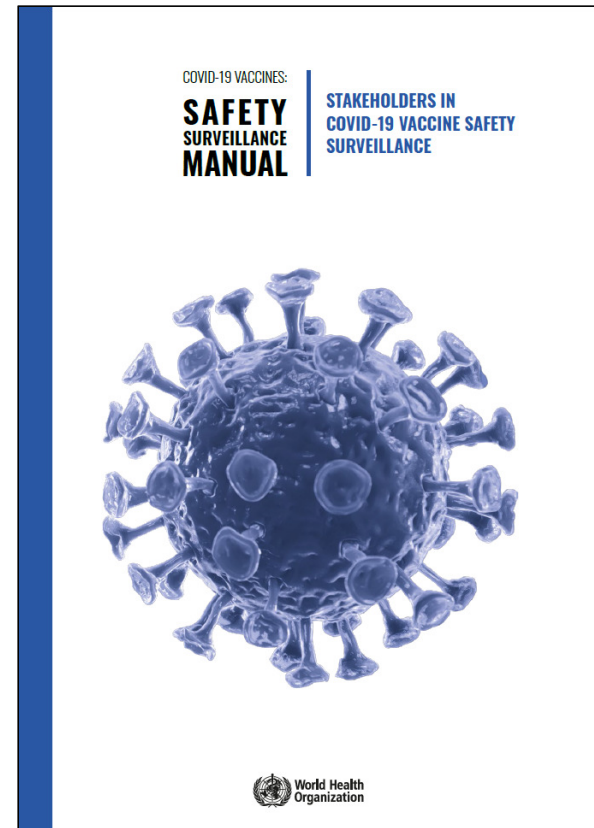
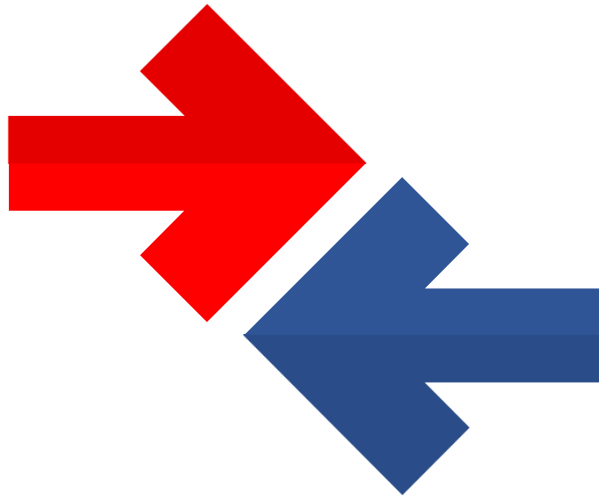
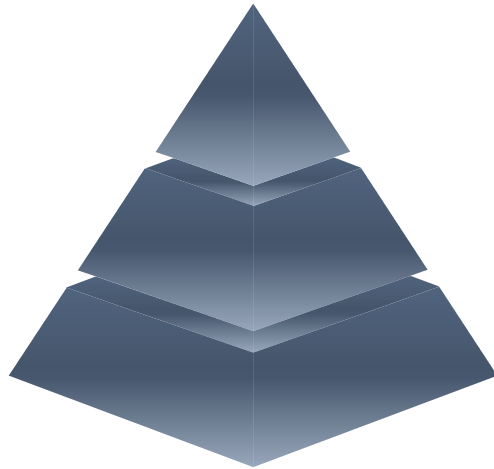


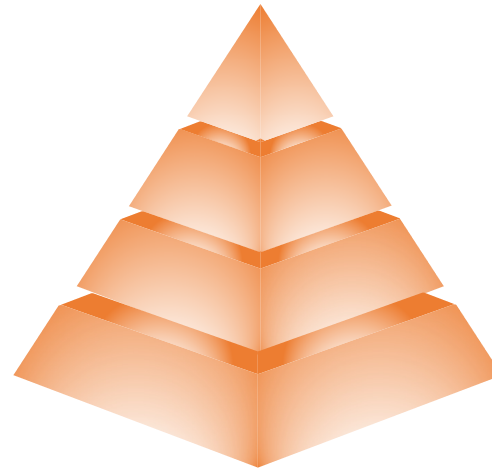
Stakeholders in COVID-19 vaccines safety surveillance



Learning objectives

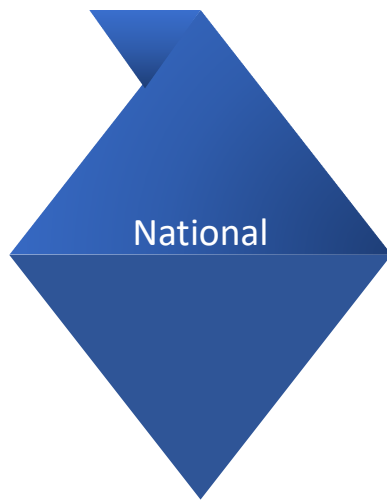


Identify the roles & responsibilities of the various stakeholders in COVID-19 vaccines safety surveillance at global, regional and national levels



Describe how the stakeholders can collaborate to ensure the efficient handling of COVID-19 vaccines safety surveillance

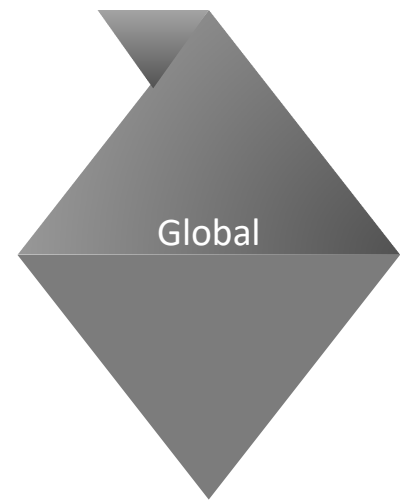
Stakeholders in COVID-19 vaccines safety surveillance



National



Regional



Global

National stakeholders



National stakeholders: Ministries of health (MoH)



Ensure availability of funding for national stakeholders to conduct key activities to strengthen safety monitoring for COVID-19 vaccines



Establish a national coordination task force or working group consisting of multi-disciplinary and multi-agency representatives to ensure inter-stakeholder coordination and cooperation



Generate vaccine demand and ensure acceptability



Establish efficient communication mechanisms for COVID-19 vaccines between regulatory authorities, immunization programmes, Ministry of Education and other authorities



Be prepared to respond to rumours and media and community concerns.

National stakeholders: NRAs



oversee preparations for emergency use listing (EUL)



verify submission and review of risk management plans prior to marketing authorization and making risk-based recommendations for post- authorization safety surveillance;



oversee communication and information sharing with immunization programmes, pharmacovigilance centres and other key institutions on COVID-19 vaccines safety updates



have authority to mandate COVID-19 vaccine safety studies by the vaccine manufacturers and importers of vaccines, as required;



have the independent authority to investigate potential safety signals and assure the continued post-authorization safety of COVID-19 vaccines;



oversee the monitoring of COVID-19 vaccine safety by reviewing the periodic safety update reports (PSURs) / periodic benefit-risk evaluation reports (PBRERs);



share safety information generated with national, regional, international decision-makers and vaccine manufacturers.

National stakeholders: Immunization program



when recommended, conduct specific active surveillance studies for COVID-19 vaccines



regularly review reports submitted to passive safety surveillance systems to identify rates and unexpected patterns, with special attention to serious outcomes, such as death, disabilities, life-threatening events, and programmatic errors;



identify and quantify public concerns surrounding vaccines through cross-sectional surveys and monitoring of social media;



develop a national framework to process vaccine safety signals and determine which should be prioritized for more rigorous evaluation and risk assessment;



measure and characterize background rates of medical outcomes that may become temporally associated with COVID-19 vaccines;



measure and characterize other AEFIs identified in active surveillance and sentinel systems



coordinate existing active and sentinel surveillance nationally, regionally and globally to ensure harmonization, avoid duplication, increase power to detect rare events and take advantage of variability in vaccination practices and target population.

National stakeholders: National pharmacovigilance centers



ensure timely submission of COVID-19 AEFIs and adverse events of special interest (AESIs) data from EPIs, NIPs and pharmacovigilance centres across the country for data compilation, analysis and signal detection; and



share information with key national stakeholders on COVID-19 vaccine safety and with the global community by uploading the information on the WHO global pharmacovigilance database, Vigibase, maintained at Uppsala Monitoring Centre (UMC) in Sweden under the WHO International Drug Monitoring Programme.

National stakeholders AEFI review committees

The committee should be independent of the NRAs, NIPs/EPIs, MoHs and vaccine manufacturers, and the members should have no conflicts of interest



assess potential causal links between AEFIs and AESIs and COVID-19 vaccines.



monitor AEFI data for identification of potential signals of previously unidentified COVID-19 vaccine related adverse events;



review all serious AEFIs presented for expert opinion and arrange further investigation to establish causality, if required;



communicate with other national and international experts, when required, to establish causality and resolve vaccine quality issues;



advise NRAs, EPIs and NIPs on COVID-19 vaccines AEFI- and AESI-related issues when requested.



advise the Ministry of Health (MoH) on COVID-19 vaccines and Immunization safety-related matters when requested

National stakeholders

National immunization technical advisory groups (NITAGs)



Provide the latest information on different COVID-19 vaccine platforms, risk/benefit analyses, COVID-19 EUL status, etc.



Review the available evidence to be considered for recommendations for COVID-19 vaccine introduction, including the identification of priority target groups for COVID-19 introduction

National stakeholders: Vaccine manufacturers



share risk management plans and information on detected signals for COVID-19 vaccines with NRAs.



conduct phase IV studies on COVID-19 vaccines and submit periodic safety update reports (PSURs) on a regular basis to help policy decisions; the frequency of PSUR submissions may be increased to bi-monthly/monthly to guide quick corrective actions and decisions.



respond to national requests to implement innovative risk minimisation measures, for example, peel-off labels on vaccine vials; .



respond to national requests to share additional and updated product information and clinical trial data.



keep the countries updated on all safety and efficacy findings in other countries, particularly from phase IV studies.

National stakeholders: Academia



Advise and facilitate research activities concerning COVID-19 vaccines, including sentinel-site based and specific studies related to AESIs.

National stakeholders: Health care workers



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National stakeholders: Beneficiaries



Understand the risk and benefits of vaccines and immunization



Play an active role in identifying what they feel is important to help define certain adverse effects, if possible



Differentiate between genuine and false information and ensure that correct information is communicated, and prevent the circulation of false information



Demand safe and effective immunization programmes as a right from their leaders and government and hold leaders and government accountable for providing them;



Participate in public-health discussions and be involved in key decisions about immunization processes



Participate and contribute to the immunization delivery process



Convey the needs and perspectives of their communities to policymakers.

National stakeholders: Media



Keep up to date with media releases, press information packages, briefing papers, web materials, talk points disseminated by MoHs on COVID-19 vaccines and vaccination



Proactively identify, filter out and prevent the spread of misinformation;



Participate in media workshops and training sessions to learn about the rationale for COVID-19 vaccine introduction and understand the key messages



Ensure the dissemination of clear, factual messages to the public that have been confirmed by the relevant authorities.

National stakeholders

Non-governmental organizations and professional societies



Participate in the development and testing of innovative approaches for the delivery of COVID -19 immunization services that reach the most vulnerable people

Regional stakeholders



Regional regulatory networks
AVAREF (African Vaccine
Regulatory Forum)
SEARN (South-East Asia
Regulatory Network)
EMA (European Medicines
Agency) and the Article 58
authorized vaccines



Regional technical advisory
committees on vaccine safety
(RTAGs)

Regional stakeholders

Regional regulatory networks

- AVAREF, SEARN or EMA Play an essential role in routine pharmacovigilance

Regional regulatory networks

- EMA's large Eudravigilance database : system for managing and analyzing information on suspected adverse reactions to medicines, including vaccines, those authorized for use outside the European Union, the Article 58 authorized vaccines (i.e. COVID-19 vaccines)

RTAGS

- Regional technical advisory groups play a key role in rapid, real-time exchange of information and joint assessment of routine safety data, should there be a safety signal .

Global stakeholders

International Coalition of Medicines Regulatory Authorities (ICMRA)



ICMRA aims to expedite and streamline the development of COVID-19 vaccines and treatments



In April 2020, ICMRA members are committed to strengthen global collaborative efforts to align the facilitation of rapid development, approval and global roll-out of safe and effective medicines and vaccines to prevent and treat COVID-19

Global stakeholders

The Council for International Organizations of Medical Sciences (CIOMS)



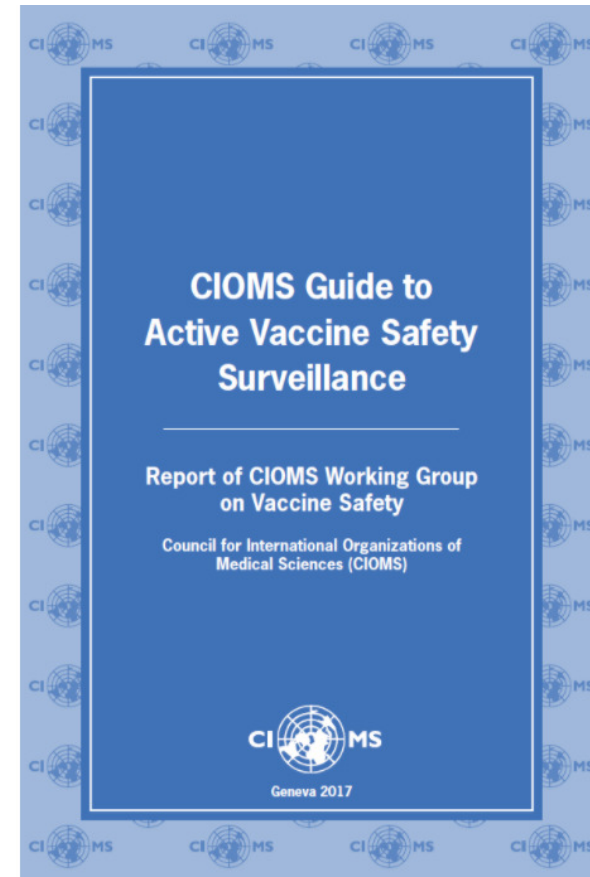
The CIOMS is an international, non-governmental, non-profit organization established jointly by WHO and UNESCO in 1949



Its mission is to advance public health through guidance on health research and policy including ethics, medical product development and safety



The CIOMS guide to active vaccine safety surveillance published in 2017 will be used for guidance for COVID-19 vaccine safety monitoring



Global stakeholders: International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)



Urgent need for a harmonized, standardized approach for coding and reporting COVID-19 infections as a global health issue



ICH M1 Points to Consider Working Group and the medical dictionary for regulatory activities (MedDRA) maintenance as well as support services organization (MSSO) are issuing notifications for MedDRA users regarding existing and new terms for COVID-19 concepts

Brings together regulatory authorities and pharmaceutical industries to discuss scientific and technical aspects of pharmaceuticals and develop ICH guidelines

Global stakeholders: WHO prequalification



Major role to assure the quality of all vaccines that could be purchased by UN agencies



Important role of WHO Prequalification team for the prequalification of new COVID-19 vaccines and for possible EUL of COVID-19 vaccines.

- *Review of the quality, safety and efficacy data*
- *Review of production process and quality control procedures*
- *Review of production process and quality control procedures*
- *laboratory testing, and*
- *WHO site audit to manufacturing facilities with the responsible NRA*

Global stakeholders

WHO Global Advisory Committee on Vaccine Safety (GACVS)



Provides advice on urgent matters as needed, such as COVID-19 vaccine safety monitoring

- *The GACVS provides independent, authoritative, scientific advice to WHO on vaccine safety issues of global or regional concern with the potential to affect in the short- or long-term national immunization programmes*

Global stakeholders: WHO Strategic advisory group of experts (SAGE) 1/3



provides continuous review of the available evidence on the progress of candidate vaccines against COVID-19



provides guidance for the development of prediction models to determine the optimal age groups and target populations for vaccine introduction and guide vaccine introduction for optimal impact, and contribute to updates of target population profiles of COVID-19 vaccines for outbreak and endemic use

The SAGE serves as the principal advisory group to WHO for the development of policy related to vaccines and immunization

Global stakeholders: WHO Strategic advisory group of experts (SAGE) 2/3



Provides policy advice to SAGE on the accelerated use of COVID-19 vaccines (pre-licensure and post-licensure) to mitigate the public health impact of COVID-19, including recommendations for early allocation of vaccines when vaccine supplies are still limited



Provides guidance to ensure equitable access to vaccination, and guidance on the safety of vaccines when safety data from wider population use become available, in close collaboration with GACVS

Global stakeholders: WHO Strategic advisory group of experts (SAGE) 3/3



WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination, 14 Sep 2020



Roadmap for prioritizing population groups for vaccines against covid-19, 27 Sep 2020

Supplementary document to session 03

ROADMAP FOR PRIORITIZING POPULATION GROUPS FOR VACCINES AGAINST COVID-19

An Approach to Inform Planning and Subsequent Recommendations Based Upon Epidemiologic Setting and Vaccine Supply Scenarios

27 September 2020 Draft

Introduction

As countries prepare to implement their respective COVID-19 immunization programs, SAGE has undertaken a three-step process to provide guidance for overall program strategy as well as vaccine-specific recommendations:

1. A Values Framework. The *WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination*, issued on 14 September 2020, outlines the prioritization, planning, the for different levels

WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination

14 September 2020



Executive Summary

This Values Framework offers guidance globally on the allocation of COVID-19 vaccines between countries, and to offer guidance nationally on the prioritization of groups for vaccination within countries while supply is limited. The Framework is intended to be helpful to policy makers and expert advisers at the global, regional and national level as they make allocation and prioritization decisions about COVID-19 vaccines. This document has been endorsed by the *Strategic Advisory Group of Experts on Immunization* (SAGE).

The Framework articulates the overall goal of COVID-19 vaccine deployment, provides six core principles that should guide distribution and twelve objectives that further specify the six principles (Table 1). To provide recommendations for allocating vaccines between countries and prioritizing groups for vaccination within each country, the Values Framework needs to be complemented with information about specific characteristics of available vaccine or vaccines, the benefit-risk assessment for different population groups, the amount and pace of vaccine supply, and the current state of the

epidemiology, clinical management, and economic and social impact of the pandemic. Hence, the final vaccination strategy will be defined by the characteristics of vaccine products as they become available.

SAGE is currently engaged in the process of applying the Values Framework to emerging evidence on specific vaccines, and the evolving epidemiology and economic impact of the pandemic. The first stage of this process was the identification of populations and sub-populations which would be appropriate target groups for prioritization under the various values-based objectives in the Framework (Table 2), before data on Phase 3 vaccine performance are not yet available. Specific priority group recommendations for specific vaccines will be made as vaccine products become authorized for use; initial vaccine specific policy recommendations are expected in the final quarter of 2020 or early 2021, depending on timing of and findings from phase 3 vaccine trials.

The Framework also complements the principles on equitable access and fair allocation of COVID-19 health products developed for the ACT Accelerator COVAX facility.

is become recommendations safety, and

has developed a ndations that nce from phase 3 s is that currently specific vaccine roadmap for

nd prioritization is that, if ified in the ould not be nmentations for n of these values

Global stakeholders:

WHO Immunization, Vaccines and Biologicals Department (IVB)



Provides guidance on national deployment and vaccination plans for COVID-19 vaccines and checklists for immunization programmes preparing for COVID-19 vaccination programmes

The IVB is responsible for targeting vaccine-preventable diseases, vaccines, immunization policy and research

Global stakeholders: UNICEF



UNICEF is expected to provide support to the immunization programmes in countries for vaccination activities and distribution of COVID-19 vaccines

UNICEF Main activities include logistics, monitoring and advocacy for immunization and acting on infodemics, and documenting vaccine coverage through the WHO/UNICEF Joint reporting form

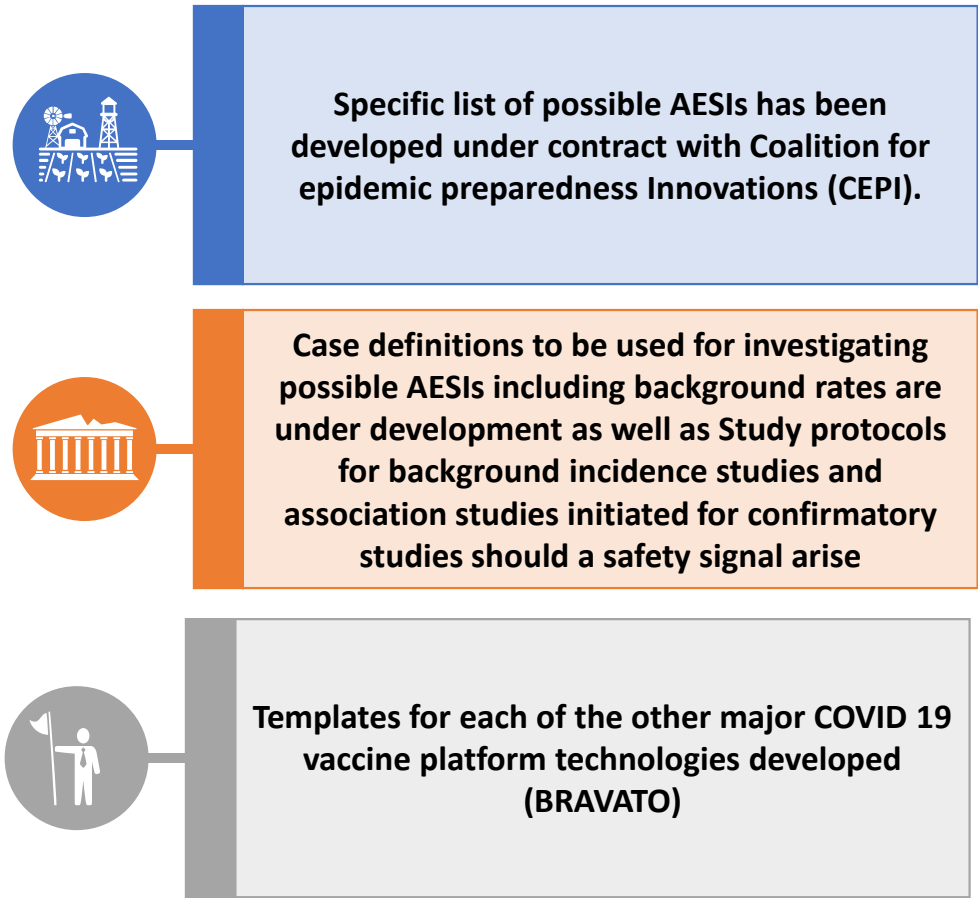
Global stakeholders: Uppsala Monitoring Center (UMC)



Is expected to be involved in safety signal detection

- *UMC Provides training, guidance and support to countries in the WHO Programme for International Drug Monitoring*

Global stakeholders: Brighton collaboration



BRAVATO (ex-V3SWG)

July 14, 2020 - Projects

Benefit-Risk Assessment of Vaccines by Technology (BRAVATO; ex-V3SWG)

In recognition of the increasing importance of viral vectors for the development of new vaccines and the need to understand their associated safety issues, the Brighton Collaboration (BC) created the Viral Vector Vaccines Safety Working Group (V3SWG) in October 2008. V3SWG was renamed to Benefit-Risk Assessment of Vaccines by Technology (BRAVATO) in July of 2020, so as to expand beyond just vaccines using viral vectors. BRAVATO has two major activities:

1. Developing [harmonized guidelines for assessing/addressing potential safety issues of concern](#) for vaccines as listed in [Table 1 of this paper](#), and initially identified in the [meeting report from a World Health Organization Informal Consultation on Characterization and Quality Aspect of Vaccines Based on Live Viral Vectors, WHO HQ, Geneva, 4-5 December, 2003](#).
2. Completing [standardized templates with key considerations for a risk/benefit assessment](#) on new vaccine candidates to: a) facilitate scientific discourse among key stakeholders by increasing the transparency and comparability of information; and b) provide a checklist like tool for managing potential complex risks.

Global stakeholders

COVID-19 Vaccines Global Access Facility (COVAX)



A global risk-sharing mechanism for pooled procurement and equitable access to COVID-19 vaccines when they become available.



Aims to end the acute phase of the pandemic by the end of 2021



COVAX Facility Explainer

Participation Arrangements
for Self-Financing Economies

Global stakeholders

Vaccine safety net



Invaluable resource for information on COVID-19 vaccines and vaccination for all stakeholders.



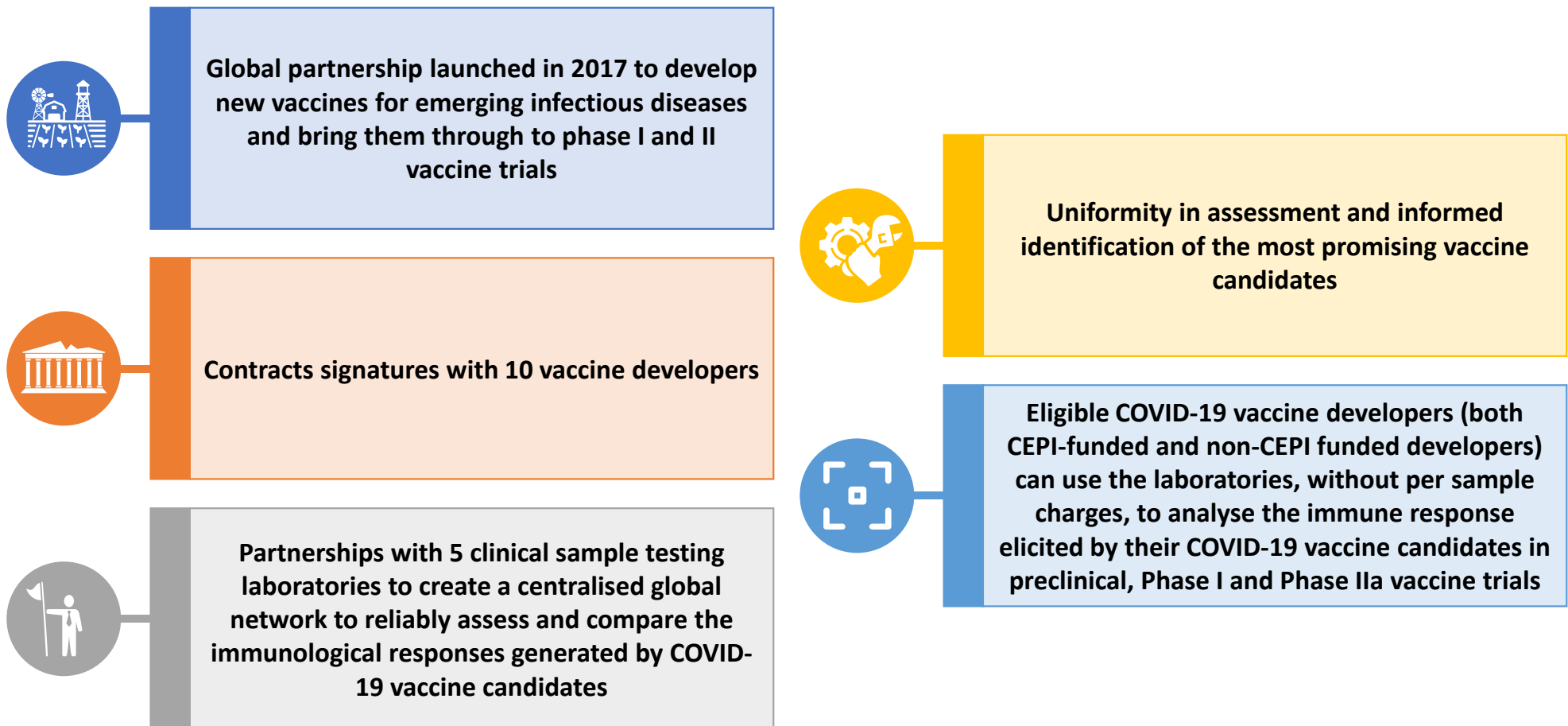
Websites' adherence evaluation

Network of a diverse group of digital information resources (websites and social media), VSN members, located in countries around the world and providing scientifically based information on vaccine safety in various languages



Global stakeholders

The Coalition for Epidemic Preparedness Innovations (CEPI)



Global stakeholders

International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)



Aim is to develop safe and effective COVID-19 vaccines

*The IFPMA
represents the
leading innovative
biopharmaceutical
companies in the
vaccine field*

Global stakeholders

Developing Countries Vaccine Manufactures Network (DCVMN)



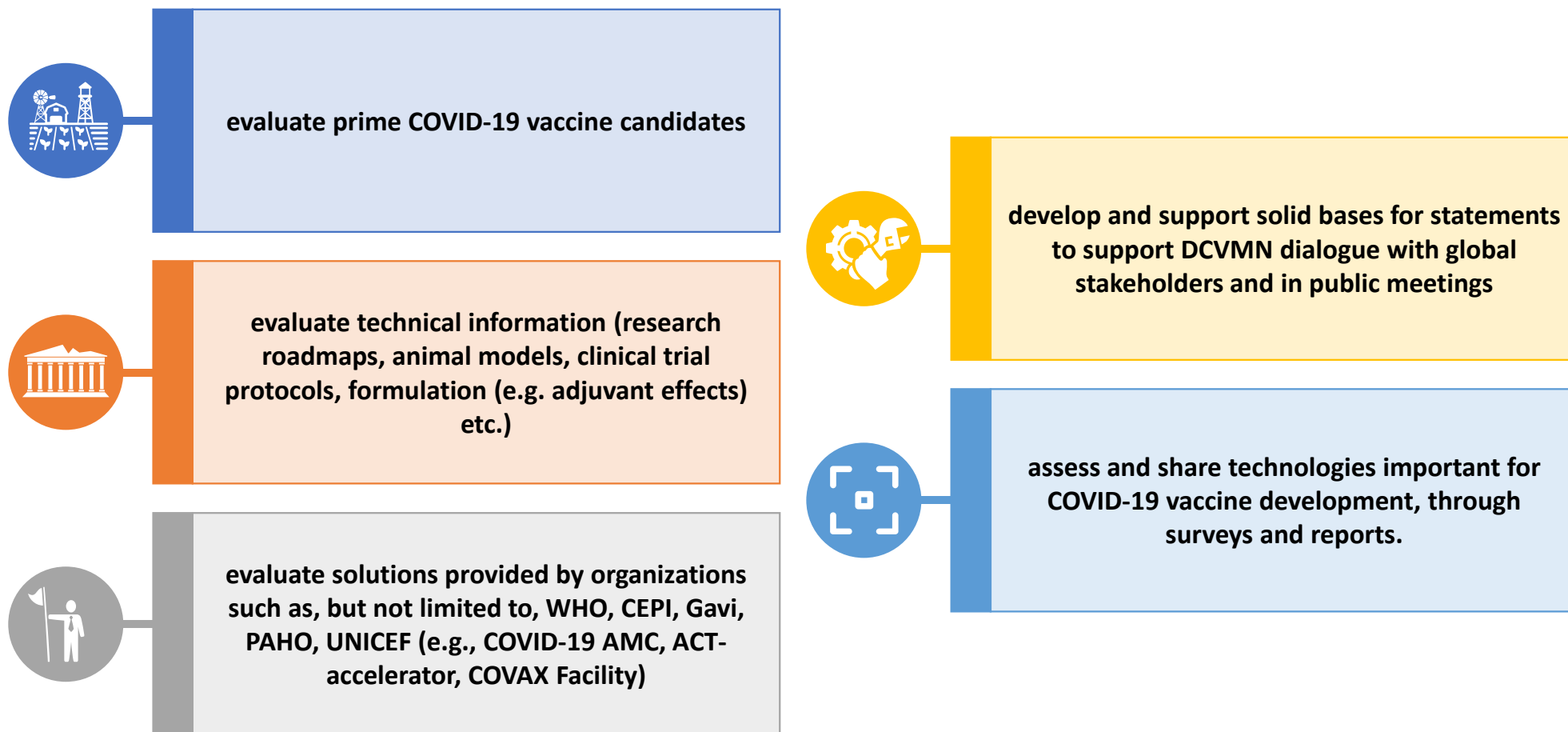
Aim: to provide a consistent and sustainable supply of quality vaccines at an affordable price that are accessible to developing countries



share technologies important for COVID-19 vaccine development, through surveys and reports.

DCVMN is an alliance of over 40 public and private vaccine manufacturing companies from 14 emerging countries/territories engaged in supply of vaccines for local and international use.

Global stakeholders: Role of the COVID-19 committee of the Developing Countries Vaccine Manufacturers Network (DCVMN)



Key points to remember...

- Vaccine safety monitoring requires broad and timely collaboration between national, regional and global stakeholders

- International collaboration will be essential to verify the safety and effectiveness of the many COVID-19 vaccines that will be broadly used

- Mapping national, regional and global stakeholders and their responsibilities is key for ensuring appropriate vaccine safety monitoring of the COVID-19 vaccines when they are deployed.

- Stakeholders will continue their regular pharmacovigilance activities and many will have additional activities, particularly during COVID-19 vaccine introduction.

References

- WHO Causality assessment of an adverse event following immunization (AEFI) User manual for the revised WHO AEFI causality assessment classification (Second edition):
https://www.who.int/vaccine_safety/publications/gvs_aefi/en/
- The Article 58 Authorized products: <https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/medicines-use-outside-european-union>
- WHO SAGE Values framework for the allocation and prioritization of COVID-19 vaccination:
<https://apps.who.int/iris/handle/10665/334299>
- Roadmap for prioritizing population groups for vaccines against COVID-19:
https://www.who.int/immunization/sage/meetings/2020/october/Session03_Roadmap_Prioritization_Covid-19_vaccine.pdf?ua=1
- Access to COVID-19 tools (ACT) accelerator: <https://www.who.int/initiatives/act-accelerator/>
- The Brighton Collaboration Benefit-Risk Assessment of Vaccines by Technology (BRAVATO) templates:
<https://brightoncollaboration.us/category/pubs-tools/templates/>
- The Vaccine Safety Net: <https://www.vaccinesafetynet.org/>