ACTaccelerator
ACCESS TO COVID-19 TOOLS
Hosted by World Health Organization

Technical presentation on mRNA Vaccines

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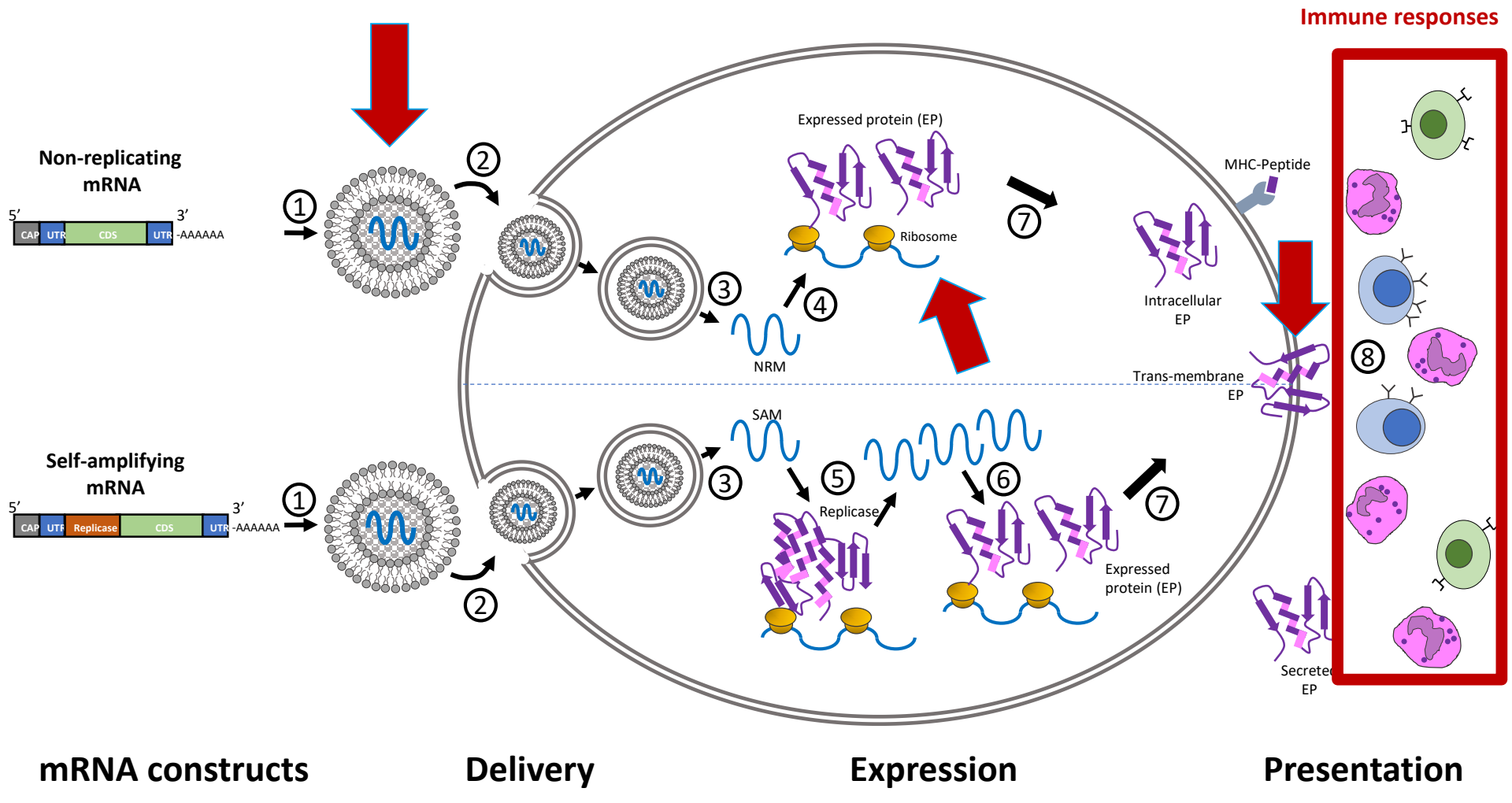
Member States COVID-19 Briefing

19 November 2020

How do mRNA vaccines work?



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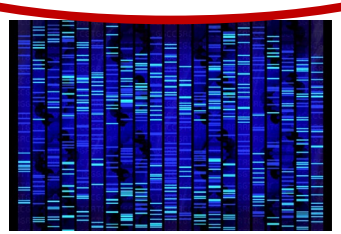
Speed: mRNA has demonstrated an unprecedented research and development pace

COVID-19 sequence release

12th January 2020



Phase 1

Phase 3

		FSFV	FSFV	1st Vaccine Efficacy
9 weeks	Moderna	March 16th	July 27th	Nov 16th ; 306 days
18 weeks	Pfizer/ BioNTech	May 14th	July 27th	Nov 9th ; 300 days
23 weeks	Curevac	June 19th		-
24 weeks	Imperial	June 23rd		-
25 weeks	Walvax	June 29th		-
31 weeks	Arcturus	August 11th		-

First vaccine efficacy results now becoming available

(from press releases)

Pfizer/ BioNTech

Full study results (released on Nov. 18)

mRNA

- 43,000 trial participants
- Efficacy of **95%**
  - Efficacy in elderly of >94%
- 170 confirmed cases,
  - 162 in placebo group vs.
  - 8 in vaccine group
- 10 were severe cases of COVID-19
  - 9 in placebo group vs.
  - 1 in vaccine group
- Median follow up of > 2 months
- No serious safety concerns observed

Moderna

Interim study results (released on Nov. 16)

mRNA

- 30,000 trial participants
- Efficacy of **94.5%** (p<0.0001)
  - Efficacy in elderly not reported (15 total cases)
- 95 confirmed cases
  - 90 in placebo group vs.
  - 5 in vaccine group
- 11 were severe cases of COVID-19
  - 11 in placebo vs.
  - 0 in vaccine group
- Median follow up of >2 months
- No safety concerns

The products and next steps

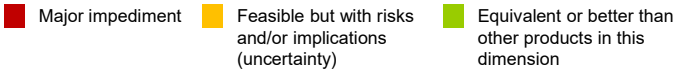
	Pfizer/ BioNTech	Moderna
Cold chain	-80˚C (UCC) 2-8 ˚C for up to 5 days	-20˚C 2-8 ˚C for up to 30 days
Full analysis of efficacy target	164 cases; complete	151 cases; **pending**
Safety data	Median follow up 2 months	Median follow up 2 months
Manufacturing	ongoing	ongoing
Regulatory pathway	Rolling reviews: US FDA EU- EMA Global - WHO	Rolling reviews: US FDA EU - EMA Engagement with WHO has started

WHO Regulatory and Safety Monitoring Coordination and Leadership

PQ/EUL	Criteria for evaluation of candidates vaccines published Call for Expressions of Interest for candidate vaccines in Phase IIb/III, with expected regulatory approvals within 6 months Rolling reviews of data from vaccine candidates meeting criteria
Roadmaps	Assessment pathways; WHO led global assessment involving “regional champions”; followed by facilitation for global national approval and active engagement with countries
Labelling	Working Position established; to facilitate harmonization and timely global access to candidate vaccines
Safety Monitoring	Global monitoring mechanisms coordinated by WHO; Regional and country support; guidance on requirements and methods

Characteristics of Pfizer vaccine present some challenges that need to be put in context and addressed

Illustration – Dynamic situation; preliminary considerations regarding Pfizer vaccine



Dimensions	Preliminary assessment
Equity	Early vaccine; aim to limit delay for access between LIC/MIC/HIC across whole vaccine portfolio
Pace of supply	Expected quantities early in 2021 will be limited
Regulatory	Regulatory process expected to flow smoothly
Programmatic – Supply chain	**UCC** complex but solutions available / feasible in some settings
Programmatic – Safety and monitoring	Needs careful attention; new vx platform, early vaccine
Programmatic – Delivery	**Diluent** availability (incl. procurement) & bundling, non-standard syringes (**0.3mL**), complexity if HCW have to come to vaccination site, management of UCC
Cost (procurement & delivery)	Quantification ongoing of investments needed
Indemnification and Liability	Likely doable as part of the current I&L solutions (under development)
Interest of AMC countries	Being assessed (AMC92 briefing, country outreach, MS briefing)

Deploying vaccines requiring UCC has costing implications

Higher delivery costs

Non-standard cold chain requirements will require investments in capital equipment and special equipment for handling deep-frozen shipments

Delivery of -80°C vaccines

$0.8- $2.38 per dose [1]

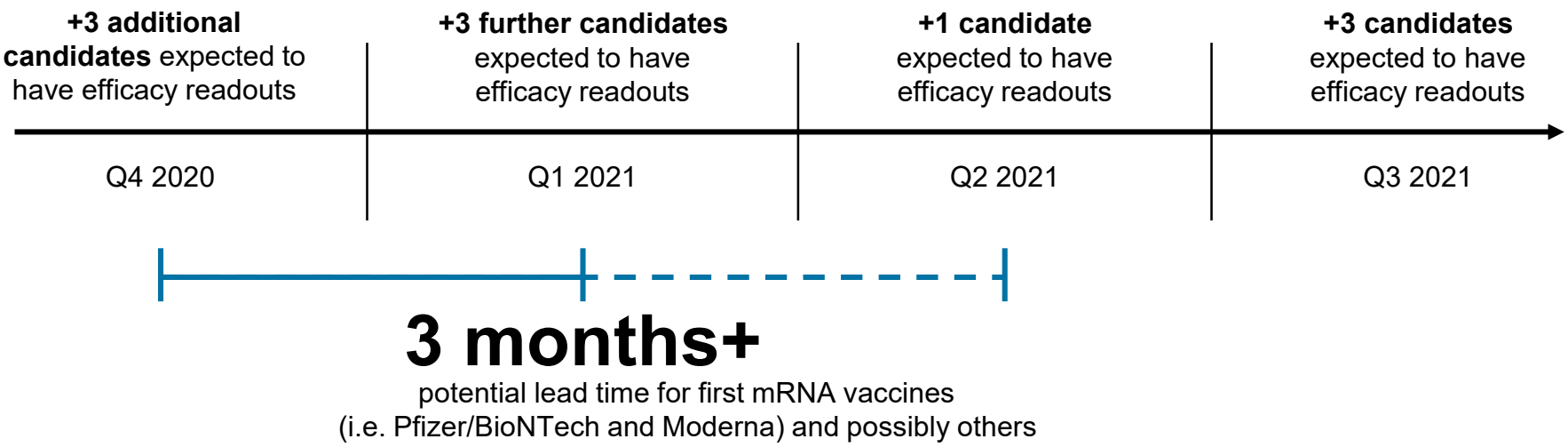
beyond the costs to deliver a 2-8°C product

1. Based on COVAX analysis (ongoing)

Other products are coming along…

First candidates with efficacy results

Pfizer BIONTECH moderna messenger therapeutics



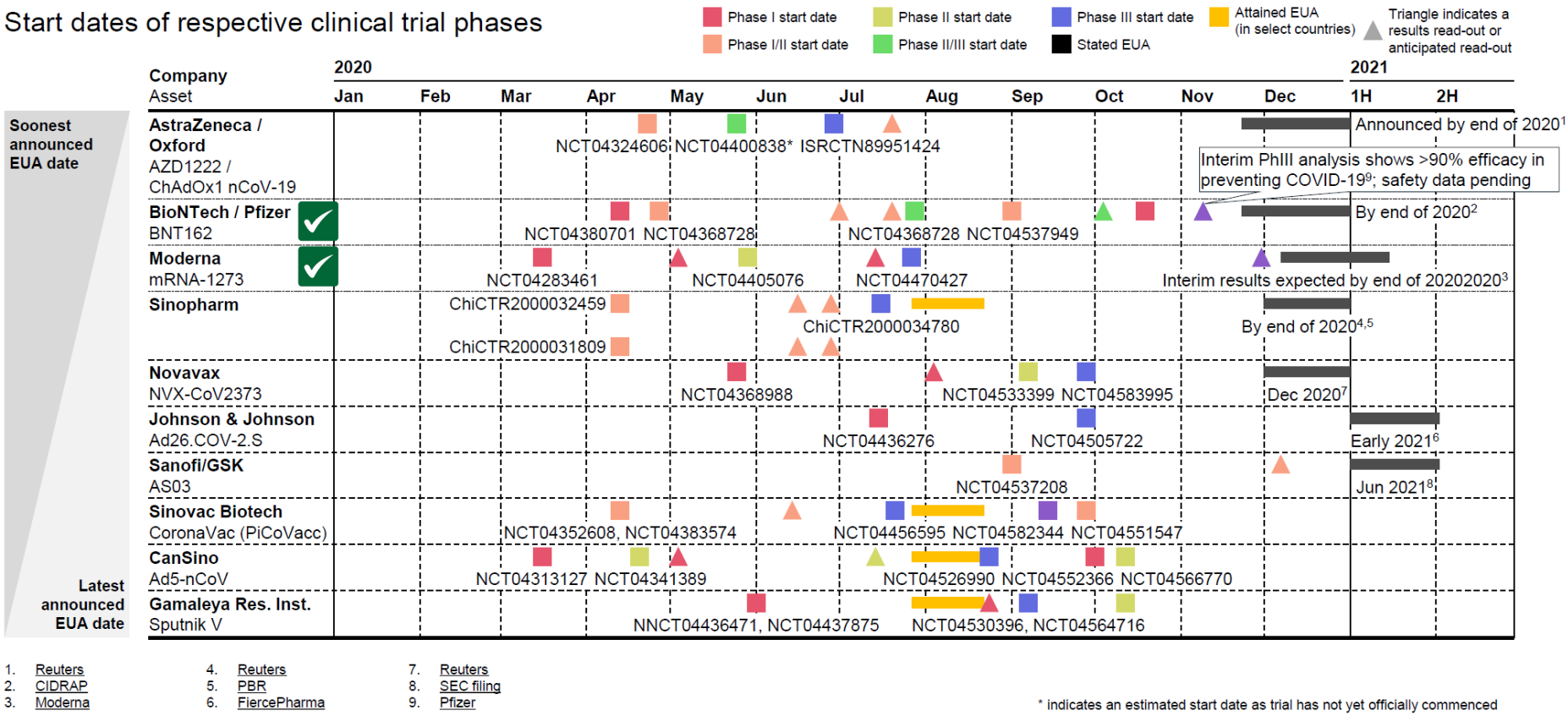
3 months+

potential lead time for first mRNA vaccines
(i.e. Pfizer/BioNTech and Moderna) and possibly others

PRELIMINARY

Detailed timeline
(from publicly available data)

✓ Efficacy results already released



1. Reuters
2. CIDRAP
3. Moderna
4. Reuters
5. PBR
6. FiercePharma
7. Reuters
8. SEC filing
9. Pfizer

* indicates an estimated start date as trial has not yet officially commenced

CRITICAL ACTIONS COUNTRIES NEED TO TAKE NOW & AVAILABLE RESOURCES

CRITICAL ACTIONS

Priority decision making on:

- **Policies** for use (in-country allocation)
- **Regulatory** approvals (e.g. WHO reliance mechanism)
- **Financing** (ensuring fiscal space, with WORLD BANK on IDA/IDRB)
- **Indemnification** & liability cover

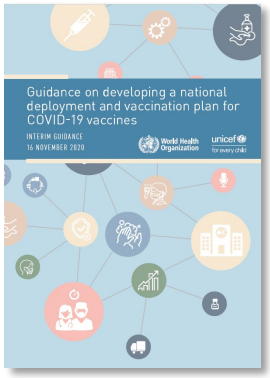
Deployment of technical & operational teams (with WHO/UNICEF/Gavi/WB)

- **Country readiness assessments**
- **Country-led plan** (preventive/Vx & clinical services/Dx,Tx,PPE,O2)
- Key bottleneck **analysis**

AVAILABLE RESOURCES *(selected)*

Vaccine Introduction Readiness Assessment Framework (VIRAF) Tool

Guidance to develop a National Deployment and Vaccination Plan (NDVP) *Link*



SAGE Policy Recommendations on Population Prioritization

Regulatory and Safety Guidance and Tools

Next steps

- Country readiness work is essential
- Country action on critical bottlenecks
- Assess countries interest in mRNA vaccines
- Support preparation for delivery of all vaccines with specific attention to UCC where needed
- Gavi Applications for AMC92 countries
- World Bank Applications

Back-up slides

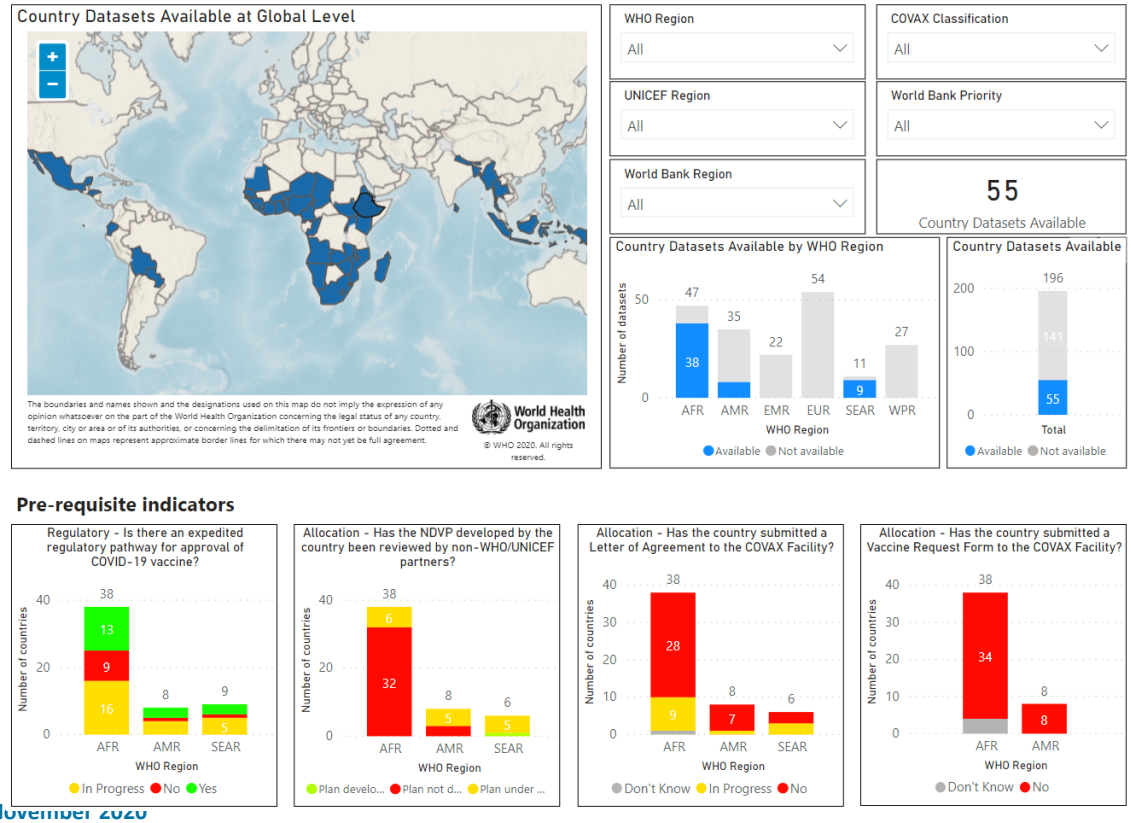
PRELIMINARY

Vaccine prices range from $3 to more than $30 a dose (based on publicly available information; does not reflect COVAX Facility prices)

Vaccine candidates	Procurement price, USD per dose	Comments
AstraZeneca / University of Oxford	**3 - 4**	Based on the deal with the European Commission[1]
Pfizer BioNTech	**20**	Price reportedly charged per dose (according to CNBC on Nov.17
sinovac®	**30**	In October, Sinovac began selling its vaccine in select Chinese cities at $60 for two shots[1]
moderna™ messenger therapeutics	**32 - 39**	In Aug. 2020, Moderna published a maximum price tag of 39 USD per dose[1]

1. Source: Financial Times, 23 Oct 2020

COVAX Country Readiness & Delivery Core Indicators Dashboard



Pre-requisite indicators

Regulatory alignment of COVID-19 vaccines under EUL/PQ

World Health Organization

Goal & objectives

Goal of this WHO regulatory work: to optimize access & availability to safe, efficacious, quality-assured COVID-19 products by further aligning regulatory processes

WHO's ongoing COVAX regulatory work

- **Alignment ongoing** (Regulatory Advisory Group, ICMRA*, regional regulators)
- Biweekly **regulatory updates**, 15 **regional update webinars**
- **Documents published**
  - EUL procedure (Jan), Q&A (Jul)
  - Draft consideration criteria (Sep), expected final publication 20 November
  - Expression of Interest (EoI) (EUL/PQ) (Oct)
- **>10 dedicated company meetings** hosted prior to EoI publication
- **Roadmap template** (Published)
- **Who working position on QR, barcodes and labelling published**
- **Safety preparedness manual**
  - PV Preparedness checklist, AESI definitions, active surveillance methods, guidance on RMPS, PSURs, data sharing platforms, reliance, work-sharing and risk communications

*ICMRA International Coalition of Medicines Regulatory Authorities

Next steps on WHO regulatory alignment activities for COVID-19 vaccines

- Continue **implementation discussions with regional networks & reference NRAs**
  - Two round tables of discussion with Regional offices for establishment of a mechanism for expedited approval in countries and monitoring performance of vaccines deployed to countries August 2020.
  - Nominations of regulatory authorities received from several regions.
  - Official communication with regulatory authorities.
  - Briefing on WHO led mechanisms to regulatory authorities and networks planned.
- Continue support for planning of **post-marketing / safety monitoring** in countries
- Continue engagement & alignment with **regulatory bodies** (e.g. ICMRA, regional regulatory networks, Reference NRAs)