

Animal Testing Replacement for Vaccines A One Health View : Global Outlook and Future Strategy

Role of Global health stakeholders in funding, cost sharing for capital investment, training and shaping global agendas.

"How future proof regulations could support vaccines' release paradigm's change"

Meenu Batolar
Global Regulatory Affairs – Asia Pacific Lead
Singapore

03 Dec 2025

CEPI: A global partnership

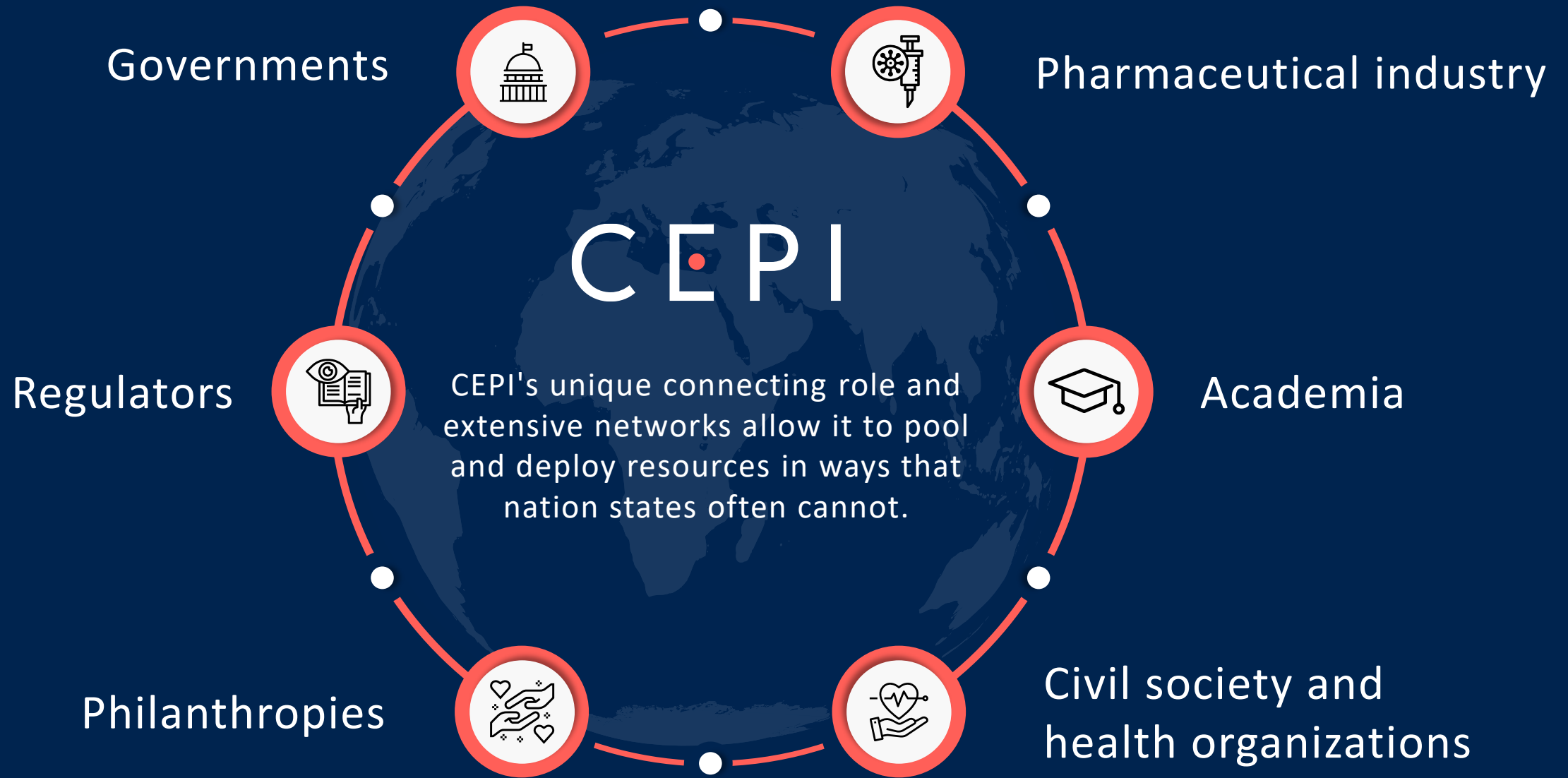
CEPI was launched at Davos in 2017, by the governments of Norway and India, the Bill & Melinda Gates Foundation, the Wellcome Trust, and the World Economic Forum, as the result of a consensus that a coordinated, international, and intergovernmental plan was needed to develop and deploy new vaccines to prevent future epidemics.

Vision

A world in which epidemics and pandemics are no longer a threat to humanity.

Mission

To accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need.



CEPI has galvanized the world to embrace the “100 Days Mission”

The 100DM is a paradigm shift to develop safe and effective vaccines faster, and requires a number of pre-requisites to be in place, including



Strengthening disease surveillance and global **early-warning** systems



Speeding up identification of **immune response** markers



Creating a **vaccine library** and establishing **vaccine platforms** against representative **prototype pathogens** across multiple **viral families**



Getting **clinical trial and laboratory networks** at the ready



Establishing **global manufacturing capacity** to make top-quality, safe, and effective new vaccines quickly



Mitigating **biosecurity and biosafety** risks

Supported by enabling regulatory, policy and financing architecture

Equitable access is core to CEPI's vision

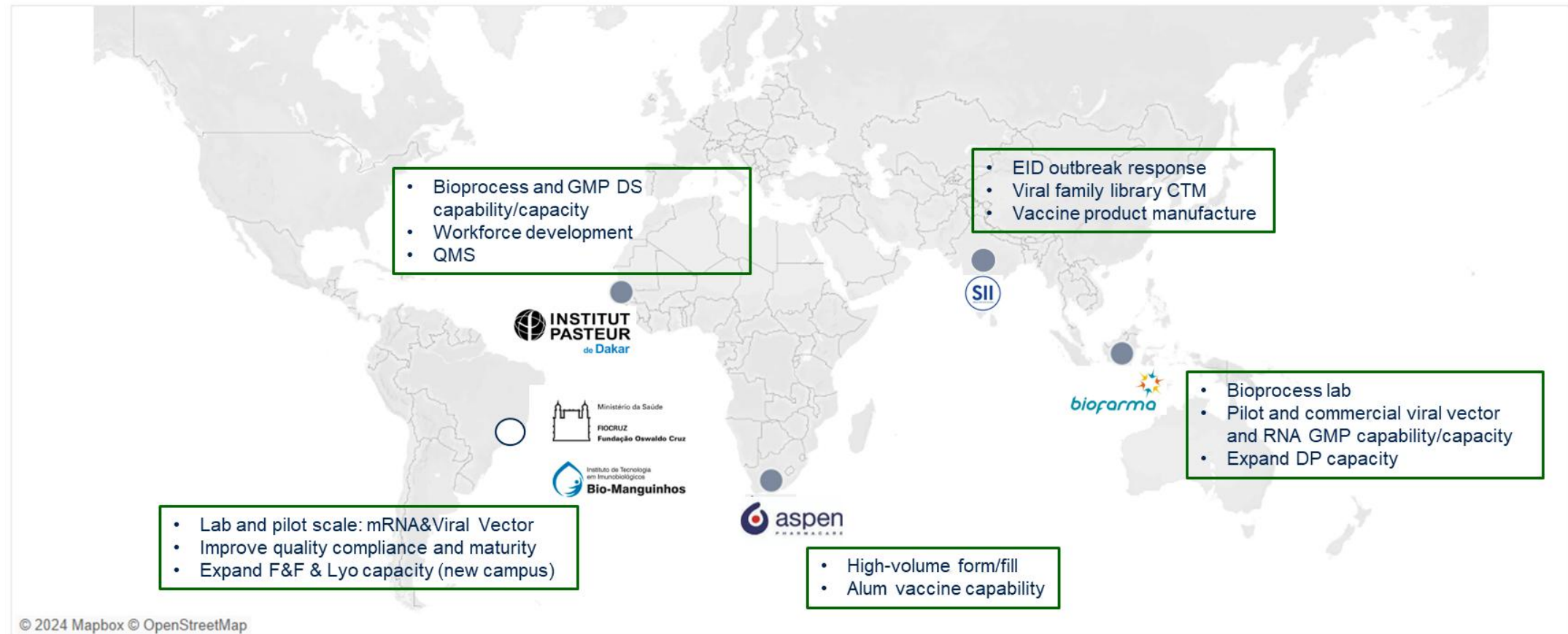
CEPI's investments and activities are focused on four key enablers of equitable access:

- Supporting system equity in the outbreak and pandemic prevention, preparedness and response ecosystem
- Connecting with other stakeholders for impact and system equity
- Making financial investments to drive equitable access
- Investing in partners with an interest in equity



CEPI Vaccine Manufacturing Network

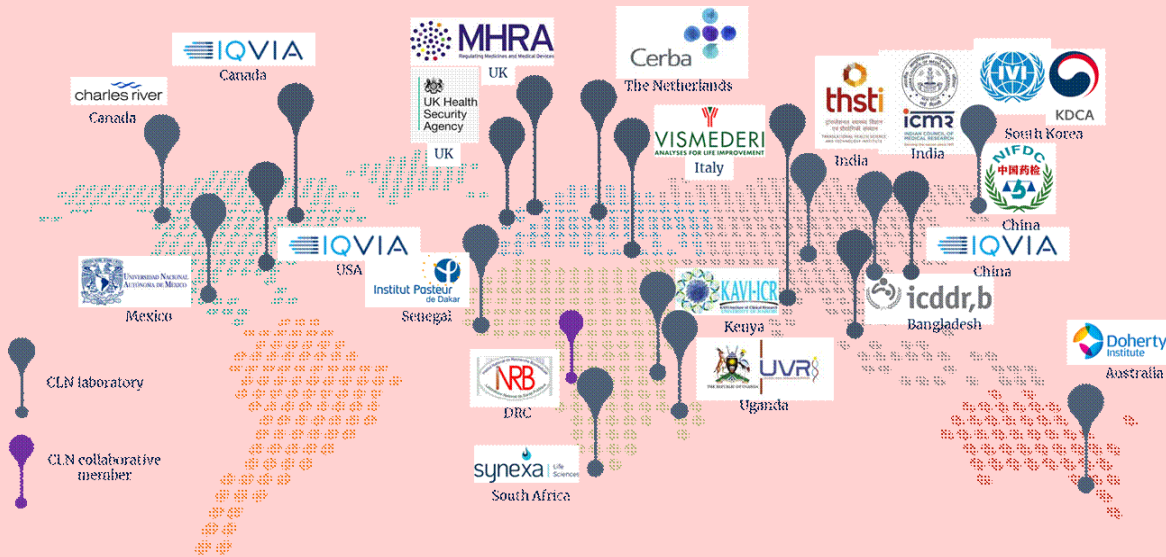
- Indonesia's PT BioFarma and India's SII have been a CEPI VMFN member since 2023 (~\$18M investment supporting mRNA and Viral Vector vaccine manufacturing capacity-capability building)
- Part of a broader network of 5 facilities in Brazil, Senegal and South Africa



Centralized Laboratory Network

Overview and achievements

- 5 Labs in Asia Pacific are part of CEPI's Centralized Lab Network
- 20 laboratories worldwide
- 6 assays available for SARS-CoV-2
- 60 developers supported for SARS-CoV-2

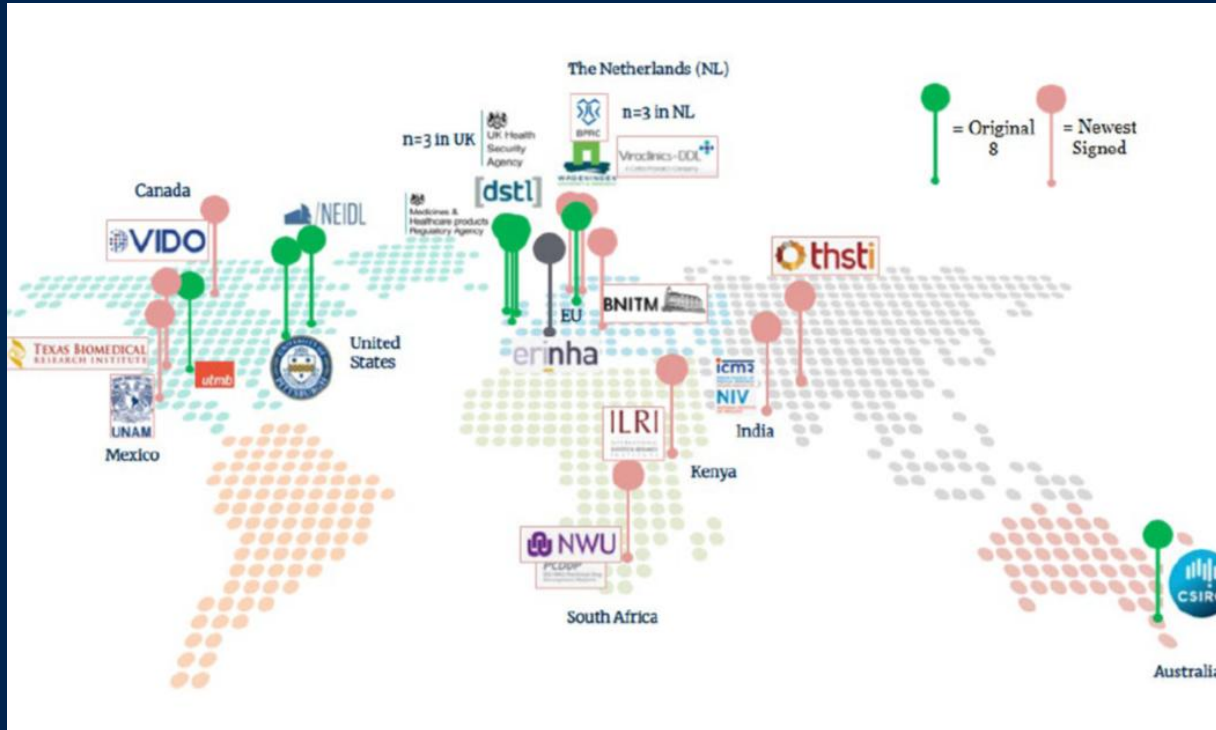


Ongoing activities

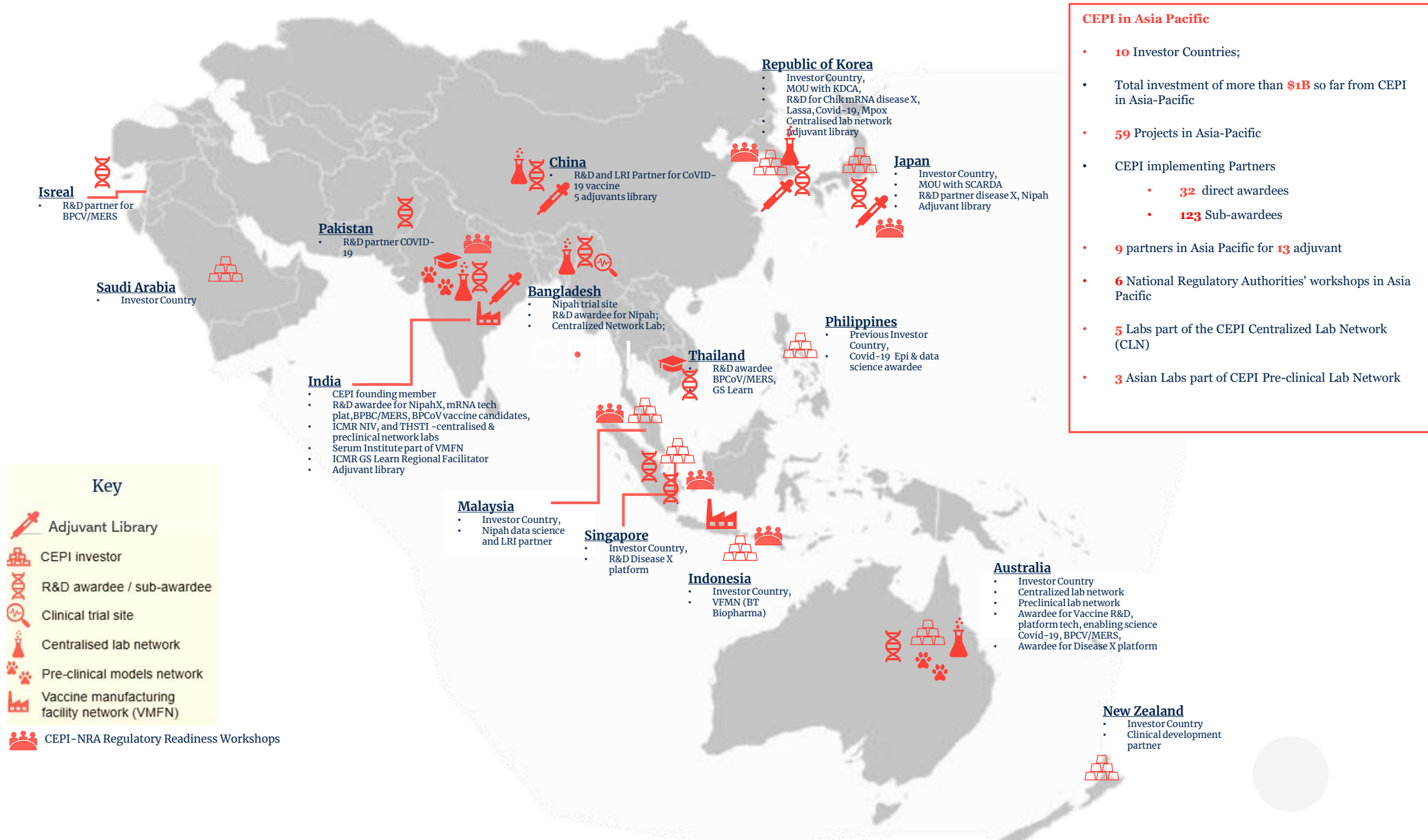
- Tackle new viruses and support testing for the Disease X program (virus libraries) and 100 days mission (Lassa, MERS, SARS-CoV-1, Nipah, Ebola Sudan, Marburg, Mpox, Pandemic flu)
- Capacity building and partnerships strengthening
- Implement and bring innovations to increase throughput and set up new assays
- Alignment with similar global initiatives
- Considering launching a Call for Proposals to add new laboratories in early 2026

CEPI Preclinical Models Network

- 3 Labs in Asia- Pacific are part of the CEPI pre-clinical model network
- CEPI network of biocontainment labs for performance of model development studies and vaccine testing
 - BSL-3 and -4 partners to handle CEPI priority pathogens: MERS-CoV, LASV, RVFV, NiV, CHIKV, SARS-CoV-2/other coronaviruses and Disease X approaches
 - Small and large species, including NHP
- Compliance with high animal ethics standards
<https://www.nc3rs.org.uk/>
- High-quality research supported by established quality systems or well-documented through protocol-specified methods



CEPI's footprint in Asia Pacific



CEPI's Focus to strengthen the end-to-end vaccine ecosystem - developing strategies, tools, networks and dashboards



Monitor

- Modelling Spread and Severity

Discover

- Immunogen Design

Pre-clinical

- Biospecimen sourcing
- Passive Transfer Studies
- Pre-Clinical Model Network

Clinical

- Clinical Assay Development
- Cross Border Response Strategy
- Patient Access Strategy during Vaccine Development
- Partnerships with CROs, researchers and other enablers
- Procedural framework to accelerate authorization processes & logistics
- Standardization, Quality management and Surge Capacity
- Unified approach by funders, industry and public health agency
- BMGF Design Analyze Communication (DAC) Assessment Tool
- Benefit Risk Assessments
- Correlate of Protection Playbook
- Clinical Laboratory Network
- Research Preparedness Network

Regulatory & Quality

- Access & Licensure Strategies
- Collaboration Frameworks
- System Strengthening
- Accumulus
- AI Dossier Preparation
- AI Dossier Review
- Developer Specific Vaccine Information (DSVI)
- FR Path
- Pathogen Disease Development File (PDDF)
- Regulatory & Quality Outbreak Response Plan
- Regulatory Readiness Dashboard
- VACCINE Regulatory Readiness Dashboard

Safety & Surveillance

- RWE Safety and Effectiveness Review Capabilities

Manufacturing

- CMC Rapid Response Framework
- Investigational Reserves
- Manufacturing Innovations
- Technology Transfer & Scale-up
- Vaccine Manufacturing Facility Network
- Platform Readiness Dashboard
- Quality Readiness Dashboard

Strategies
Tools
Networks
Dashboards

Partial list of the capabilities created.

The Regulatory Innovations Consortium was formed in 2023 to enhance and expand global collaboration on our work

Mission Support **acceleration of the regulatory processes for pandemic preparedness** allowing for the deployment of pandemic vaccines in high-risk populations as soon as the totality of available evidence (including prior knowledge, manufacturing platform and pathogen data) support an ongoing benefit/risk assessment.

Vision CEPI, developers and regulators work proactively to consolidate available data, information and expectations in a regulatory **pandemic preparedness playbook** to facilitate regulatory documentation preparation, submission, review and authorization for vaccine use, targeting the potential for **simultaneous access to high-risk populations in whichever countries they reside**. High priority regulatory challenges for pandemic preparedness are identified and there is **collaboration on solutions**.



CEPI

4 priority areas were identified to support the 100 Days Mission

1

Data and information from platform technologies are leveraged

Regulators, developers, academic institutions and funders are engaged

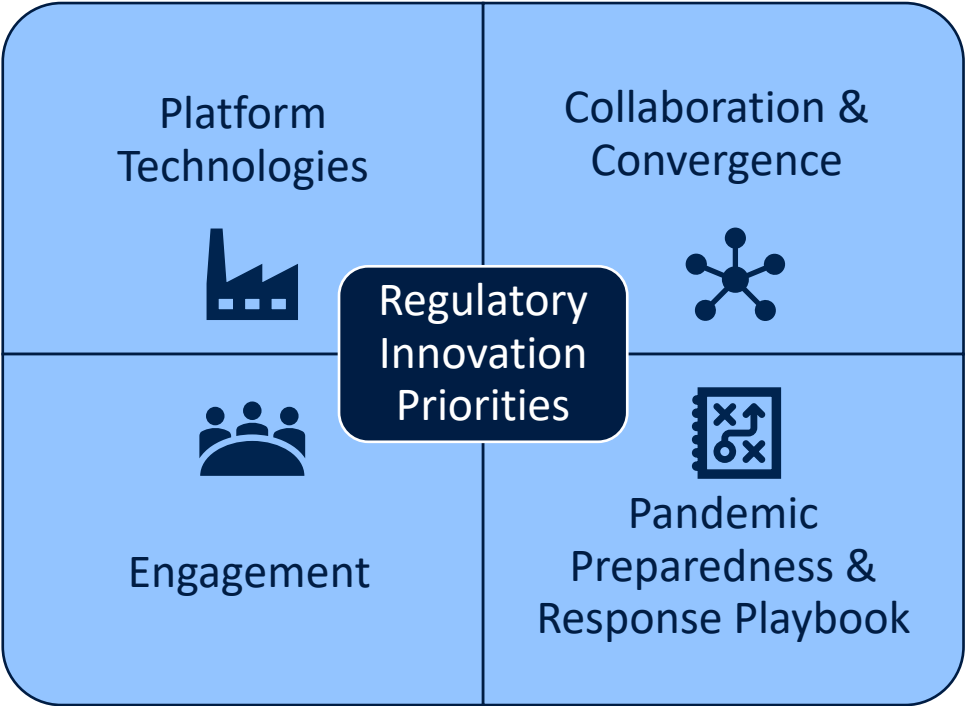
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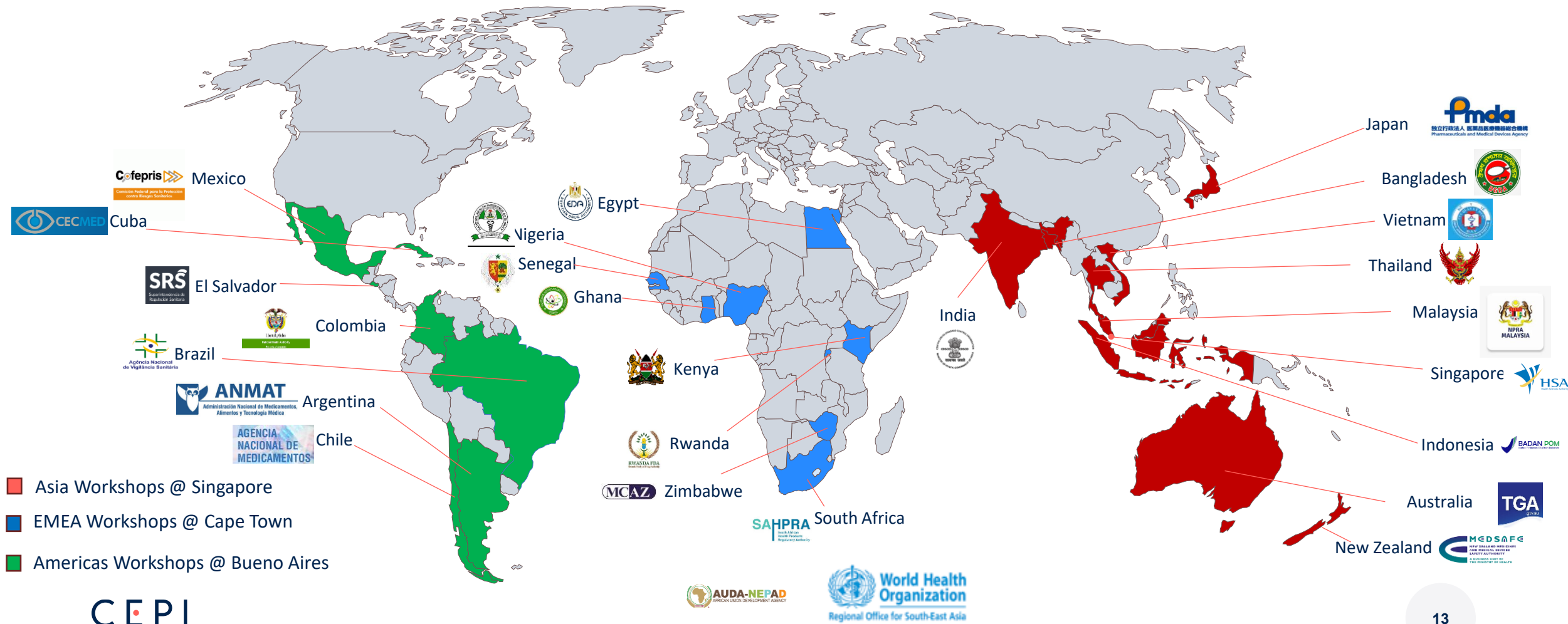
Requirements converge and information sharing is improved

Regulatory innovations are consolidated and documented

3



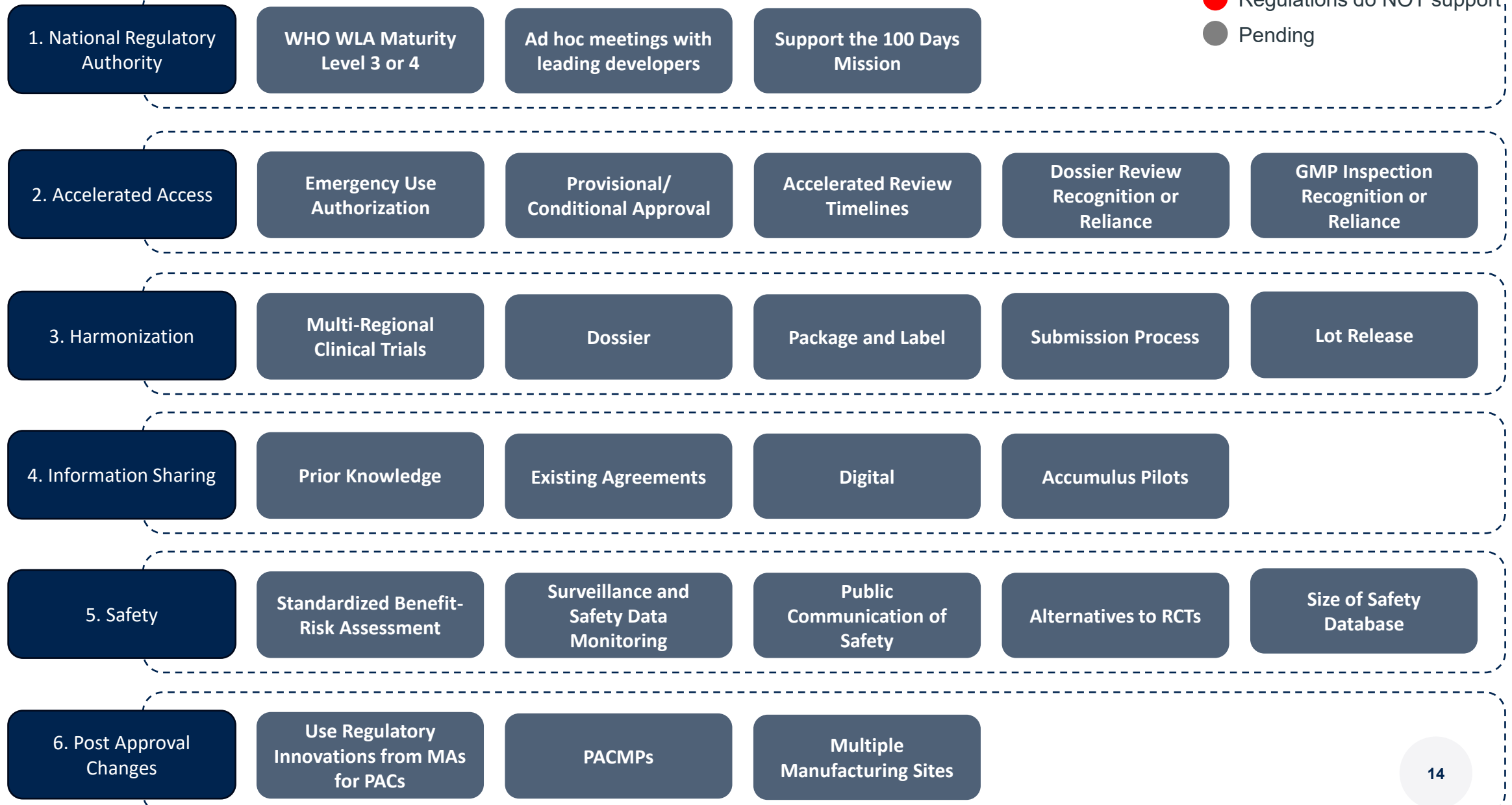
Regional Innovation Workshops were held in 2025 to foster engagement Singapore, Cape Town, Bueno Aires!



CEPI

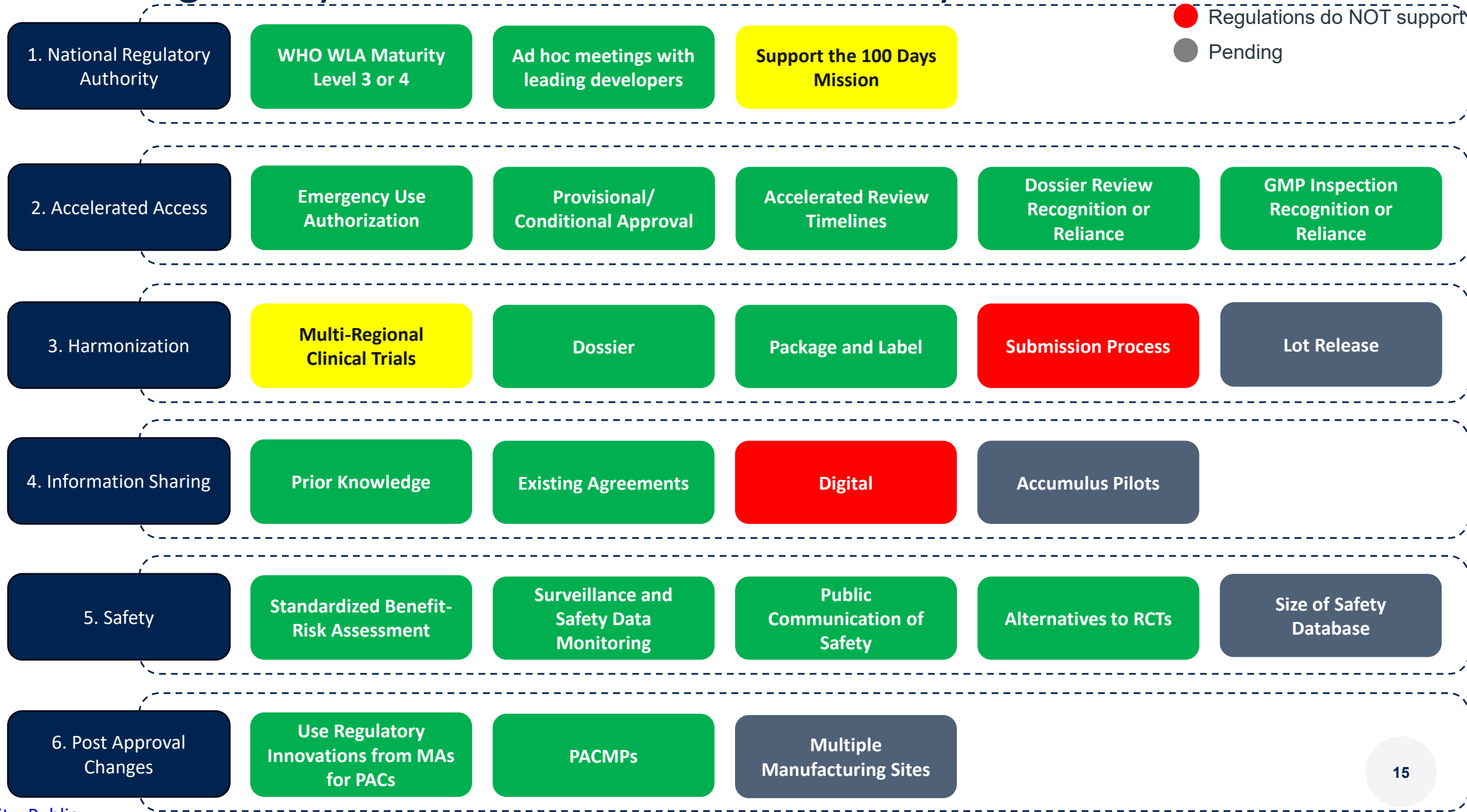
CEPI's Regulatory Readiness Dashboard

- Regulations support
- Regulations may support
- Regulations do NOT support
- Pending



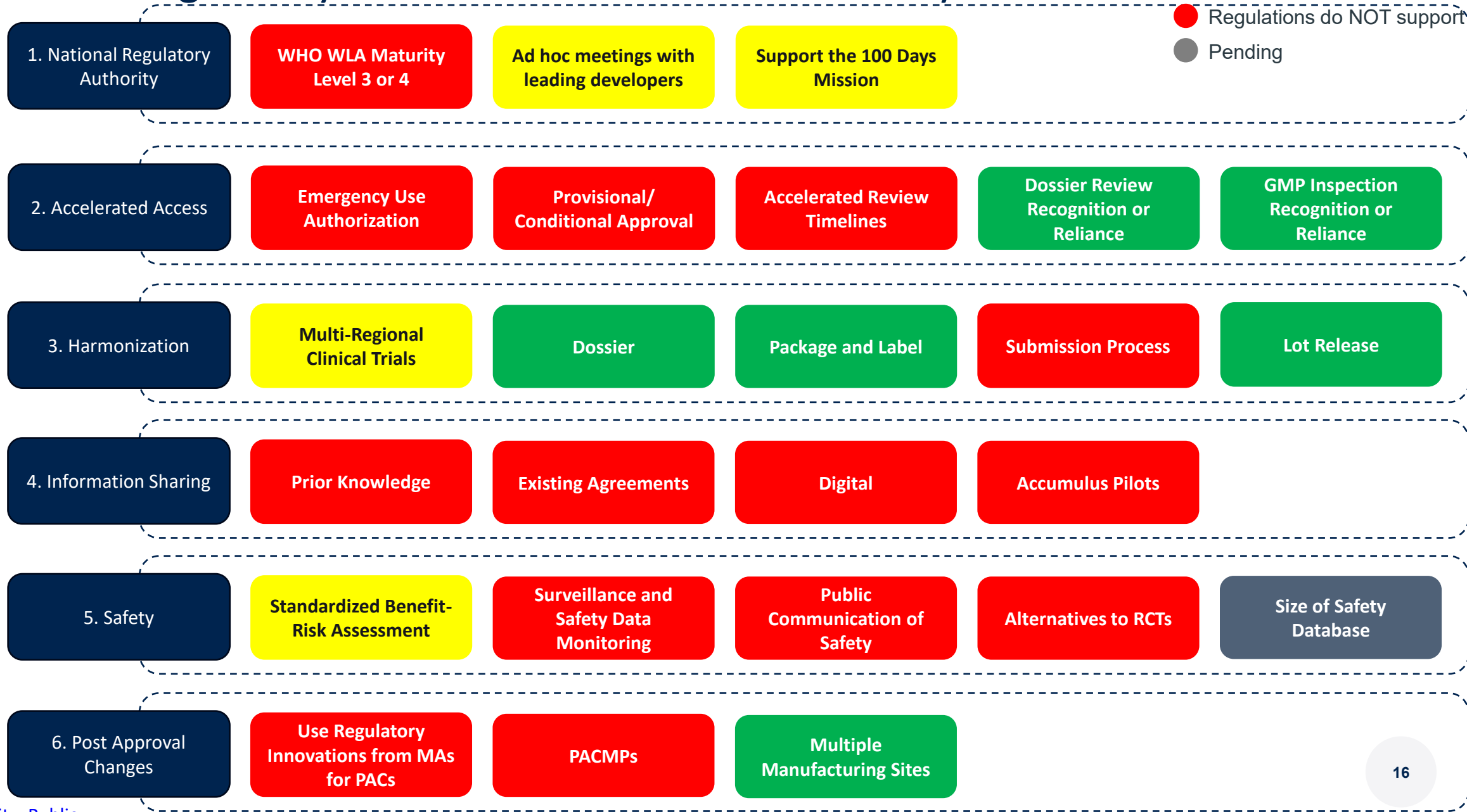
CEPI's Regulatory Readiness Dashboard – Country 1

- Regulations support
- Regulations may support
- Regulations do NOT support
- Pending



CEPI's Regulatory Readiness Dashboard – Country 2

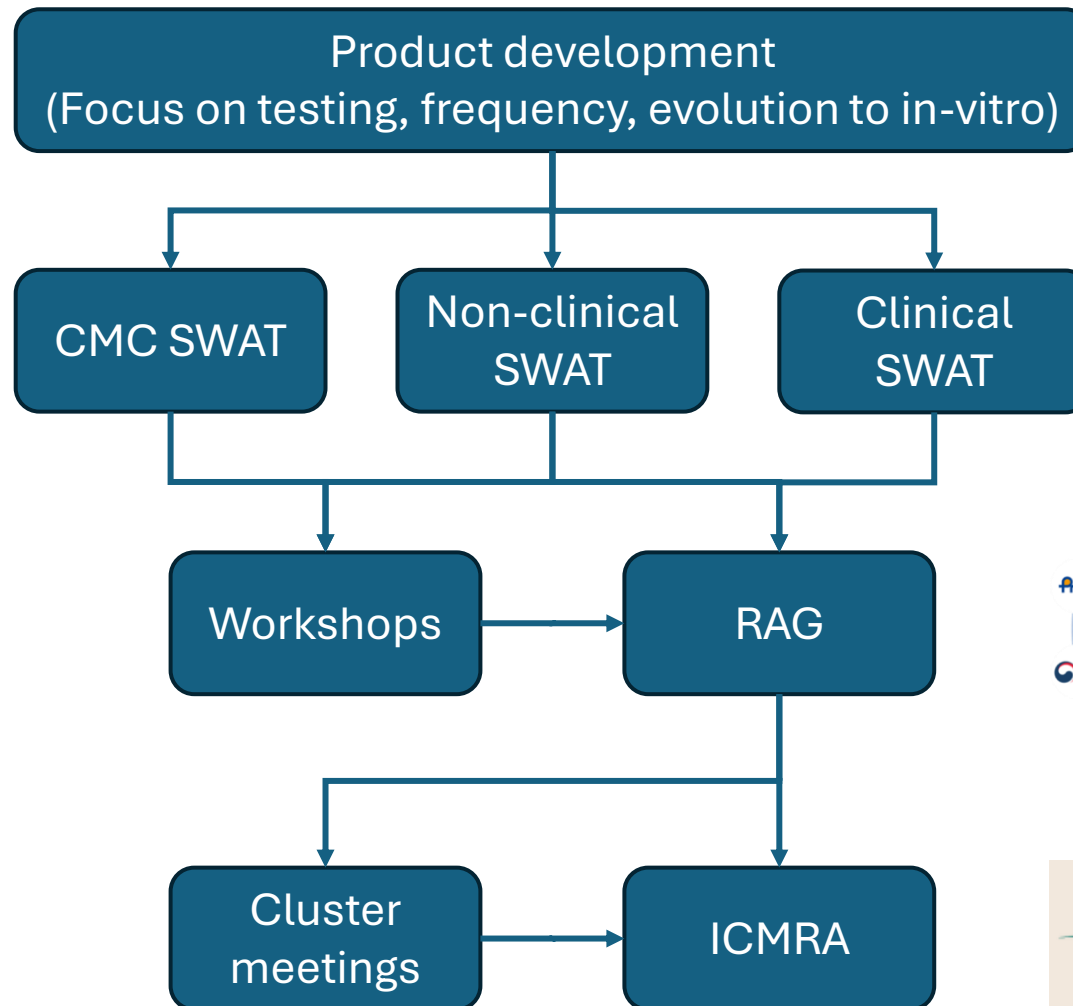
- Regulations support
- Regulations may support
- Regulations do NOT support
- Pending



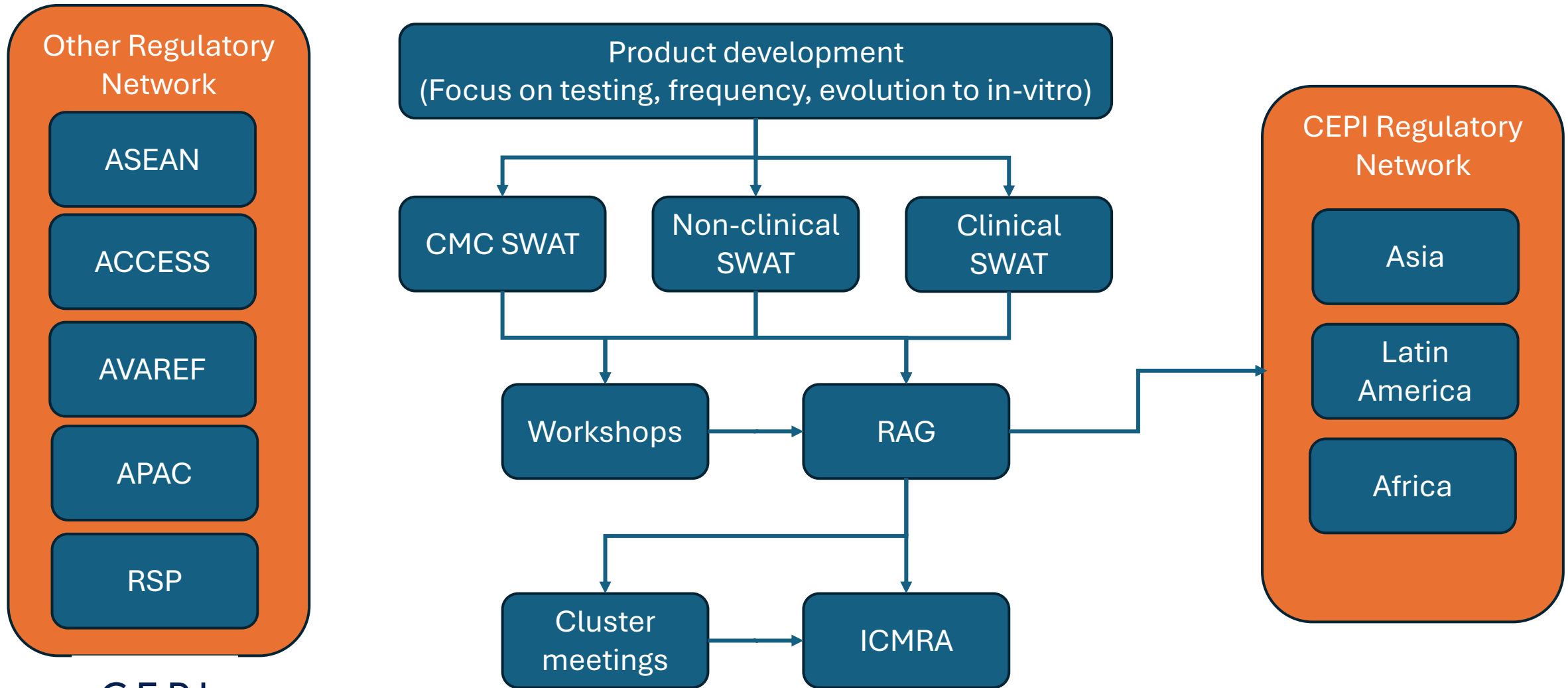


Integrating Regulatory Collaboration Forums

Integrating regulatory collaboration forums



Integrating regulatory collaboration forums



Global engagements improving regulatory readiness to support the 100DM



Customizing the Approach – APAC Region



INDIA

- 28th-29th JAN 25 (2 half days)
- Divisions of MAA, CTA, QA, BA/BE, Vx
- 40+ officials (CDSCO)
- 1st RIM SG meeting proceedings sharing
- Bi-Lats NITI AAYOG; ICMR; DBT; Value in ecosystem engagement
- ML3 (Vx Producing)
- Discussion with Excel and RIM slides – INSIGHTS for DASHBOARD, PREPn.
- Supportive use-cases from COVID

INDONESIA

- 10th MAR 25 (Full day)
- Divisions of MAA, CTA, QA, BA/BE, Vx
- 45+ officials (BPOM)
- BPOM CEO reports into President – UNLIKE NRAs
- ML3 (Vx Producing), Transitional WLA (In-process)
- Structured Readiness Dashboard – Ramadhan day

JAPAN

- 12th MAR 25 (half day)
- Divisions of MAA, CTA, QA, BA/BE, Vx
- 25+ officials (PMDA)
- SCARDA members
- Transitional WLA
- Structured Readiness Dashboard - SCARDA
- Translation strengthens coalesces
- Pre-work immensely supports trust and alignment

KOREA

- 13th MAR 25 (Full day)
- Divisions of MAA, CTA, QA, BA/BE, Vx
- 45+ officials (MFDS + KDCA)
- MFDS Head, DG Health, KDCA commissioner
- ML4; WLA; Vx Producing
- Structured Readiness Dashboard
- Translation strengthens coalesces
- Pre-work immensely supports trust and alignment

SINGAPORE

- 28th-29th APR 25 (2 half days)
- Divisions of MAA, CTA, QA, BA/BE, Vx
- 40+ officials (HSA + CDA)
- HAS CEO, DG Health, CIDER, COP, CORE
- ML4; WLA; Vx non-Producing
- CEPI-filled regulatory readiness dashboard – pre-work
- Structured approach with Starting point : HSA filled dashboard

MALAYSIA

- 30th APR 25 (Full day)
- Divisions of MAA, CTA, QA, BA/BE, Vx
- 35+ officials (NPRA)
- NPRA Head, DG Health
- ML2; Vx Non-Producing
- CEPI-filled regulatory readiness dashboard – pre-work
- Structured approach with Starting point : HSA filled dashboard

AUSTRALIA

- 13th JUN 25 (half day)
- Medical Division Office and regional regulatory ambassador
- 2 officers (TGA)
- CEPI-filled regulatory readiness dashboard – pre-work
- TGA Head, Chief Medical Officer, Regulatory strengthening Lead (4th NOV 25)
- ML3; Vx Producing

THAILAND

- 20th AUG 25 (half day)
- Biologicals division Head
- One-on-one meeting
- CEPI-filled regulatory readiness dashboard – pre-work
- Head of Thai-FDA, one-on-one meeting 16th NOV 25
- ML3; Vx Producing

Emergency Preparedness Regulatory Opportunities for Future Collaboration with CEPI – APAC Region

Information Sharing

- Work-sharing, review-sharing (PARs)
- Digital (cloud-based tools e.g.: Accumulus)

Safety Considerations

- Standardized Benefit-Risk Assessments
- Size of Safety Database (WHO guidance - 3000)

Accelerated Access

- Reliance
 - for approvals
 - site inspections

Alignment / Harmonisation

- One label, one dossier, one submission, one review, one release
- ACCESS consortium (UK, AUS, SG, HC, SWISS, EMA) - Stabilizing operationally
- WHO JAIMS / ASEAN

Customizing the Approach – EMEA Region



Continental TTX held in collaboration with the African Union Development Agency and PPB of Kenya

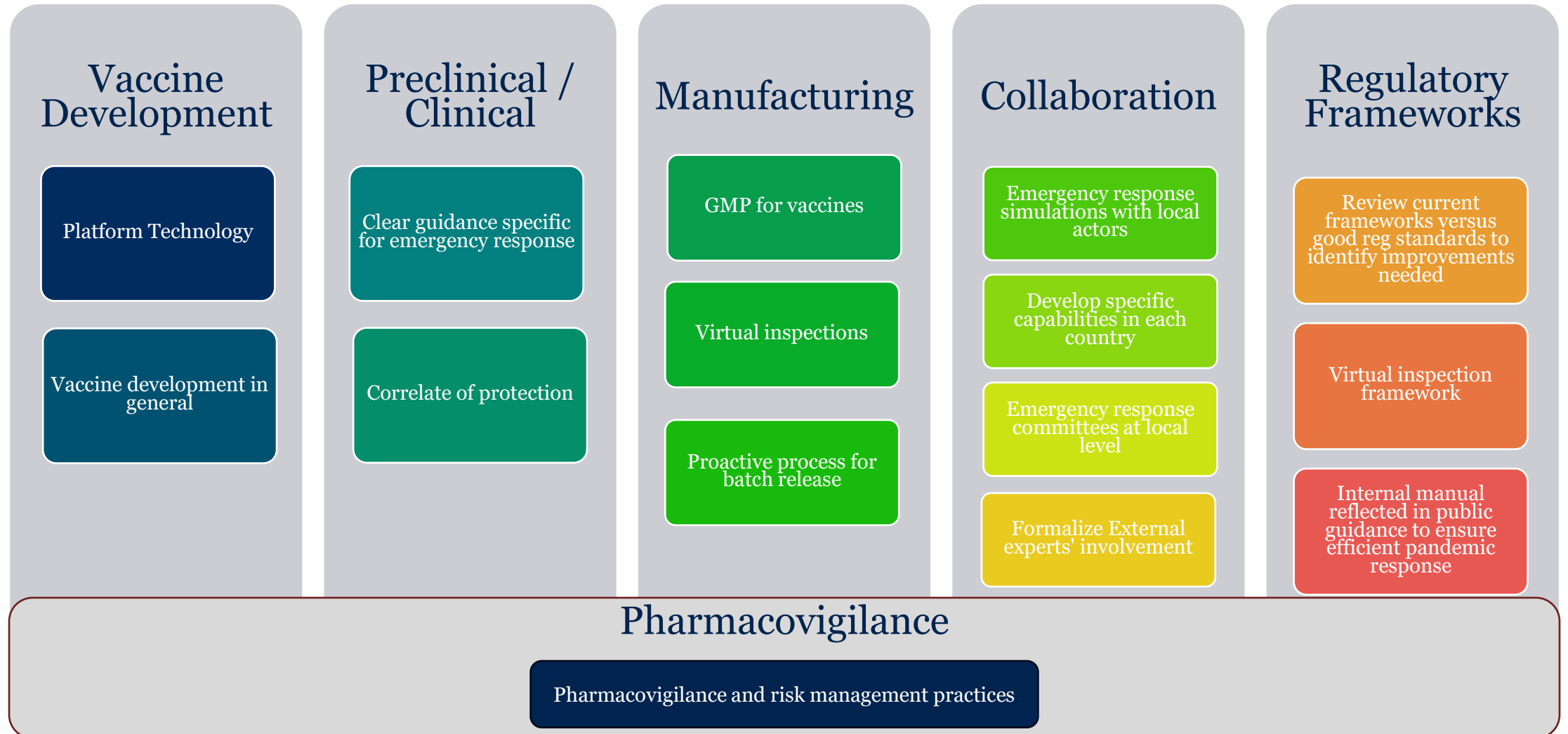
- Nov 2025 as part of AMA Launch
- AMA DG and Snr. Advisor to AMA DG, AMRH Programmed Lead, AVAREF, AUDA-NEPAD reps, SAHPRA, TMDA, Uganda FDA, Kenya PPB, Tunisia, NAFDAC(Nigeria), ACOREP (DRC), Sierra Leone, Senegal, Liberia, EAC, OCEAC, Congo, SADC, North African Rec
- 35+ officials both in the room and online in total

South Africa,
April 2025 with
DG and
divisional leads
20+ officials in
total

Egypt July 2025
with Vice DG and
divisional leads
30+ officials in
total

Rwanda
September 2024
with Head of
partnerships and
divisional leads
20+ officials in
total

Themes of Growth Areas from the TTX – EMEA Region



Emergency Preparedness Regulatory Opportunities for Future Collaboration with CEPI – EMEA Region

Technical Capacities

- Capacity Building (Adaptive clinical trial designs, Pre-approved clinical trial protocols, Regulatory considerations for early clinical development)

Embedding Agility

- Institutionalization of regulatory agilities

Information Sharing

- Use of digital tools

Customizing the Approach – Americas Region



Tri-partite Meeting: El Salvador, Honduras, Guatemala

- 22-25 July
- 45+ Participants covering marketing authorization, inspections, clinical, preclinical, and pharmacovigilance functions
- Simulated sub-regional responses to a global flu outbreak and a regional ChikV-X outbreak
- Reliance and risk-based decision-making were key themes

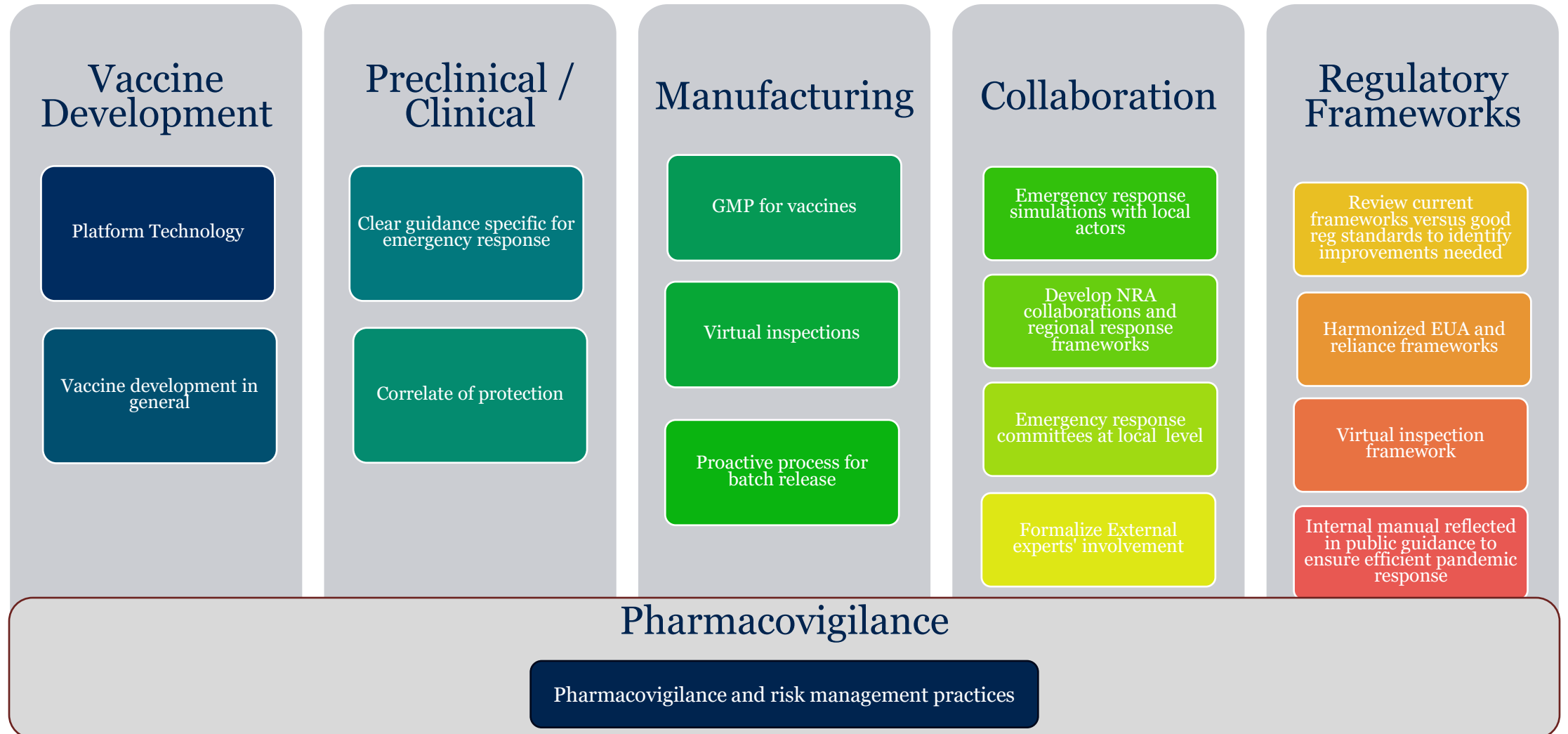
Argentina

- 1 Sep
- 20 Participants covering marketing authorization, inspections, preclinical, and pharmacovigilance functions
- Completed dashboard alignment and simulated the local response to a new global pandemic
- Highlighted the importance to conclude issuance of several emergency response regulations that are in process and identified the need to strengthen their reliance frameworks by issuing new regulations using good regulatory practices

Brazil

- 5-6 Nov
- 30+ Participants including the MOH Emergency Response group and MOH PNI
- Simulations addressed concepts of platform technology adaptation and use of prior platform knowledge for a locally approved vaccine
- Tested established cross-departmental WoW and highlighted the importance of integrated responses

Themes of Growth Areas from the TTX – Americas Region



Emergency Preparedness Regulatory Opportunities for Future Collaboration with CEPI – Americas Region

Subject Matter Expertise and Capacity

- Local, pre-identified subject matter expert (SME) should be available for all areas including clinical, CMC, pre-clinical and PV.

Governance and Structure (Rapid Response Expert Committees)

- Expert committees should be pre-established in advance of epidemic and pandemic events.

Training: People and Skills

- Additional training resources are needed to support further development of internal SMEs, especially for new innovations.

Regulatory Frameworks in PHE

- Collaborative spaces to harmonize approaches to emergency response



Impact

Driving Regulatory Alignment: CEPI's Regulatory Network

◆ For CEPI

Strategic Alignment: Ensures national regulatory pathways are aligned with CEPI's 100-Day Mission for accelerated vaccine development.

Risk Mitigation: Helps identify bottlenecks and systemic regulatory delays early, supporting CEPI's goal of rapid outbreak response.

Partnership Strengthening: Builds trust and coordination with NRAs and regional bodies, enhancing cooperation during emergencies.

Informed Investment: Provides insights into regulatory readiness that guide CEPI's technical assistance and capacity-building efforts.

Global Preparedness Benchmarking: Facilitates cross-country comparisons to prioritize support and technical innovation deployment.

◆ For National Regulatory Authorities

Capacity Building: Identifies gaps in systems, SOPs, and emergency protocols that can be strengthened ahead of a crisis.

Process Optimization: Encourages review and streamlining of regulatory processes for faster emergency approvals.

Policy Awareness: Increases familiarity with international standards and best practices in emergency regulation.

Stakeholder Coordination: Fosters intra-NRA divisional dialogue and multisectoral dialogue between regulators, policymakers, and emergency response teams.

Enhanced Credibility: Demonstrates readiness to international partners, increasing trust in local regulatory decisions during emergencies.

Keys to success in support of the 100 DM

- **Solidarity and empowerment** of experts in each region
- Commitment to **information sharing and transparency**
- **Collaboration for funding** from
 - Regional private and public vaccine development institutions
 - Regional academic institutions
 - Regional funders (Africa CDC, RVMC)
 - Global funders (EDCTP, HERA, Gates, CEPI)

CEPI

Driving Regulatory Alignment: CEPI's Regulatory Network

◆ For CEPI

Strategic Alignment

Risk Mitigation

Partnership Strengthening

Informed Investment

Global Preparedness Benchmarking

◆ For National Regulatory Authorities

Capacity Building

Process Optimization

Policy Awareness

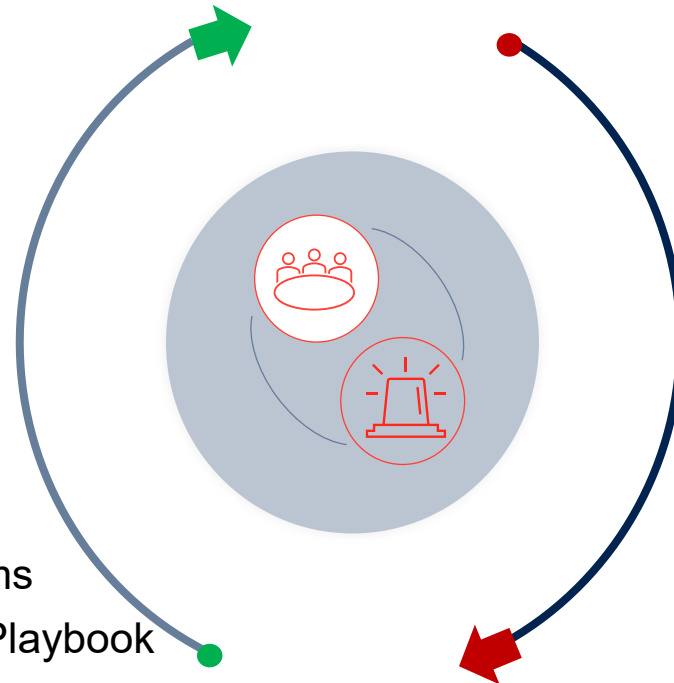
Stakeholder Coordination

Enhanced Credibility

Gathering deep insights and engaging with stakeholders

Preparedness Phase

Regulatory Readiness Dashboard
Regulatory Tabletop Exercises
Platform Readiness Dashboard
Regulatory Innovations Workshops
Regional Regulatory Preparedness Forums
Pandemic Preparedness and Response Playbook
Disease Programme Regulatory Workshops



Emergency Phase

Outbreak response priorities and strategies (e.g. COVID, Mpox in DRC, Marburg in Rwanda, Chikungunya in Réunion)