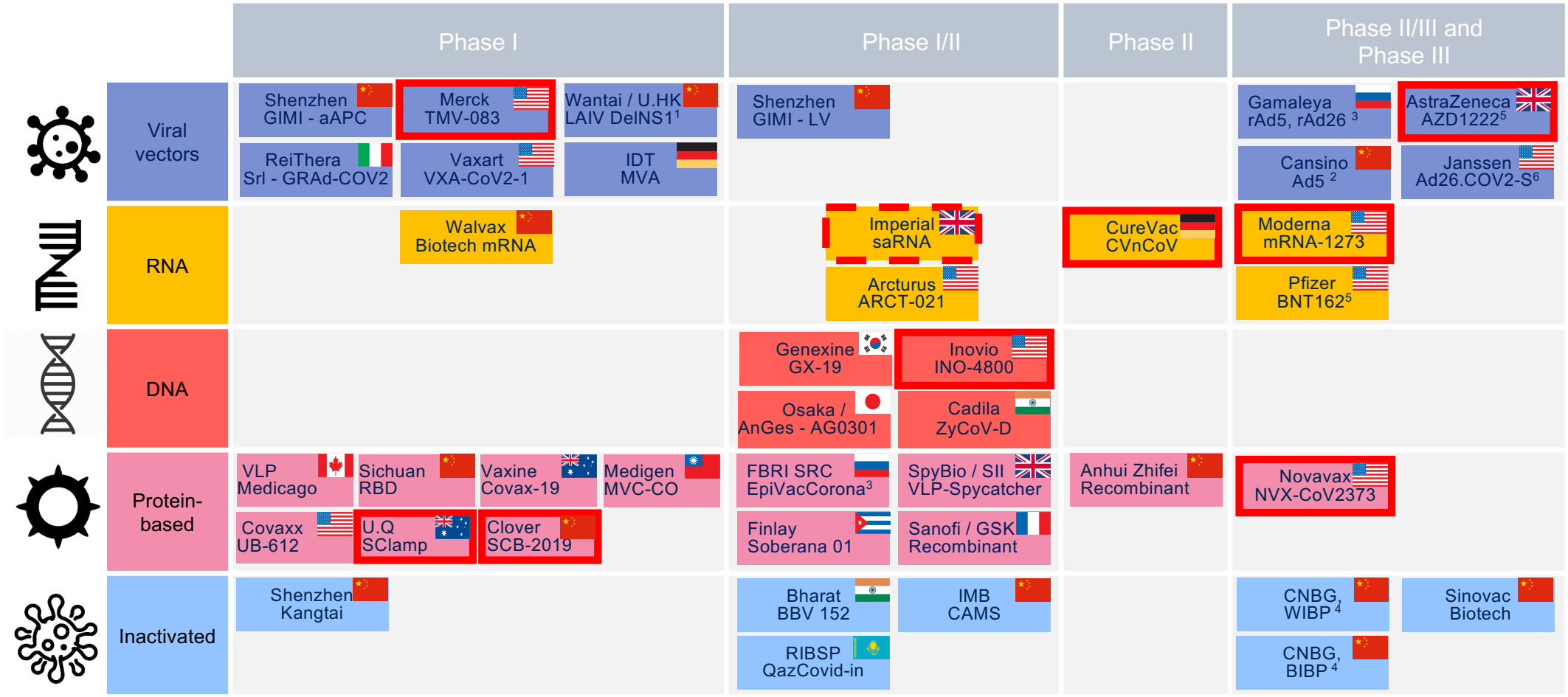
Date: 21 October 2020

The COVAX R&D&M portfolio consists of 8 candidates in clinical development

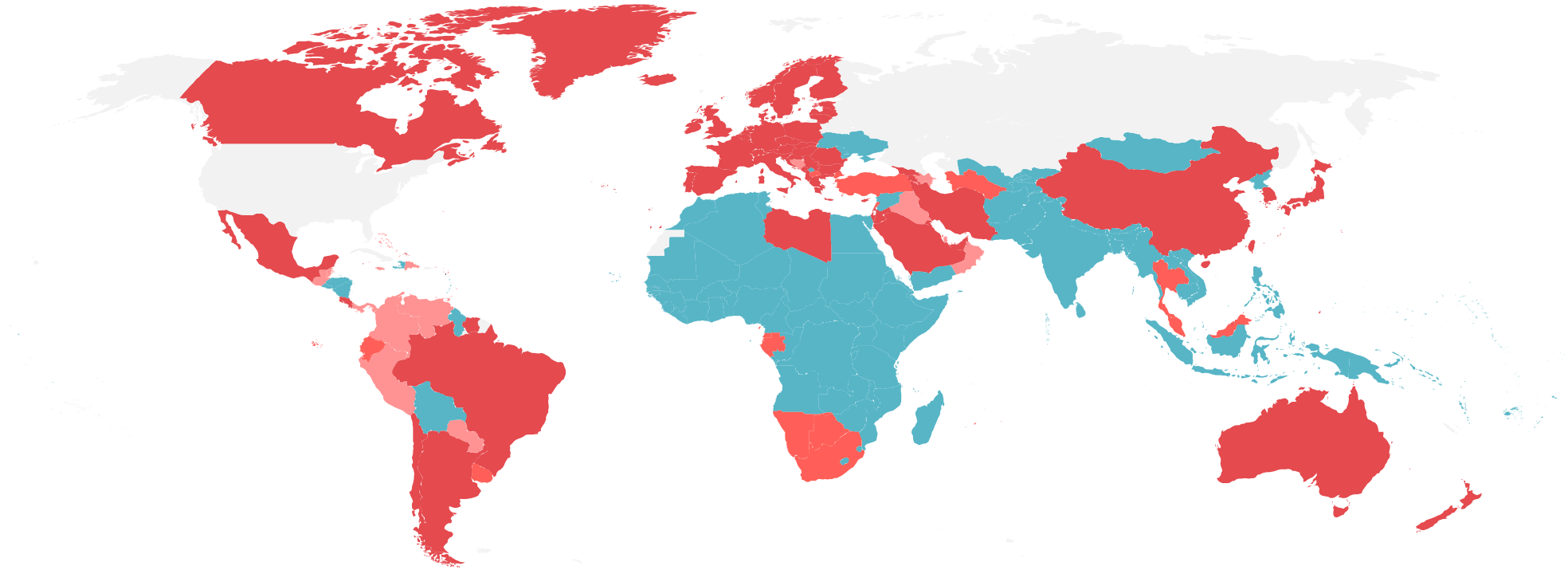
COVAX-funded *CEPI-funded but outside Covid-19 funding pool*



[1] *U.HK programme distinct from CEPI-funded programme*
[2] *Cansino has been approved for military use in China*
[3] *Gamaleya (rAd5, rAd26) and FBRI SRC (EpiVacCorona) has been conditionally registered in Russia*
[4] *Emergency use approval in China and UAE*
[5] *Under regulatory rolling review*
[6] *Under study pause*

AS OF OCT 19

94 self-financing economies joined the COVAX Facility and the 92 AMC. Total of 184 economies



AMC Countries

Self Funded Countries

COVID-19 vaccine development guidance

FDA/CBER

- June: Development and Licensure
  - Primary efficacy endpoint point estimate at least 50% and with the lower bound 30%
- October: Emergency Use Authorization
    - Data from phase 3 should a median follow up duration of at least 2 months after completion of the full vaccination regimen
- October: VRBPAC
  - Guidance for continuation of blinded phase 3 trials if EUA issued
  - What studies following licensure

EMA

- Conditional Marketing authorization the most likely scenario
  - Positive benefit/risk, with post authorization commitments needed
- Compassionate use program – support EU nationals – lower bar and would need a solid benefit/risk per country.

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WHO EUL or Pre-Qualification?

EUL

- Risk benefit assessment of essential set of quality, safety and efficacy data for use during PHEs
- Rolling review of data
- Assessment performed by WHO independent experts in collaboration with National Regulatory Authorities (WLA)
- Reliance on WLA -abbreviated process under oversight of mature regulators (evaluation and oversight of programmatic aspects by WHO)
- Pre-submission meetings encouraged
- Post-deployment monitoring
- Time limited recommendation
- Development should continue for MA/PQ

Pre-qualification

- Review of extensive quality, safety and efficacy and PSPQ for international supply
- Assessment performed by WHO independent experts
- Reliance on WHO Listed Authority (WLA) - abbreviated process under oversight of mature regulators (evaluation and oversight of programmatic aspects by WHO)
- Pre-submission meetings encouraged
- Post-PQ monitoring
- Reassessment/requalification

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Challenges 1/2

- Long term safety and efficacy data
  - Interim analyses
  - Placebo cross over
  - Need for booster
- Expanded access versus Emergency Use versus licensure?
- PASS/PAES

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Challenges (2/2)

- Regulatory acceptance for the use of:
  - QR codes
  - Barcodes
  - Simplified label
- Authority batch release testing:
  - Widespread acceptance of batch release certificates/information generated by a limited number of NCLs
  - “Global” agreement on tests to be performed per vaccine type needed.
- GMO regulations
- Post-approval changes
- Stability data

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Call for Regulatory pragmatism

- Change/Allow:
  - WHO to rapidly grant prequalification or EUL status based on the approval of a MRA,
  - Establish a standardized vial label without further review and approval by a country/region
  - QR codes for expiry date and package leaflet in multiple languages
- Waive:
  - GMO requirements for COVID-19 vaccines
  - Country-specific regulations that require product developers to submit country-specific dossiers
  - Specific batch release testing requirements for MRA emergency/fully authorized or WHO PQ listed/EUL products.

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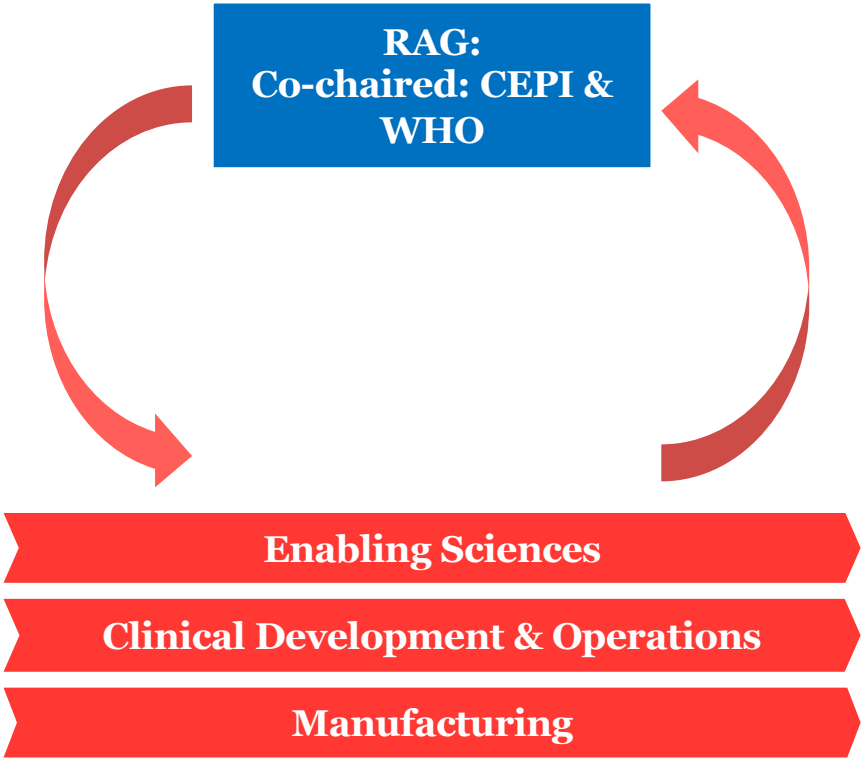
A Regulatory Advisory Group (RAG) supports SWAT teams



- Monthly meetings
- Questions/issues from SWAT teams
- Publish Q&As on WHO website
- Additional Communication via COVAX newsletter

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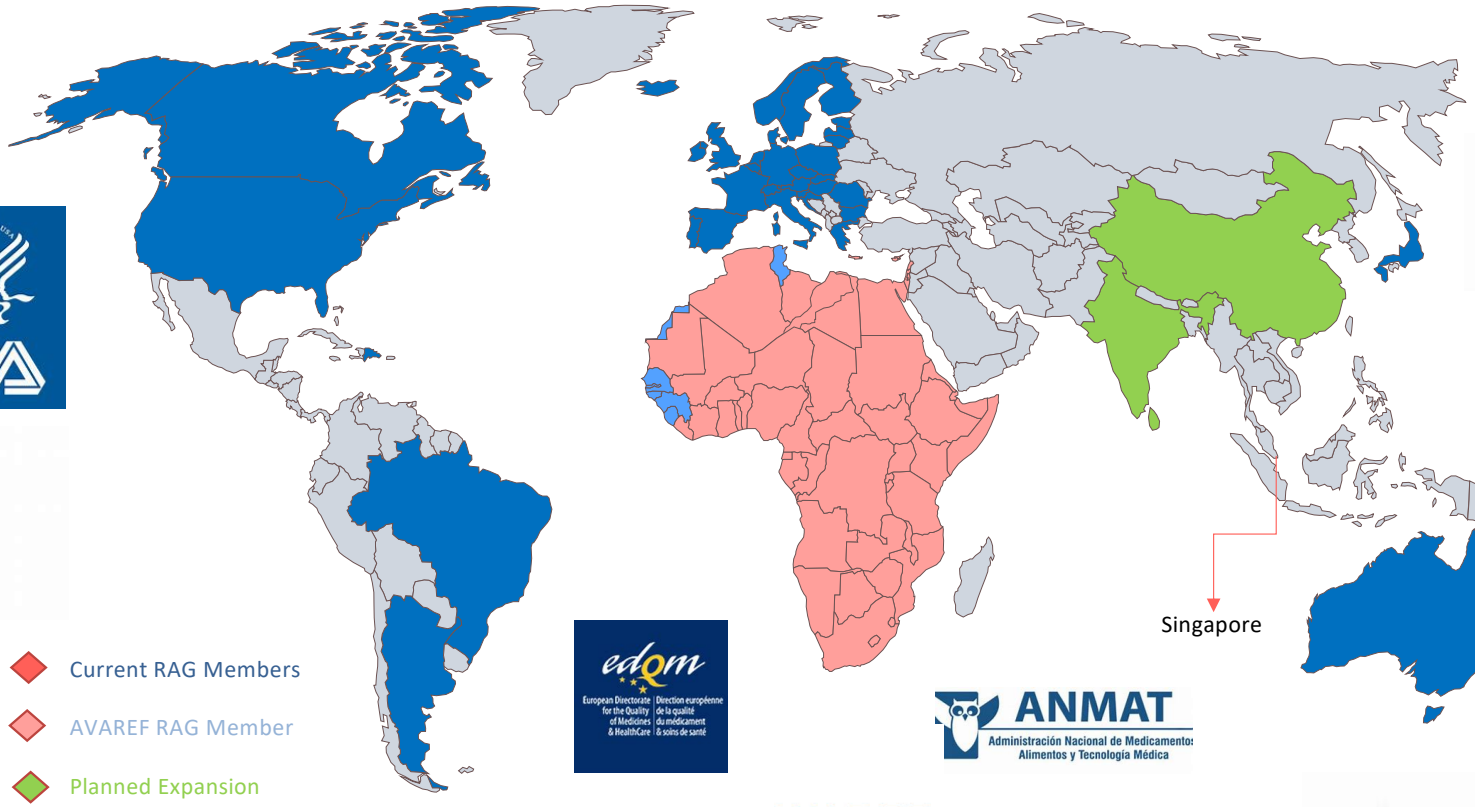
COVAX Regulatory Advisory Group Members



- Current RAG Members
- AVAREF RAG Member
- Planned Expansion

ANVISA Agência Nacional de Vigilância Sanitária

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World Health Organization

Health Canada Santé Canada Canada

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

edqm European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

ANMAT Administración Nacional de Medicamentos Alimentos y Tecnología Médica

AVAREF

pmda 独立行政法人 医薬品医療機器総合機構 Pharmaceuticals and Medical Devices Agency

Australian Government Department of Health Therapeutic Goods Administration

World map by www.freeworldmaps.net

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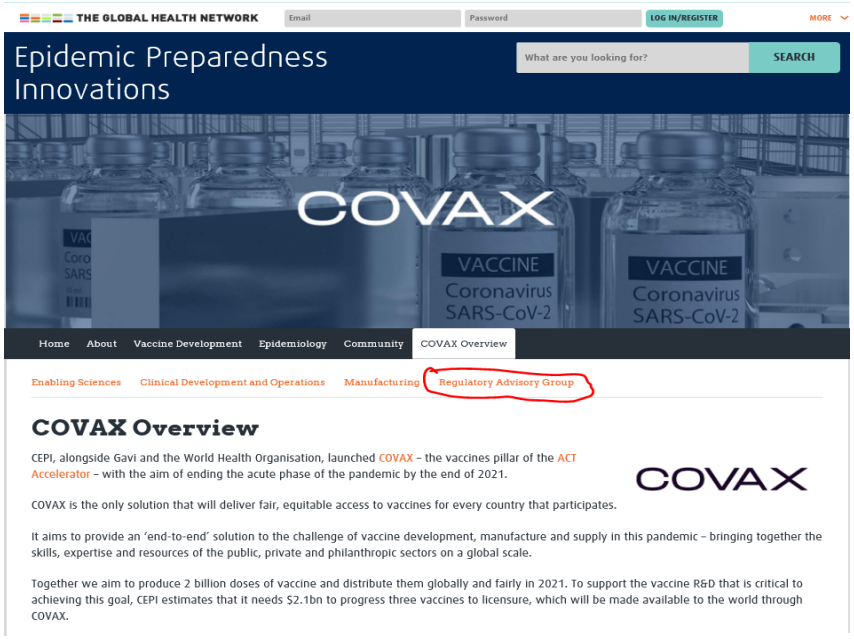
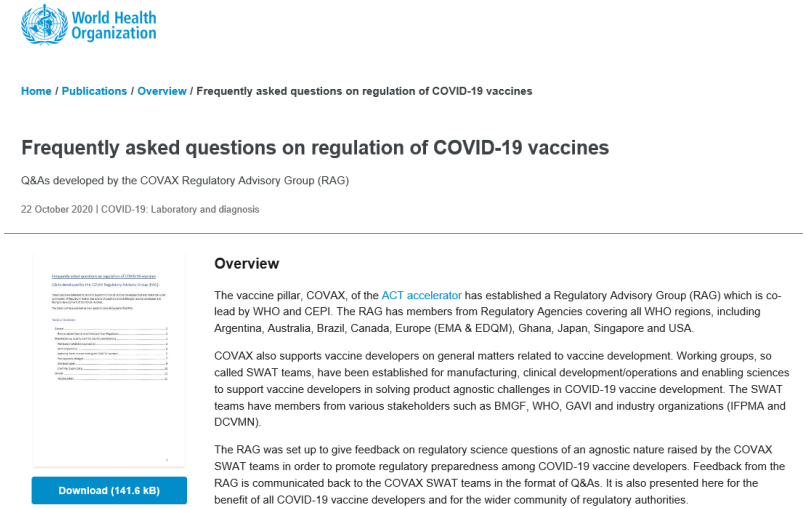
COVAX Regulatory Advisory Group – external communication



https://epi.tghn.org/covax-overview/



https://www.who.int/publications/m/item/frequently-asked-questions-on-regulation-of-covid-19-vaccines

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Newsletter from SWAT teams and RAG

https://tghn.us2.list-manage.com/subscribe?u=2146a0400e260163a7dfb5b83&id=cc13a5df53

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