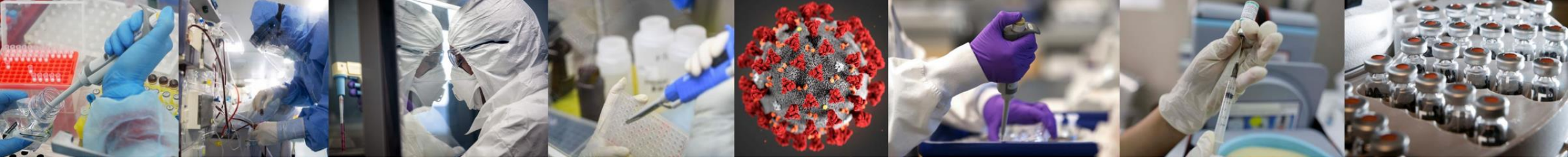
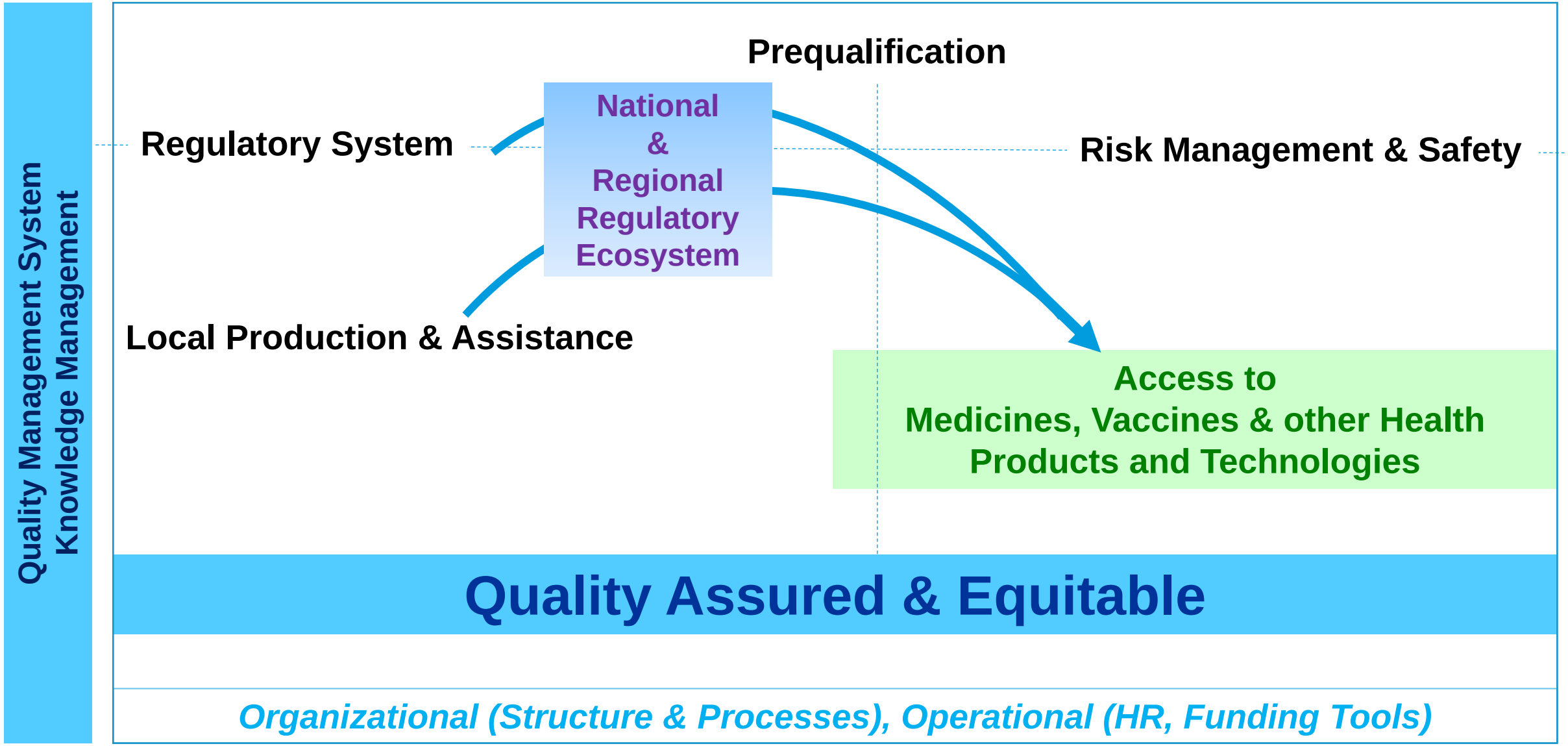


WTO Technical Workshop on Covid-19 Vx R&D, Manufacturing and Distribution

11 February 2022: 13:00-15:00 CET

Carmen Rodriguez ¦ Team Lead, Vaccine Prequalification, Department of Regulation and Prequalification (RPQ)

Regulation and Prequalification (RPQ)



RPQ Strategic priorities:

DELIVERING QUALITY-ASSURED MEDICAL PRODUCTS FOR ALL

2019–2023

WHO's five-year plan to help build effective and efficient regulatory systems

1

SP 1:

Strengthen country and regional regulatory systems

2

SP 2:

Improve regulatory preparedness for public health emergencies

3

SP 3:

Reinforce and expand WHO prequalification and product risk assessment

4

SP 4:

Increase the impact of WHO regulatory support activities

Features of PQ and EUL

Prequalification (PQ) 1987

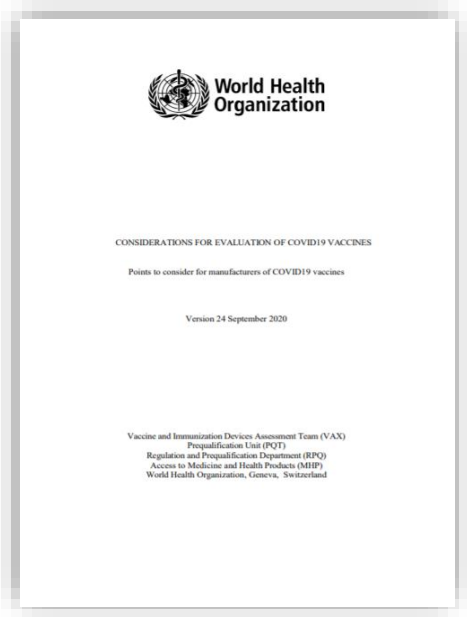
- Review of extensive quality, safety and efficacy and PSPQ for international supply
- Assessment performed by WHO independent experts
- Reliance on WHO Listed Authority (WLA) - abbreviated process under oversight of mature regulators (evaluation and oversight of programmatic aspects by WHO)
- Pre-submission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

Emergency Use Listing (EUL) 2015

- **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**

WHO regulatory preparedness for COVID-19 vaccines

WHO released “Considerations for the assessment of COVID-19 vaccines” (2020)



World Health Organization

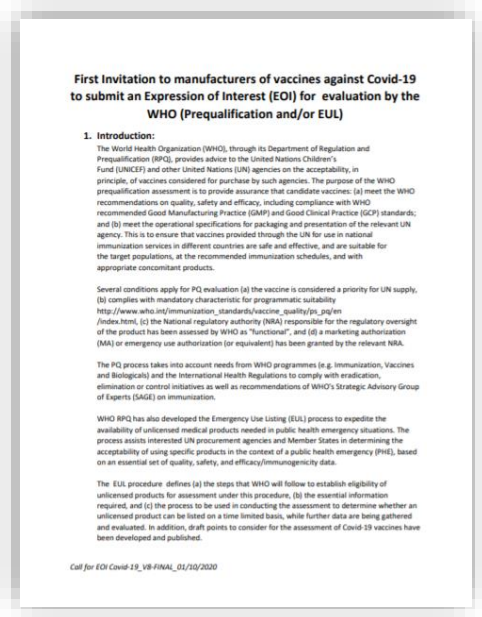
CONSIDERATIONS FOR EVALUATION OF COVID19 VACCINES

Points to consider for manufacturers of COVID19 vaccines

Version 24 September 2020

Vaccine and Immunization Devices Assessment Team (VAX)
Prequalification Unit (PQT)
Regulation and Prequalification Department (RPQ)
Access to Medicine and Health Products (MHP)
World Health Organization, Geneva, Switzerland

WHO issued a call for Expressions of Interest for Emergency Use Listing of COVID-19 Vaccines (2020)



First Invitation to manufacturers of vaccines against Covid-19 to submit an Expression of Interest (EOI) for evaluation by the WHO (Prequalification and/or EUL)

1. **Introduction:**

The World Health Organization (WHO), through its Department of Regulation and Prequalification (RPQ), provides advice to the United Nations Children's Fund (UNICEF) and other United Nations (UN) agencies on the acceptability, in principle, of vaccines considered for purchase by such agencies. The purpose of the WHO prequalification assessment is to provide assurance that candidate vaccines: (a) meet the WHO recommendations on quality, safety and efficacy, including compliance with WHO recommended Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) standards; and (b) meet the operational specifications for packaging and presentation of the relevant UN agency. This is to ensure that vaccines provided through the UN for use in national immunization services in different countries are safe and effective, and are suitable for the target populations, at the recommended immunization schedules, and with appropriate concomitant products.

Several conditions apply for PQ evaluation (a) the vaccine is considered a priority for UN supply, (b) complies with mandatory characteristic for programmatic suitability http://www.who.int/immunization_standards/vaccine_quality/ps_pq/en /index.html, (c) the National regulatory authority (NRA) responsible for the regulatory oversight of the product has been assessed by WHO as "functional", and (d) a marketing authorization (MA) or emergency use authorization (or equivalent) has been granted by the relevant NRA.

The PQ process takes into account needs from WHO programmes (e.g. Immunization, Vaccines and Biologicals) and the International Health Regulations to comply with eradication, elimination or control initiatives as well as recommendations of WHO's Strategic Advisory Group of Experts (SAGE) on immunization.

WHO RPQ has also developed the Emergency Use Listing (EUL) process to expedite the availability of unlicensed medical products needed in public health emergency situations. The process assists interested UN procurement agencies and Member States in determining the acceptability of using specific products in the context of a public health emergency (PHE), based on an essential set of quality, safety, and efficacy/immunogenicity data.

The EUL procedure defines (a) the steps that WHO will follow to establish eligibility of unlicensed products for assessment under this procedure, (b) the essential information required, and (c) the process to be used in conducting the assessment to determine whether an unlicensed product can be listed on a time limited basis, while further data are being gathered and evaluated. In addition, draft points to consider for the assessment of Covid-19 vaccines have been developed and published.

Call for EOI Covid-19_V8-FINAL_01/10/2020

... aiming for timely regulatory process while maintaining high evaluation stds for EUL/PQ

Source: https://www.who.int/medicines/regulation/prequalification/prequal-vaccines/WHO_Evaluation_Covid_Vaccine.pdf?ua=1

In-country expedited approval for use & post-listing monitoring: the WHO regulatory alignment roadmap*

World Health Organization

1. Preliminary activities

- **Global regulatory cooperation**
- Establishment of **strategies for expedited approval** in participants & post-listing monitoring

2. Launching of EOIs

- **Manufacturers EOIs** (Phase IIb/III & approval by NRA/SRA in charge of oversight within 6 months & compliance with criteria for assessment)
- Discussions on **rolling submission** procedure

3. Submissions & assessment

- Establishment of **assessment pathway** according to NRA/SRA in charge of oversight
- Establishment of **Review Committee** (NRA/SRA in charge of oversight & regulators /reviewers from potential user participants)

4. Recommendation for listing

- **Approval** granted by NRA/SRA in charge of oversight
- **Advisory committee** convened (post-listing commitment)
- **WHO EUL/ PQ recommendation** with conditions

5. Post-listing monitoring

- Implementation of **strategies for safety, quality & effectiveness monitoring**
- **Validity of listing** based on new data generated
- Possible **conversion of EUL to PQ**

COVAX | EUL/PQ | NRA reliance on EUL/PQ

Facilitated access to countries

- **Sharing of assessment/ inspection reports / lot release** with regional-designated country reps
- WHO-facilitated **national approval process**

* *Roadmap for WHO Assessment of* vaccine x *during the COVID-19 Public Health Emergency*

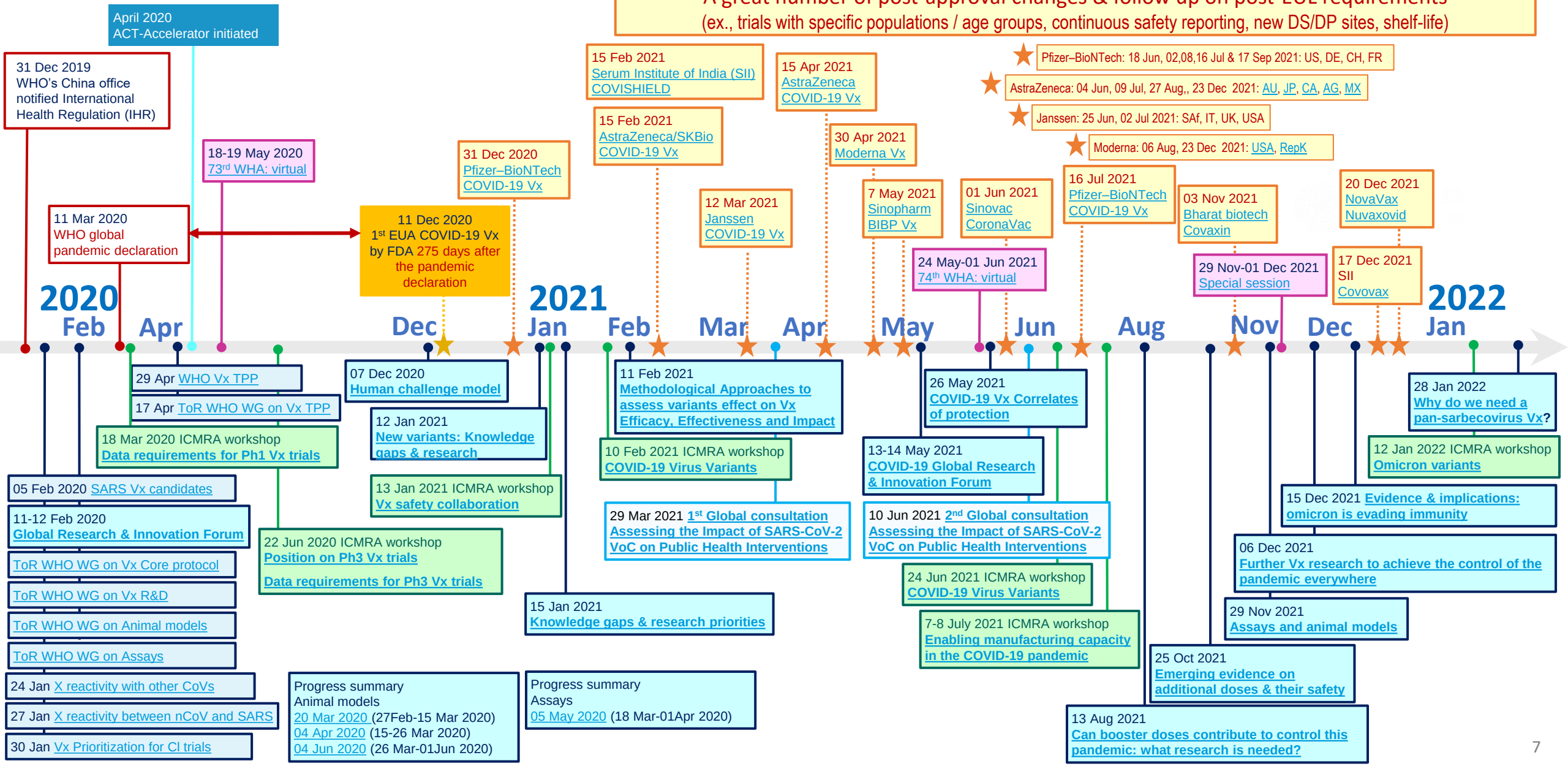
Timeline of events: (selected Covid-19 Vx related events)

COVAX RAG events, co-chaired by WHO & CEPI, are not listed

★ WHO Emergency Use Listing (EUL)

World Health Organization

A great number of post-approval changes & follow up on post-EUL requirements
(ex., trials with specific populations / age groups, continuous safety reporting, new DS/DP sites, shelf-life)



Emergency regulatory authorizations issued by >150 LMI countries/territories

update: as of 01 February 2022

AZ (incl. SII)	Janssen	Moderna	Pfizer	Sinopharm	Sinovac	Novavax
142 countries/territories	**115** countries/territories	**77** countries/territories	**156** countries/territories	**80** countries/territories	**61** countries/territories	**34** countries/territories
1470 regulatory clearance	**786** regulatory clearance	**500** regulatory clearance	**299** regulatory clearance	**80** regulatory clearance	**90** regulatory clearance	**34** regulatory clearance
8 DS sites 12 DP sites	3 DS sites 7 DP sites	2 DS sites 3 DP sites	4 DS sites 10 DP sites	1 DS/DP site	1 DS/DP site	1 DS/DP site
Viral vector		mRNA		Inactivated		Protein subunit

Assessment, monitoring, and adjustments to variants is critical

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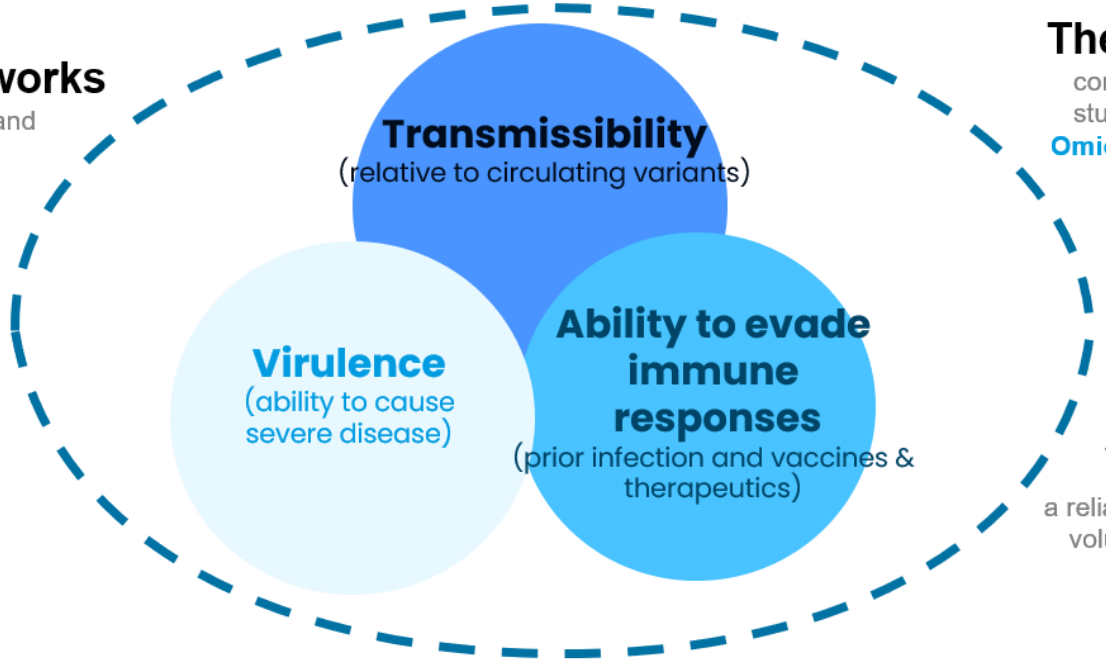
TAG for SARS-CoV-2 Virus Evolution

is assessing its effect on transmission, disease severity, vaccines, therapeutics and diagnostics, and the effectiveness of PHSMs



WG for Clinical Management Networks

is assessing impacts of VOCs on current vaccines and **WHO Global Clinical Platform for COVID**

The Joint Advisory Group on Therapeutics Prioritization

is analyzing the possible effects on treatment of hospitalized patients.

WG on outpatient platform trials

is reviewing trial designs and challenges

The R&D Blueprint for Epidemics is

convening researchers to identify knowledge gaps, and studies needed to answer the most pressing questions.
Omicron variant assays & animal models study tracker

The WG on vaccines TPPs

is reviewing current desirable and minimum criteria for vaccines.

WHO BioHub system

a reliable, safe, and transparent mechanism to voluntarily share novel biological materials

TAG for COVID-19 Vaccine Composition*

Is assessing impacts of VOCs on current vaccines and determining whether changes to the composition of vaccines are needed.

SAGE on Vaccines & Immunization

is reviewing data to develop evidence based recommendations on the vaccination policies and target populations.

Thousands of researchers around the world are contributing data and expertise to the deliberations

***Interim Statement on COVID-19 vaccines in the context of the circulation of the Omicron SARS-CoV-2 Variant from the WHO Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC)** https://www.who.int/news/item/11-01-2022-interim-statement-on-covid-19-vaccines-in-the-context-of-the-circulation-of-the-omicron-sars-cov-2-variant-from-the-who-technical-advisory-group-on-covid-19-vaccine-composition

World Health Organization

WHO/Otto B.

WORKING TOGETHER

Carmen Rodriguez ¦ Team Lead, Vaccine Prequalification
Department of Regulation and Prequalification (RPQ)