# Working together to build Effective and efficient regulatory systems

## From pandemic response into supporting global regulatory strengthening, a critical role to provide affordable access to quality-assured medical products

USP - Regulatory Best Practices for Global Access to Medicines, Including Anti-TB Medicines (August 16th 2022)

**Rogério Gaspar** ¦ Director, Department of Regulation and Prequalification (RPQ)

# Access to Medicines and Health Products (MHP)

## ADG - Mariângela Simão

World Health Organization

## Health Products Policy and Standard (HPS)
Clive Ondari

## Regulation and Prequalification (RPQ)
Rogério Gaspar

### Prequalification (PQT)
**Deus Mubangizi**

- Office of the Unit Head
- Inspection Services — **Joey Gouws**
- IVD Assessment — **Irena Prat**
- Medicines Assessment — **Matthias Stahl**
- Vaccines & Immunization Devices Assessment — **Carmen Rodriguez**
- Vector Control Products Assessment — **Marion Law**
- Medical Devices — **TBD**

### Regulation and Safety (REG)
**Hiiti Sillo**

- Office of the Unit Head
- Regulatory Systems Strengthening — **Alireza Khadem Broojerdi* & ****
- Regulatory Convergence and Networks — **Samvel Azatyan**
- Facilitated Product Introduction — **Samvel Azatyan*&****
- Laboratory Network and Services — **Gaby Vercauteren**
- Pharmacovigilance — **Shanthi Pal**
- Incidents and SF Medical Products — **Rutendo Kuwana**

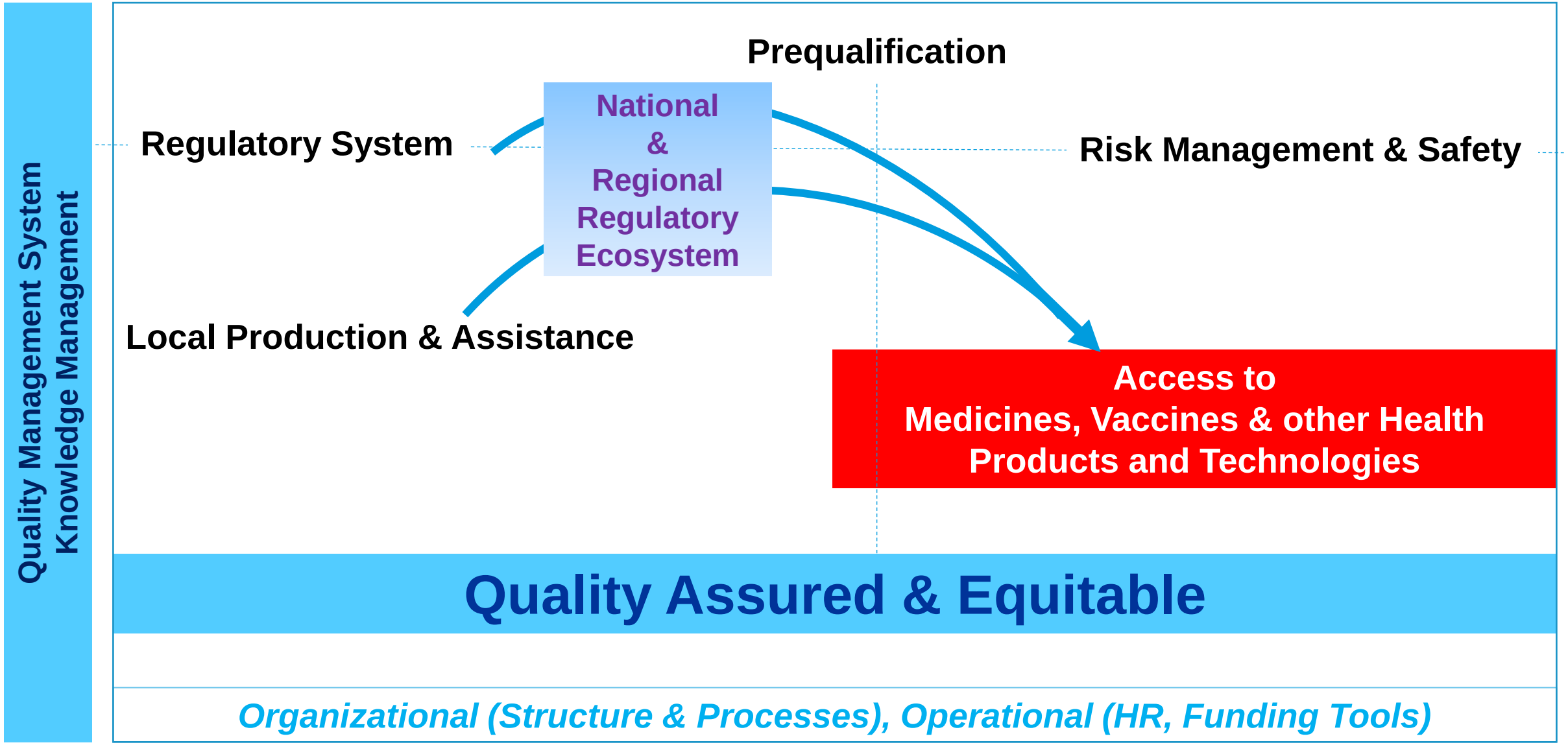
### Local Prod. & Assist. (LPA)
**Jicui Dong**

### Office of the Director

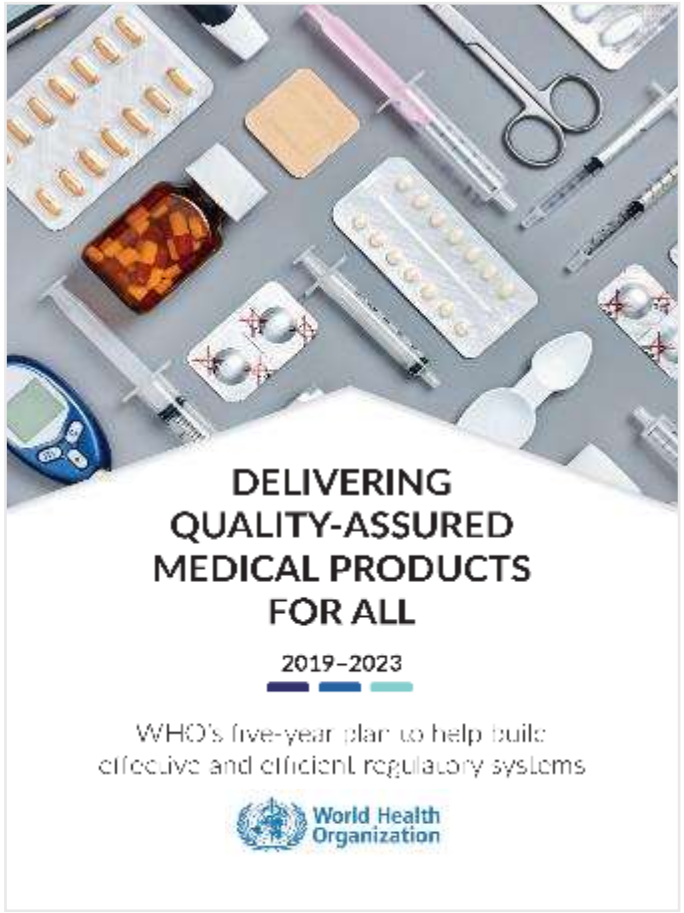
- Quality Management Systems** — **(Jan-Anton Norder)**
- Knowledge Management**

* acting
** under recruitment

# Regulation and Prequalification (RPQ)



# WHO's Regulatory Strategic Priorities: 2019-2023




1. Strengthen country and regional regulatory systems
2. Improve regulatory preparedness for public health emergencies
3. Reinforce and expand WHO prequalification & product risk assessment
4. Increase the impact of WHO regulatory support activities

These strategic guide WHO regulatory activities

- ✓ Benchmarking and technical assistance to address regulatory gaps
- ✓ Promoting regulatory convergence, harmonization, work-sharing and reliance mechanisms
- ✓ Improving countries' ability to carry out risk-based post-marketing surveillance to securing supply chains against SF products
  - Includes strengthening national quality laboratories
- ✓ Broaden the prequalification programme
- ✓ Leverage political attention and commitment to advance accountability
- ✓ Promote and support sustainable and quality-assured local production through technical assistance

https://www.who.int/medicines/news/2019/strong-reg-systems-to-reach-UHC/en/

# A reminder: WHO Regulatory Activities

## Ensuring normative and technical excellence drives impact at country level

### Technical Standards & Specifications

- Set global norms and standards (written & physical) and nomenclatures
- Increase common understanding on regulatory requirements by authority & manufacturer
- Standardize approach used by quality control labs

### Prequalification

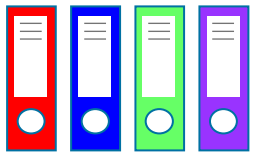
- Assure safety, quality efficacy & appropriateness of medical products used in LMICs, including medicines, vaccines, medical devices, cold chain equipment, vector control products & in vitro diagnostics
- Increase competition to shape the market

### Regulation & Safety

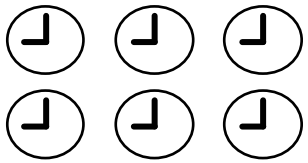
- Strengthen regulatory systems in countries and regions
- Promote regulatory cooperation, convergence and transparency through networking, work-sharing and reliance
- Mitigate risks and protect against substandard / falsified products

### Local production & assistance

- Provide holistic & coordinated support to strengthen local production and technology transfer
- including
  - guidance tools, situational analyses for sustainable quality local production
  - strengthening local production, capacity building and specialized technical assistance



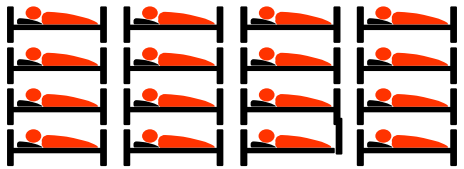
Decreased regulatory burden



Reduced time for regulation

Increased regulatory capacity in LMIC

Decreased cost of regulation



Reduced mortality and morbidity

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World Health Organization

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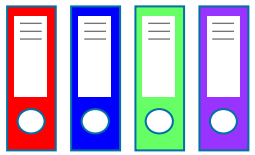
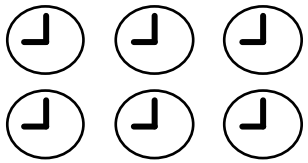


Decreased regulatory burden



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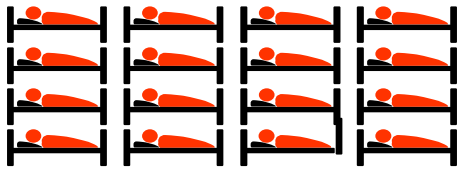
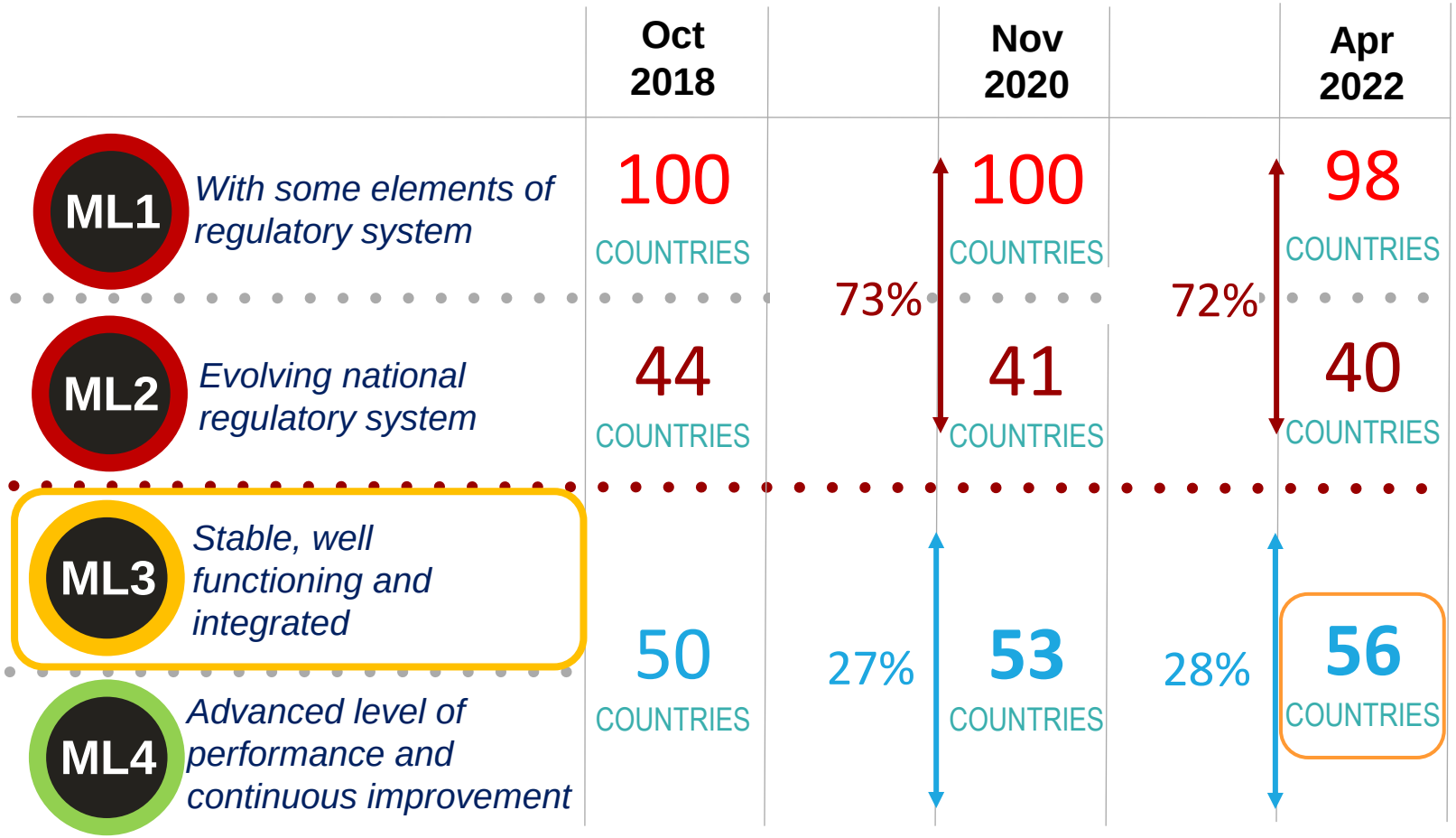


Reduced mortality and morbidity

# Global status of national regulatory systems, April 2022

World Health Organization




Vaccines developed in countries with weak regulatory systems, i.e., ML1/ML2, are not eligible for EUL or prequalification

[Singapore medicines regulator world's first to achieve the highest maturity level (ML4) following assessment](#) (28 Feb 2022)

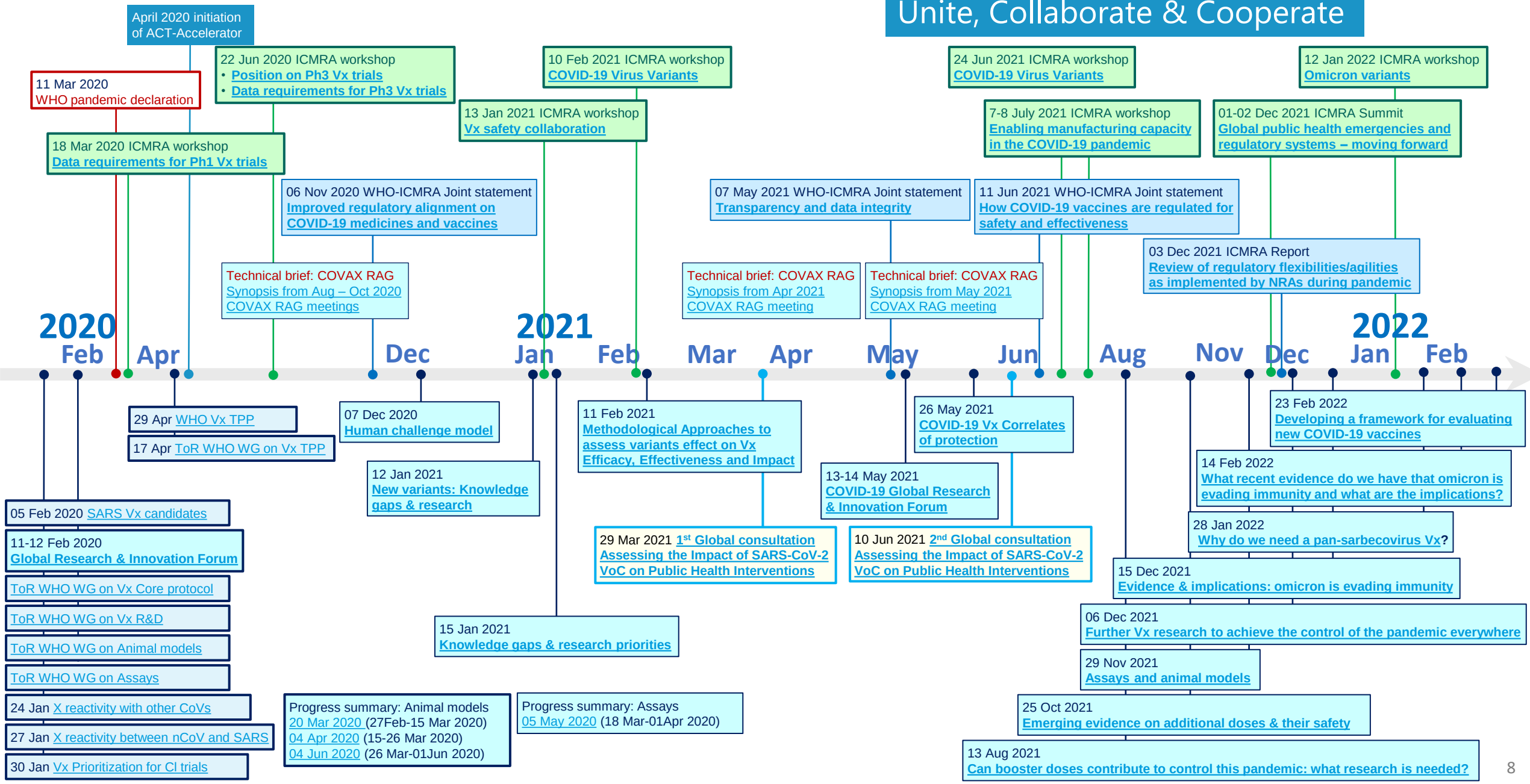
ML3 **GOAL of WHA Resolution 67.20**

ML: *(regulatory system) maturity level*

*Nigeria and Egypt announced as ML 3 in March 2022*

# Timeline of events: ICMRA, COVAX RAG and R&D Blueprint

## Unite, Collaborate & Cooperate



# How can reliance help in case of public health emergency?


**Facilitate authorization or emergency use authorization**

based on WHO PQ EUL or stringent regulatory authorities approvals

**Encourage use of reliance and work-sharing**

(e.g. WHO Covid-19 vaccines safety surveillance manual encourages reliance, review of risk management plans at regional and WHO prequalification level, pharmacovigilance inspections, etc.)

Avoid retesting through **reliance** on the batch release testing from releasing NRAs/NCLs

# Emergency regulatory authorizations issued by >150 LMI countries/territories

World Health Organization

update: as of 18 May 2022

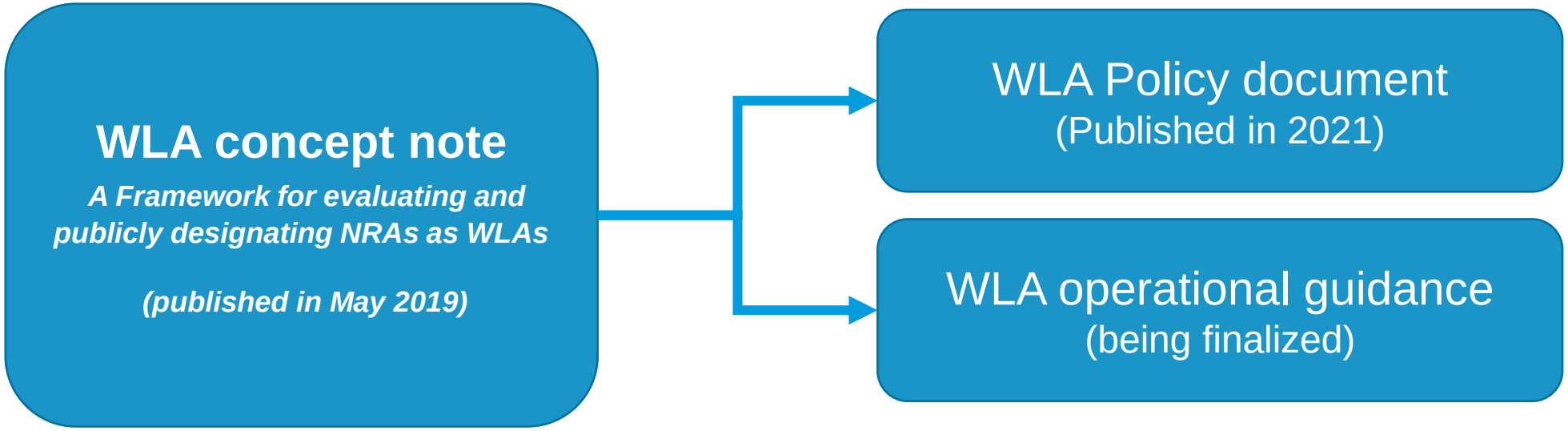
| mRNA | Viral vector | | | | Inactivated | | | | Recombinant adjuvanted |
|---|---|---|---|---|---|---|---|---|---|

| **Pfizer** COMIRNATY | **Moderna** SPIKEVAX | **AZ** VAXZEVRIA | **SII** COVISHIELD | **Janssen** Covid-19 Vx | **CanSino** Convidecia | **Sinopharm** BIBP Covid-19 Vx | **Sinovac** CoronaVac | **Bharat** Covaxin | **Novavax** Nuvaxovid | **SII** Covovax |
|---|---|---|---|---|---|---|---|---|---|---|
| **314** regulatory clearance **in 162** country/territory | **506** regulatory clearance **in 78** country/territory | **1'364** regulatory clearance **in 142** country/territory | **147** regulatory clearance **in 114** country/territory | **807** regulatory clearance **in 115** country/territory | **1** regulatory clearance **in 1** country/territory | **81** regulatory clearance **in 80** country/territory | **91** regulatory clearance **in 61** country/territory | X On suspension 02 Apr 2022 | **34** regulatory clearance **in 34** country/territory | **1** regulatory clearance **in 1** country/territory |
| Shared EUL reports with **60 NRAs** | Shared EUL reports with **51 NRAs** | Shared EUL reports with **81 NRAs** | Shared EUL reports with **58 NRAs** | Shared EUL reports with **67 NRAs** | EUL granted 18 May 2022 | Shared EUL reports with **60 NRAs** | Shared EUL reports with **47 NRAs** | Shared EUL reports with **17 NRAs** | Shared EUL reports with **20 NRAs** | Shared EUL reports with **9 NRAs** |
| 4 DS sites 12 DP sites | 2 DS sites 3 DP sites | 8 DS sites 12 DP sites | 2 DS sites 2 DP sites | 3 DS sites 7 DP sites | 1 DS sites 1 DP sites | 1 DS site 1 DP site | 1 DS site 1 DP site | 1 DS site 1 DP site | 2 DS sites 1 DP site | 2 DS sites 2 DP sites |
| Ref NRA: • EMA • US FDA | Ref NRA: • EMA • US FDA • MFDS | Ref NRA: • EMA • MFDS • MHLW • TGA • DS: COFEPRIS • DP: ANMAT | Ref NRA: • DCGI | Ref NRA: • EMA • US FDA | Ref NRA: • NMPA | Ref NRA: • NMPA | Ref NRA: • NMPA | Ref NRA: • DCGI | Ref NRA: • EMA | Ref NRA: • DCGI |

DS: Drug substance / DP: Drug product

# Operationalizing WHO Listed Authorities (WLAs)

## The WLA Framework




**The WLA framework is envisaged to be operational in 2022**

Definition of WLA: Adopted by the ECSPP in October 2020, TRS 1033

A regulatory authority or a regional regulatory system which has been documented to comply with all the relevant indicators and requirements specified by WHO for the requested scope of listing based on an established benchmarking and performance evaluation process

# Benefits of WHO-Listed Authority (WLA) framework

**Enable efficient use of regulatory resources**

by providing a robust framework to promote **trust, confidence** and **reliance**

**Encourage continuous improvement** of regulatory systems and **regulatory convergence**

**Help procurement decisions**

on medical products by UN and other agencies, as well as countries (especially LMICs)

**Contributes to WHO PQ programme**

by expanding the pool of trusted regulatory authorities

**Fosters health equity**

by enabling an environment for innovation and local production, and accelerating access to medical products

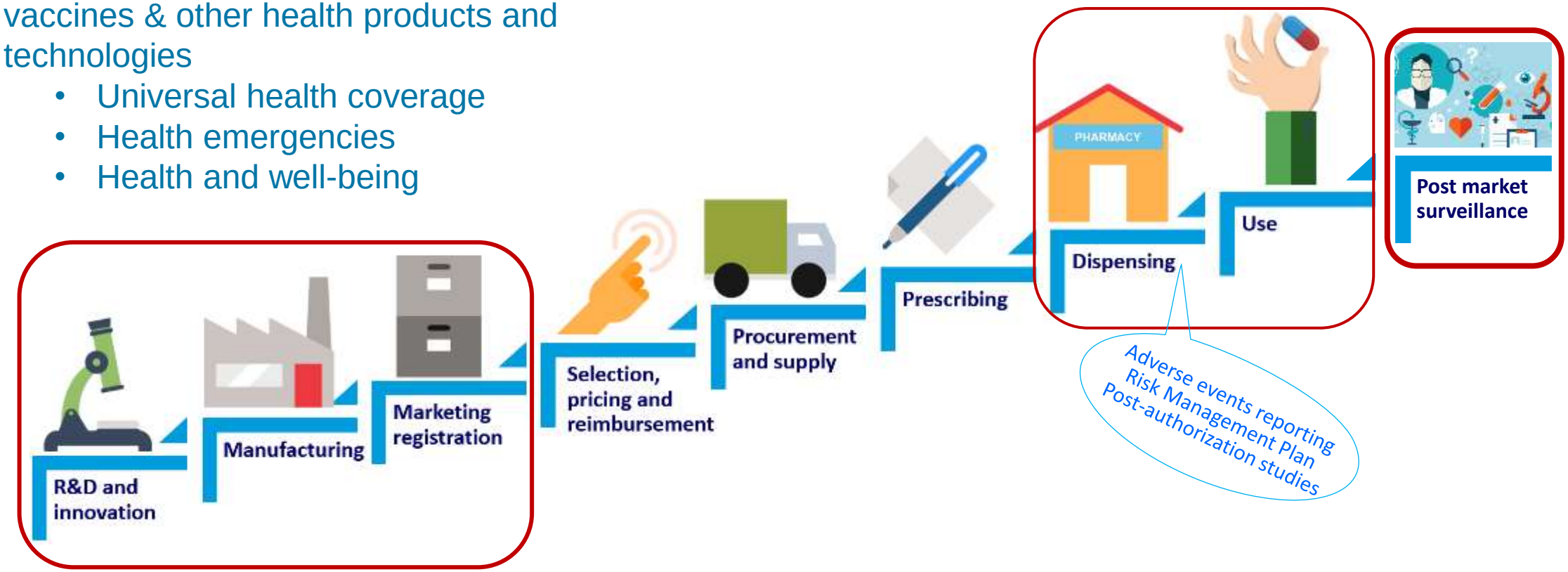
# “End-to-end” health products’ management: shared responsibilities

World Health Organization

## Legislation, regulation, governance, monitoring

Access to quality-assured medicines, vaccines & other health products and technologies

- Universal health coverage
- Health emergencies
- Health and well-being

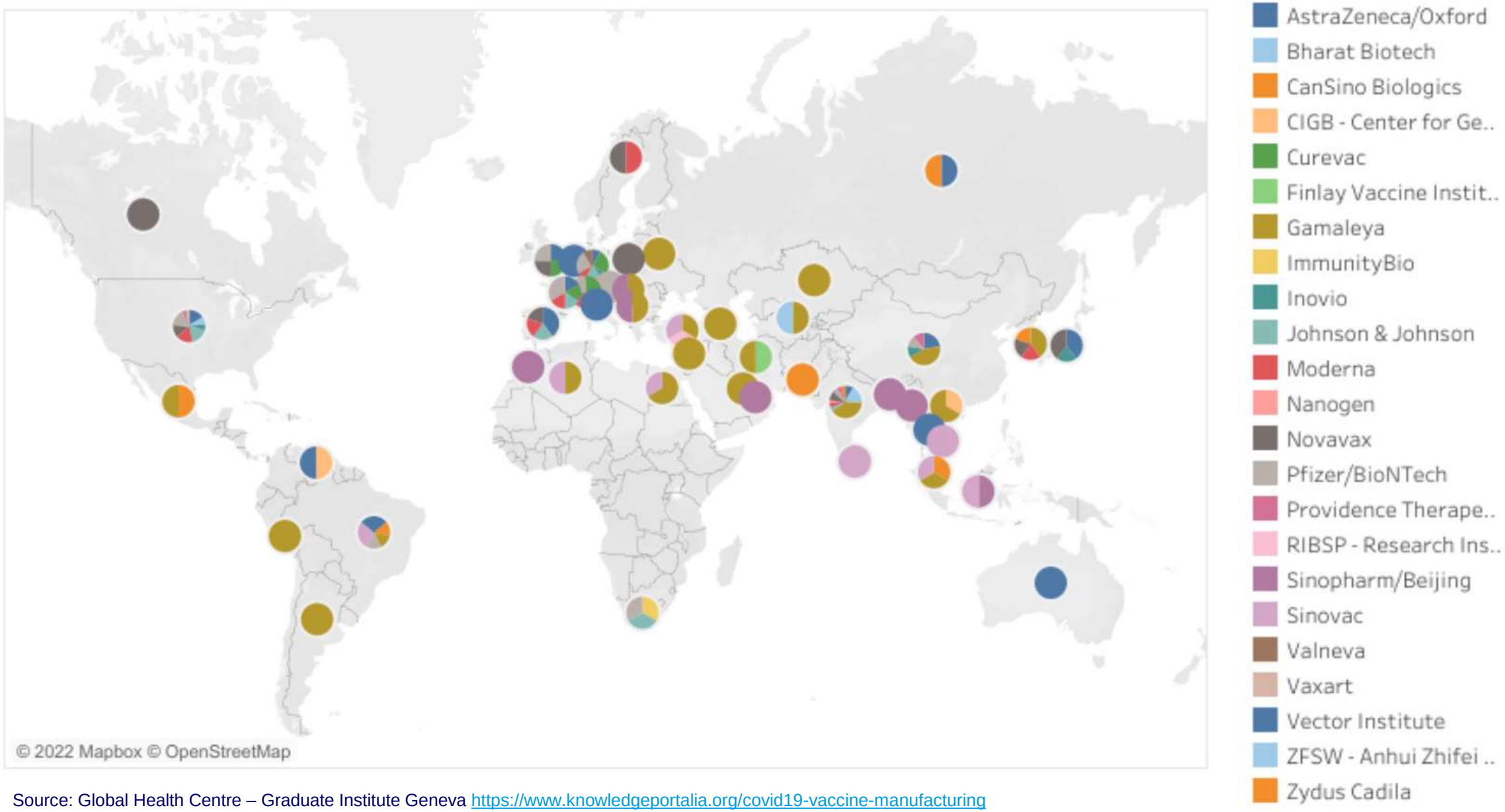



Joint reviews & assessments of clinical trials

Long term Good Regulatory Practice

Regulatory Reliance, Collaboration and Harmonization

# Locations of Covid-19 Vaccine Manufacturers




Source: Global Health Centre – Graduate Institute Geneva https://www.knowledgeportalia.org/covid19-vaccine-manufacturing

# Local Production and Assistance

**WHO VACCINE MANUFACTURING WORKSHOP for SOUTHEAST ASIAN and WESTERN PACIFIC REGIONS**

**ONGOING PQ/EUL-RELATED SPECIALIZED TECHNICAL ASSISTANCE**

**MEMBER STATE SUPPORT IN STRENGTHENING LOCAL PRODUCTION**

**DZA, EUC, EGY, ETH, GHA, KAZ, NGA, SEN, SRB, etc.**

**IMPLEMENTATION OF WORLD LOCAL PRODUCTION FORUM RECOMMENDATIONS**

Access to quality medicines and other health products requires **an integrated approach** with all stakeholders

World Health Organization

WORKING TOGETHER

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