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CEPI

Overview of the Nipah Strategy within the LRI Department at CEPI

Selorm Avumegah, Trevor Brasel, Ali Azizi

Department of Laboratory Research & Innovations (LRI), CEPI

May 2026

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Disclosure

- The presenters do not have anything to disclose.

Outline of Presentation

- CEPI: Introduction and Overview
- Nipah Virus
- Outcomes from Nipah Virus Expert Consultation
- CEPI Preclinical Model Network (PMN)
- Overview of the CEPI-Centralized Laboratory Network (CLN)

#100DaysMission

Learning Objectives

- By the end of this event, participants will be able to:
  - Describe the Coalition for Epidemic Preparedness Innovations (CEPI) Preclinical Model and Centralized Laboratory Networks (PMN and CLN), including capabilities and capacity.
  - Describe the “gold standards” of Nipah virus animal models and standardized assays for assessment of Nipah immunogenicity.
  - Discuss challenges associated with the assay transfer to other laboratories and quality systems implementation in the Biosafety Level 4 (BSL-4) environment.

The Coalition for Epidemic Preparedness Innovations (CEPI)

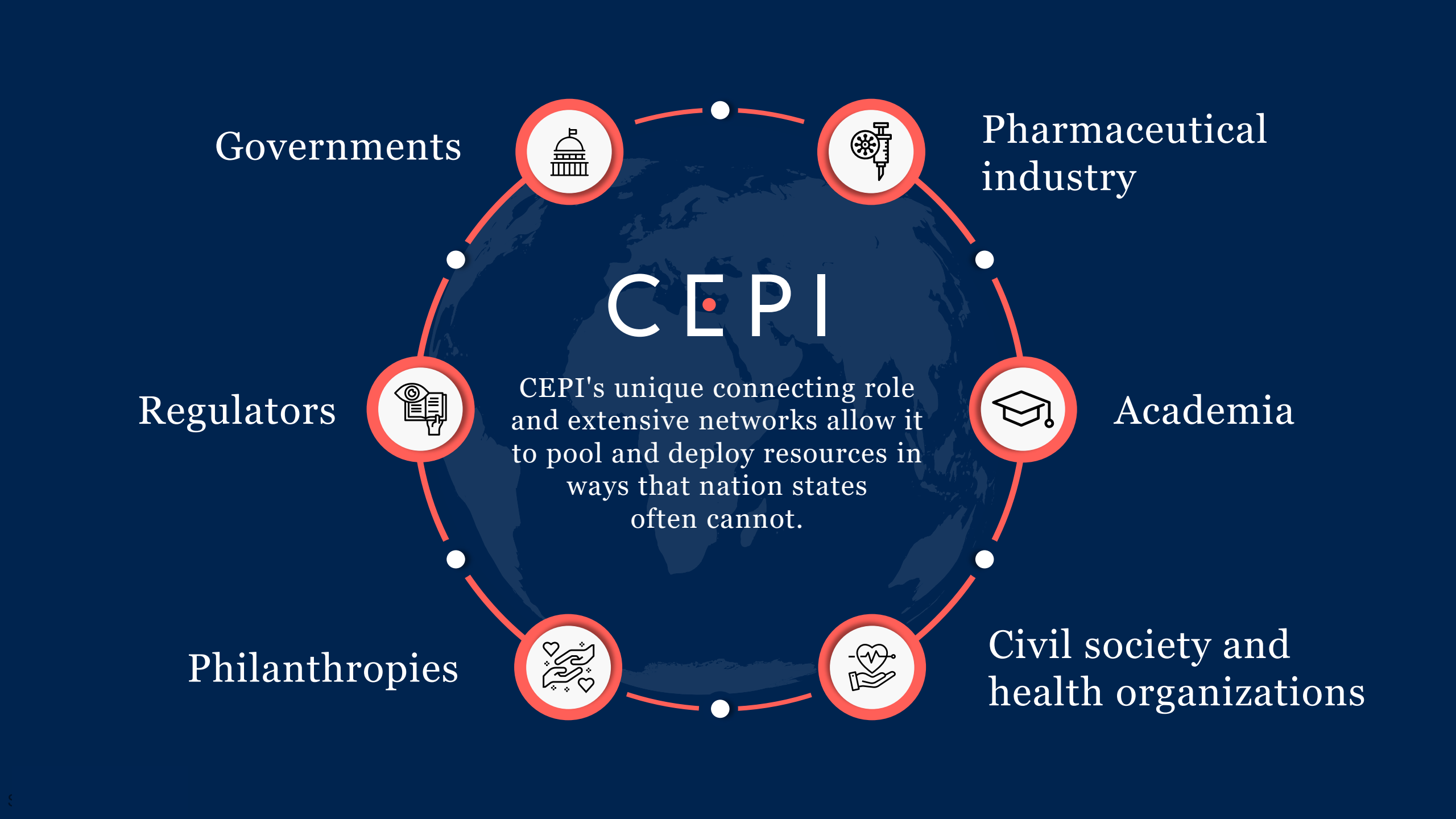
A Global Partnership

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.


Governments
Pharmaceutical industry
CEPI
CEPI's unique connecting role and extensive networks allow it to pool and deploy resources in ways that nation states often cannot.
Regulators
Academia
Philanthropies
Civil society and health organizations

R&D Priorities for Nipah Virus Outbreak Preparedness

Outcome from Expert Consultation, Malaysia

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Project Lead / Scientist
Department of Laboratory Research & Innovations
Coalition for Epidemic Preparedness Innovations (CEPI)

PHO Microbiology Rounds
07 May 2026

Avumegah S et al, Research and development priorities for Nipah Virus outbreak preparedness, *Nature Health*, 2026.

WHY WAS THIS WORKSHOP IMPORTANT?

Global Health Threat

Nipah virus poses a serious global health threat due to high fatality and zoonotic transmission risks.

Learning from Past Outbreaks

Lessons from outbreaks in Malaysia, Bangladesh, and India inform current preparedness strategies.

Priority Research Areas

Research priorities include vaccines, diagnostics, surveillance, and basic virus research for outbreak response.

Coordinated Global Response

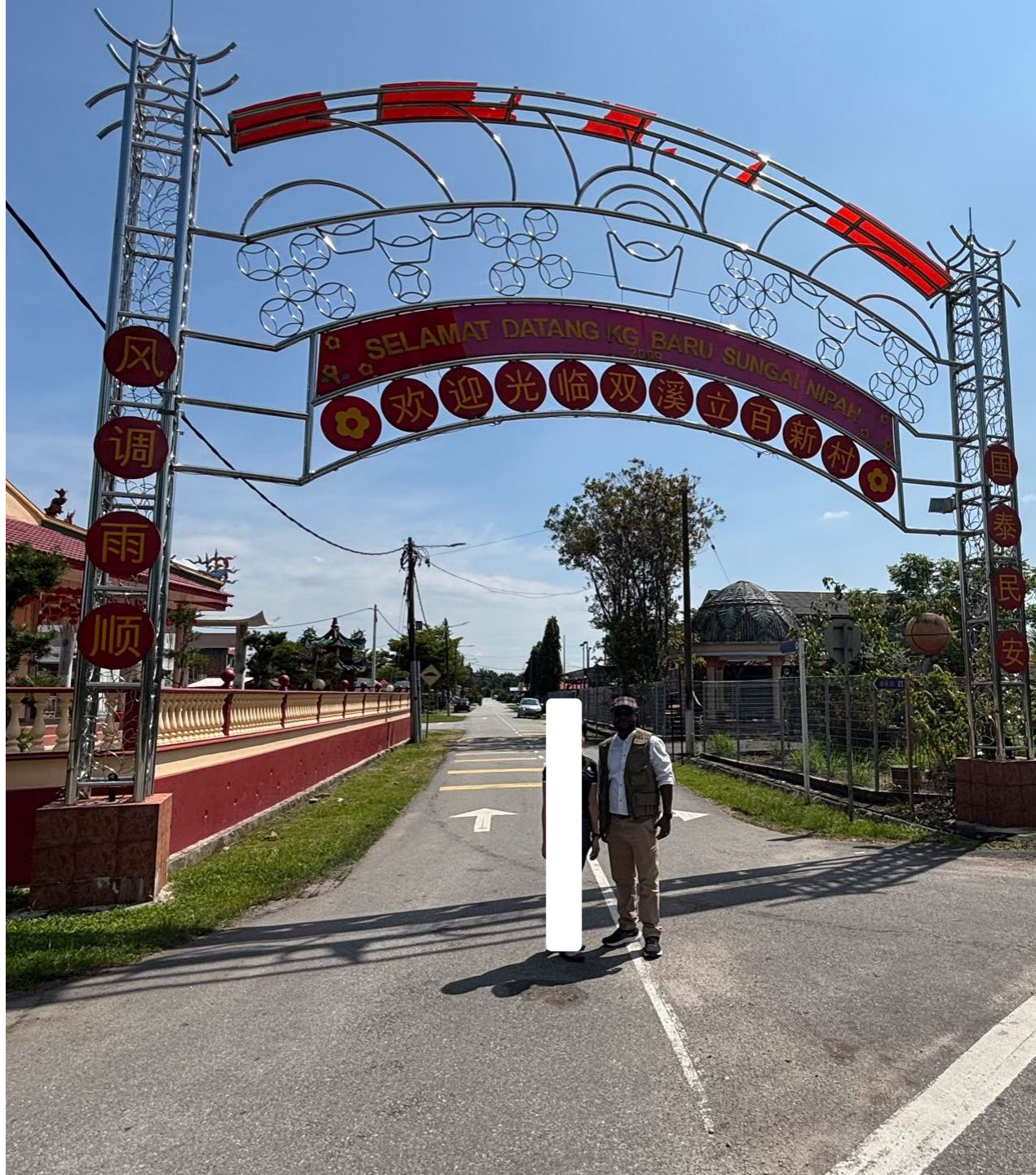
Effective outbreak preparedness requires coordinated global investments and rapid detection systems.

What is Nipah Virus (NiV)?

Virology: NiV is zoonotic pathogen and belongs to the genus Henipavirus along with the Hendra virus, which has also caused disease outbreaks

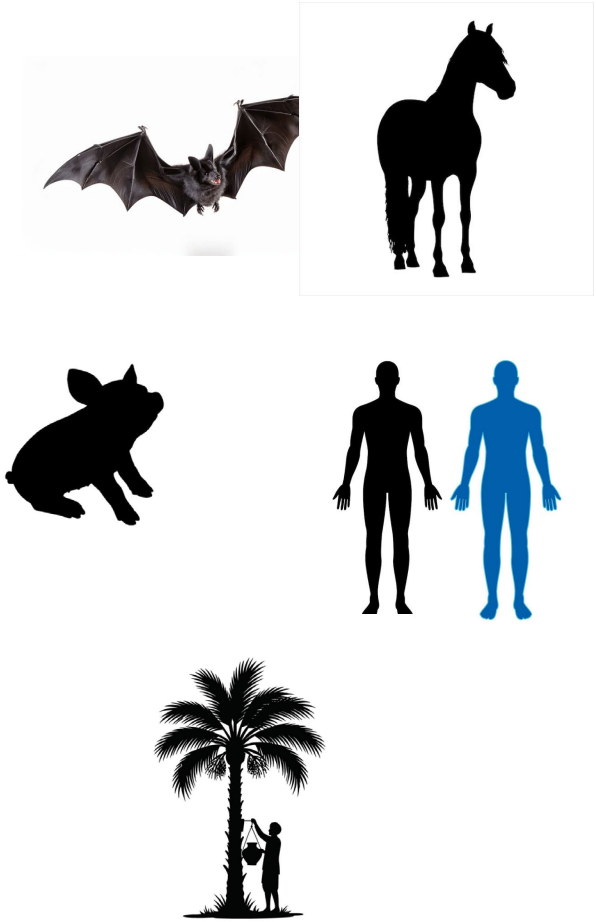
Emergence: First detected during a 1998–99 encephalitis outbreak in Malaysia.

Reservoir: Fruit bats (Pteropus genus) serve as natural hosts, carrying the virus with little illness.



Global Occurrences of Nipah Virus Outbreaks

Country	Key Year(s)	Reported Cases	Reported Deaths	Main Reservoir & Intermediate Hosts
Malaysia	1998–1999	~283	105–109	Pteropus bats (Reservoir); Pigs (Intermediate)
Singapore	1999	11	1	Imported infected pigs from Malaysia
Bangladesh	2001–2026*	~347	~241	Pteropus bats (Reservoir); raw date palm sap
India	2001–2026**	~102	~74	Pteropus bats (Reservoir); person-to-person spread
Philippines	2014	17	9	Horses (Intermediate host involved in 2014)



**Outbreaks occur almost annually in Bangladesh during the date palm sap harvesting season.*
***Recent Indian outbreaks have been concentrated in Kerala (since 2018) and West Bengal (2001, 2007, and January 2026*

KEY LESSONS FROM PAST OUTBREAKS

Understanding Zoonotic Spillover

Transmission dynamics between wildlife, domestic animals, and humans remain partially unclear, posing challenges for outbreak prevention.

Early Detection Importance

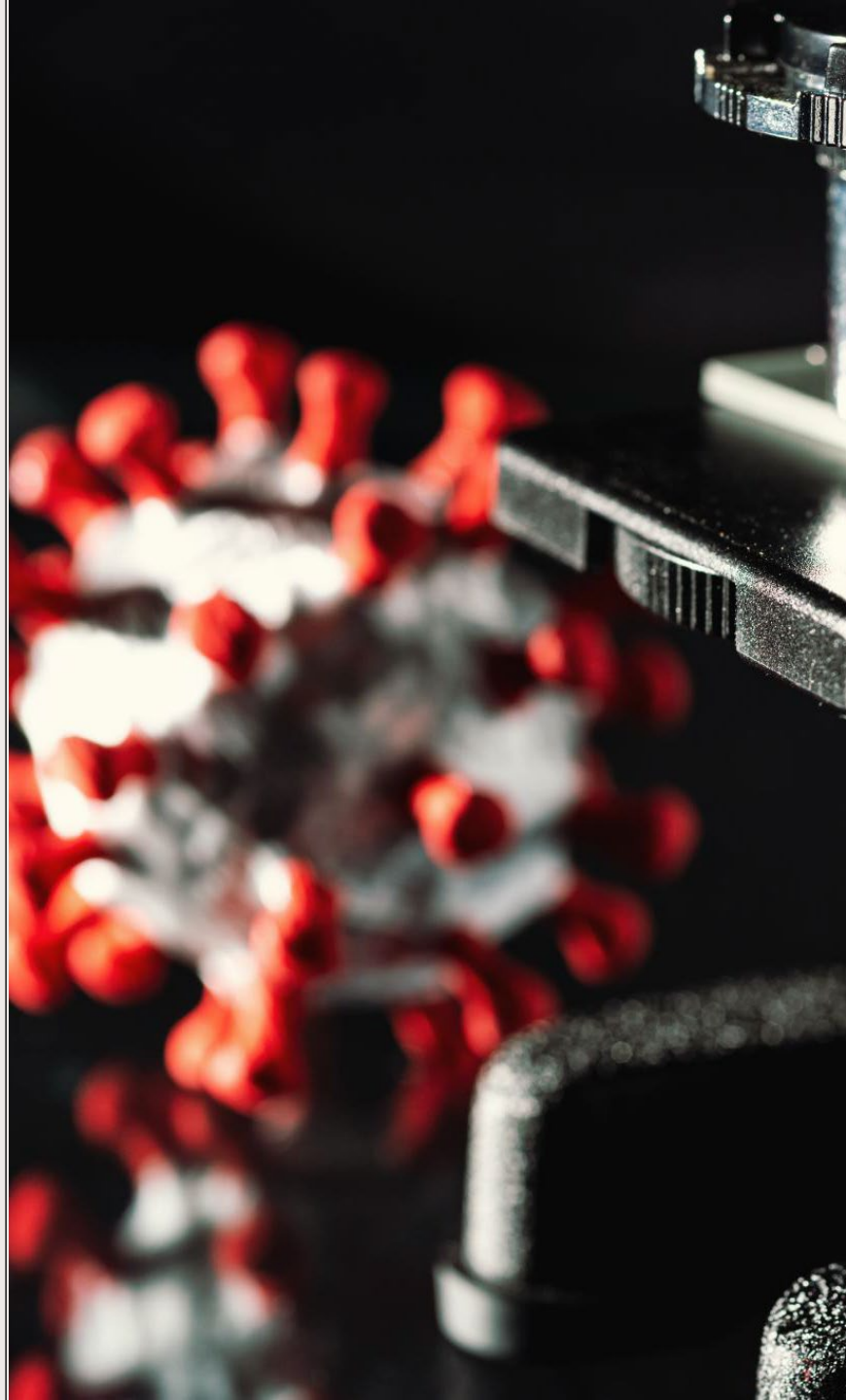
Rapid laboratory confirmation and early detection are critical for containing virus outbreaks effectively and minimizing spread.

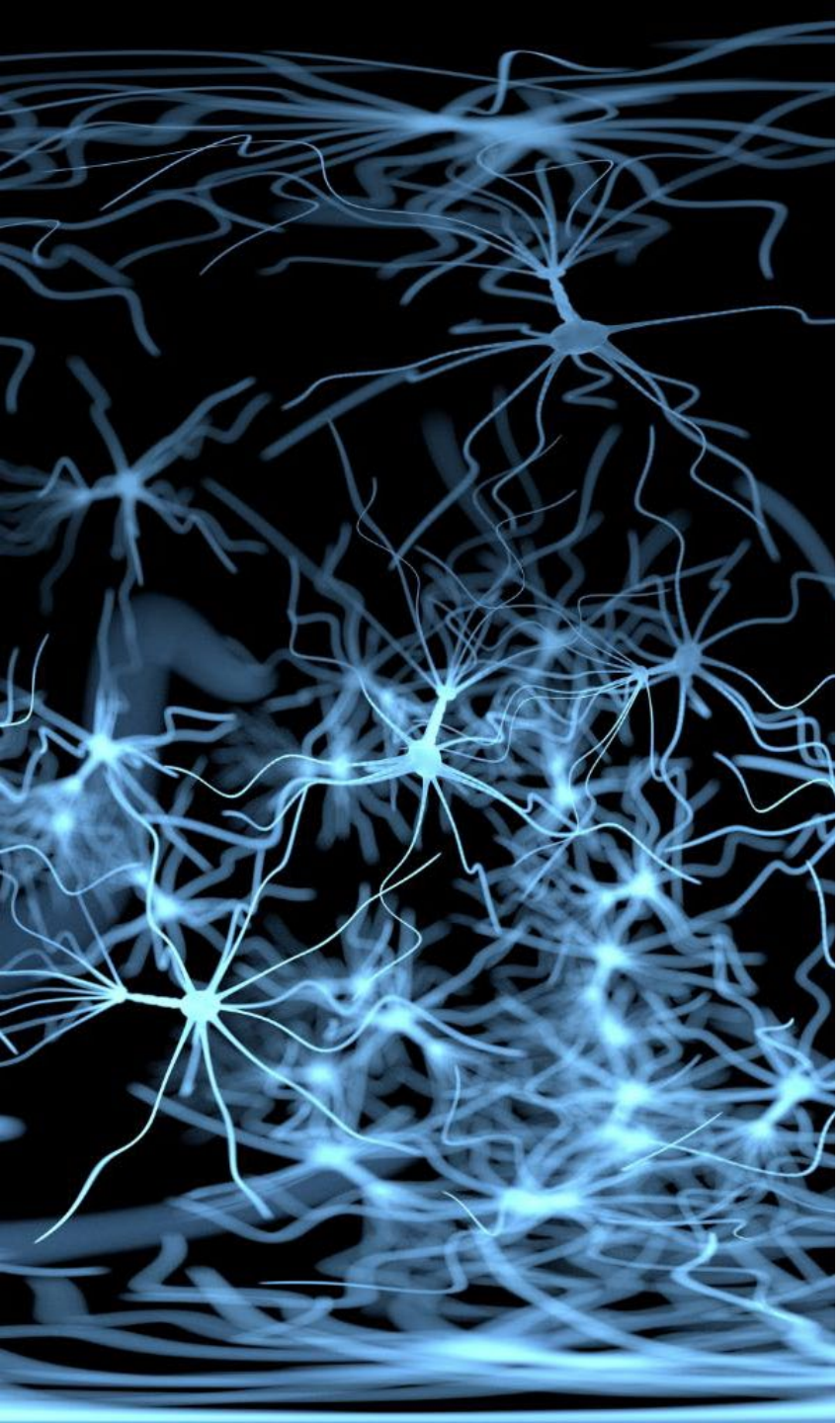
Preparedness Capacity Variability

Countries differ in outbreak preparedness influenced by surveillance systems, diagnostic access, and health system strength.

Strengthening Response Foundations

Enhancing surveillance, diagnostics, and health resilience is essential to reduce outbreak impact and improve public health response.





NEUROLOGICAL DISEASE IN NIPAH VIRUS INFECTION

Neurological Impact of Nipah Virus

Nipah virus severely affects the central nervous system causing encephalitis and chronic neurological issues.

Persistence in Central Nervous System

The virus can invade and persist in the CNS, contributing to long-term neurological morbidity in survivors.

Underexplored Neurological Pathways

Neurological disease pathways in Nipah virus infection are less studied than respiratory effects, needing more research.

Need for Comprehensive Countermeasures

Developing treatments targeting both immediate and long-term neurological effects is essential for better outcomes.

VACCINE DEVELOPMENT

Vaccine Candidates in Development

Two Nipah virus vaccine candidates are progressing through CEPI-supported pipelines using vectored platforms.

Preclinical and Clinical Progress

Preclinical studies show promising safety and efficacy; early-phase clinical trials are ongoing for some vaccines.

Importance of Investment

Sustained investment is crucial for developing outbreak-ready vaccines capable of rapid deployment during emergencies.

REFERENCE STANDARDS AND ASSAYS

International Standard Importance

WHO's International Standard for anti-Nipah virus antibodies enhances assay harmonization worldwide.

Assay Comparability

Standardized materials enable data comparability across labs and support vaccine immunogenicity assessments.

Regulatory Confidence

Reference standards build regulatory confidence by ensuring consistency in preclinical and clinical data.

Research Ecosystem Support

Standards accelerate correlates of protection research and support Nipah virus study ecosystems.

DIAGNOSTICS AS A CRITICAL PREPAREDNESS GAP

Weakness in Diagnostic Validation

Few nucleic acid and serological assays for Nipah virus have independent validation or regulatory approval.

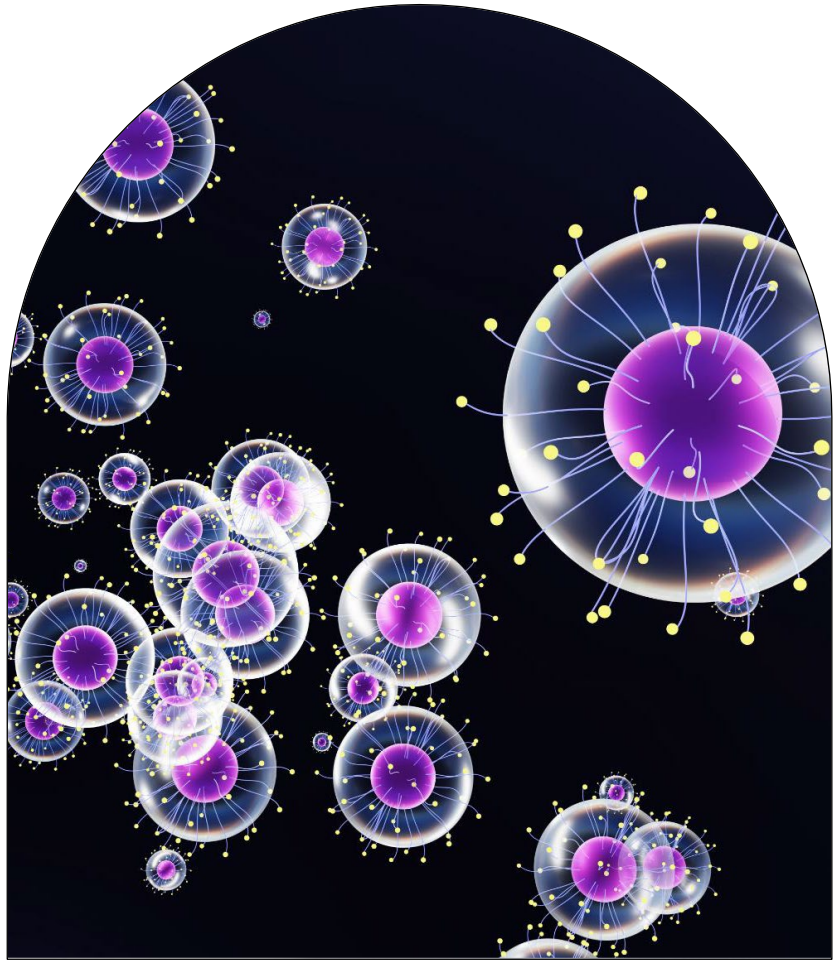
Challenges in Scaling Tests

Endemic regions rely on in-house tests that are difficult to scale during outbreaks or decentralised deployment.

Need for Rapid Point-of-Care Tests

Urgent demand exists for rapid, affordable diagnostics for district hospitals and community use for early outbreak detection.

CORRELATES OF PROTECTION FOR NIPAH VIRUS



Neutralizing Antibodies Role

Neutralizing antibodies are key indicators considered in protecting against Nipah virus infection.

Cellular Immune Responses

Cellular immunity and Fc-mediated antibody functions also significantly contribute to protection mechanisms.

Research Challenges

Limited human data and need for harmonised assays hinder definitive understanding of immune protection.

Integrated Studies Importance

Animal and human studies integration is vital to elucidate immune mechanisms and support vaccine development.

KEY RESEARCH GAPS AND OPPORTUNITIES

Asymptomatic Infection Understanding

Limited knowledge of asymptomatic Nipah infections hampers understanding of transmission dynamics.

Surveillance in Endemic Regions

Insufficient longitudinal monitoring in endemic areas limits early outbreak detection and response.

Viral Diversity in Bats

Incomplete characterization of Nipah virus variants in bat reservoirs restricts risk assessment.

Integrated Preparedness Strategies

Combining diagnostics, vaccines, animal models, and epidemiology is vital for outbreak prevention.

CEPI

Supporting Nipah Vaccine Development through CEPI's Preclinical Model Network

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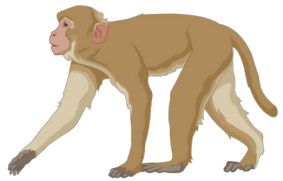
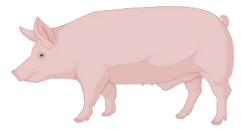
The CEPI Preclinical Model Network (PMN)

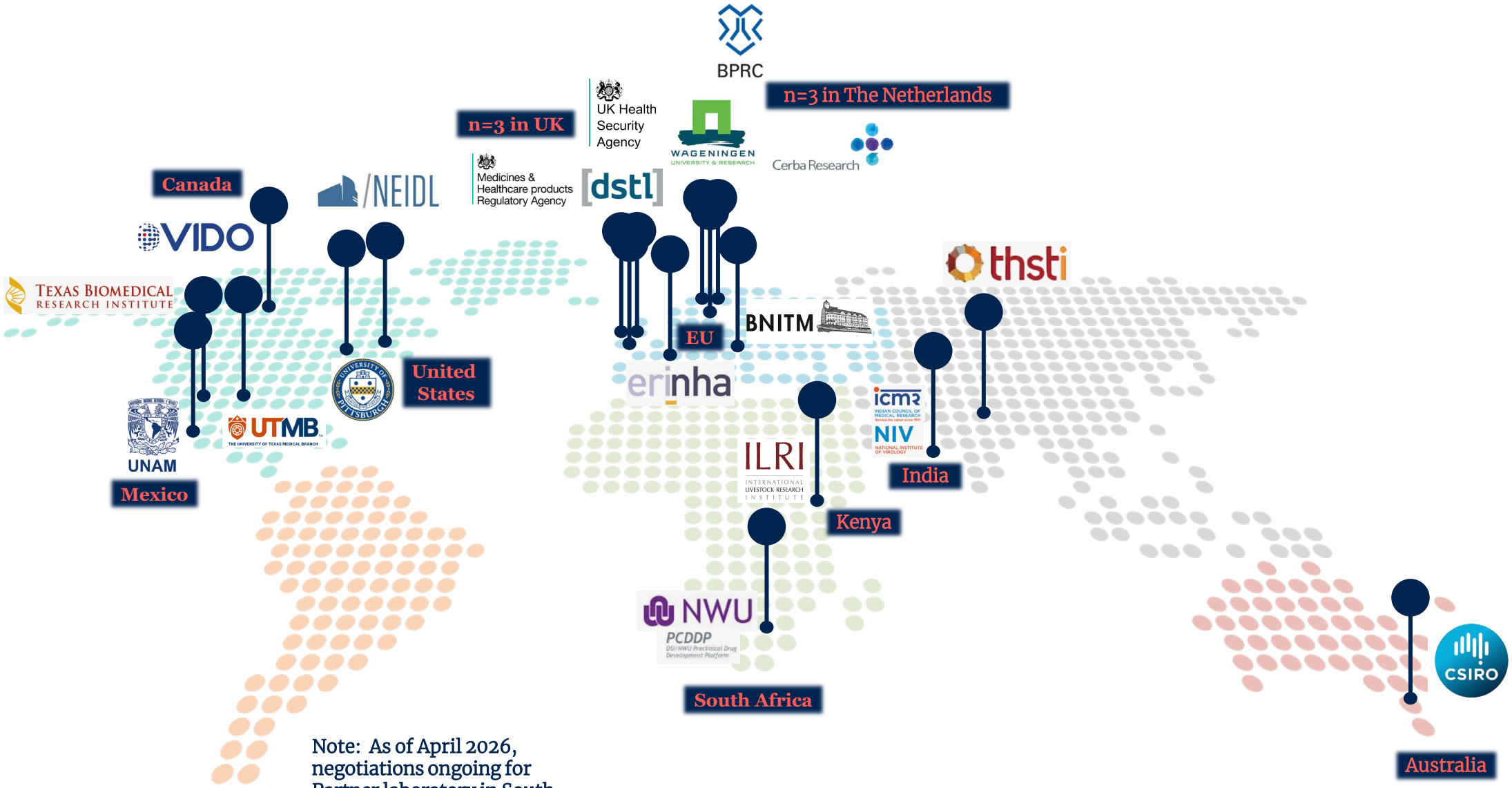
- A global network of laboratories that serve CEPI developer's preclinical needs from model development through IND-enabling vaccine testing
- Comprises 19 laboratories representing five distinct global regions: North America, Europe, Asia, Africa, and Australia/Oceania. Ongoing initiatives aim to broaden participation by including representation from South America
- Early preclinical studies including immunogenicity assessments and vaccine candidate down-selection through pivotal vaccine efficacy studies under maximum biocontainment conditions
- BSL-3 and BSL-4 laboratories to manage CEPI priority pathogens (**Nipah virus**, Lassa virus, SARS-CoV, SARS-CoV-2, MERS-CoV and other coronaviruses, Chikungunya virus, Rift Valley Fever virus, filoviruses, and various Disease X families) and other pathogens including influenza and Mpox viruses
- Preclinical model expertise encompasses standard rodent models-such as mice, hamsters, and guinea pigs-through more complex models, including nonhuman primates. Several laboratories further possess the capabilities required for handling agricultural species such as swine, cattle, and other ruminants
- Compliance with the highest ethical and welfare standards, including alignment with NC3Rs guidelines (https://www.nc3rs.org.uk/)
- Increased prioritization on the development of non-animal approaches, including innovative research utilizing organoids culture technology, organ-on-a-chip platforms, and *ex vivo* tissue modelling
- High-quality deliverables supported by established quality systems or well-documented through protocol-specified methods




National Centre
for the Replacement
Refinement & Reduction
of Animals in Research

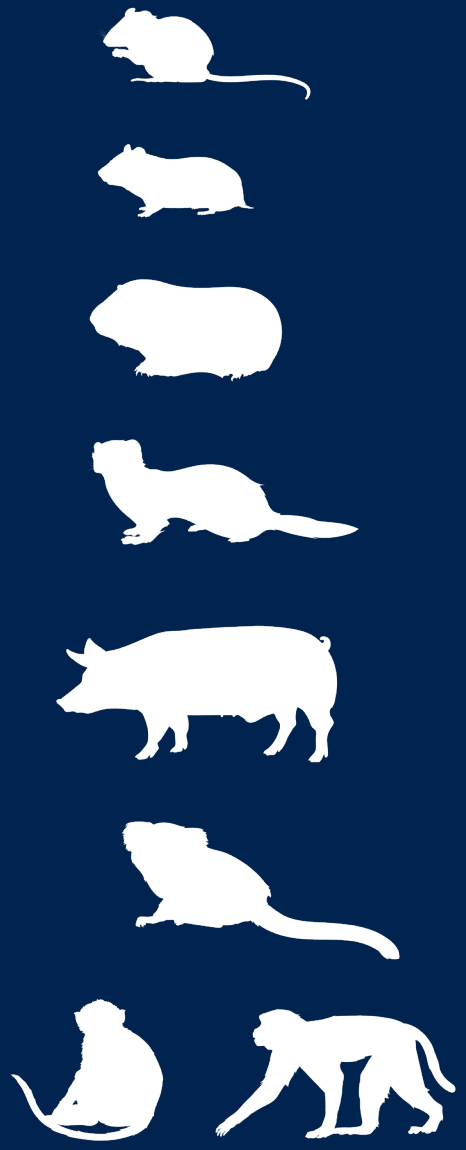
The CEPI Preclinical Model Network (PMN)



Note: As of April 2026, negotiations ongoing for Partner laboratory in South America; if successful, this will be number 20

CEPI-Supported/Developed Models within the PMN

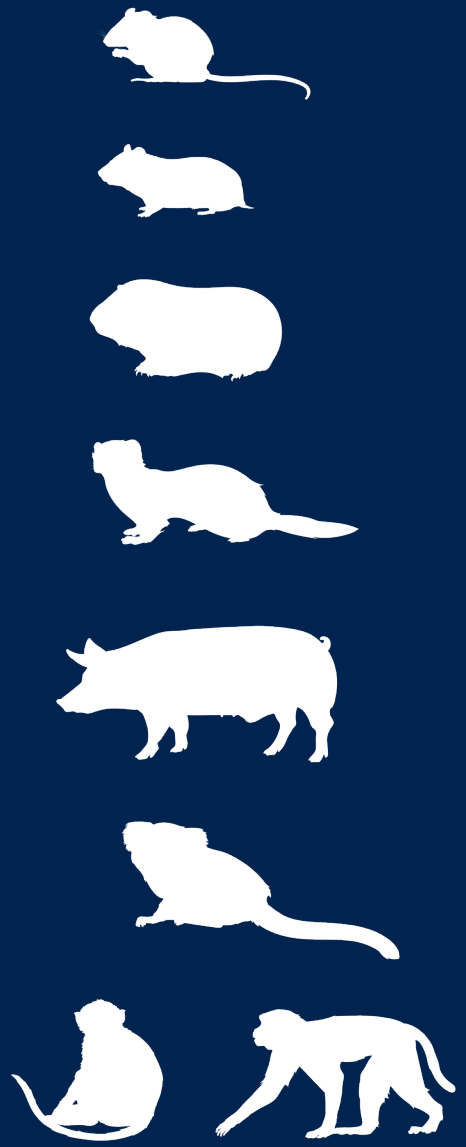
- *Arenaviridae*
  - Guanarito virus: Guinea pig*
  - Lassa virus: Mouse (STAT1$^{-/-}$), *Mastomys* spp.*, guinea pig (adapted and non-adapted*), macaque (rhesus and cynomolgus)
  - Junin virus: Guinea pig, macaque (rhesus and cynomolgus)*
- *Coronaviridae*
  - SARS-CoV-2: Mouse (various, including Tg hACE2), hamster (including Tg hACE2), ferret, NHP (various), swine
  - SARS-CoV: Mouse (Tg hACE2), hamster (including Tg hACE2*)
  - MERS-CoV: Mouse (Tg hDPP4), hamster (Tg hDPP4*), marmoset*, macaque (rhesus and cynomolgus)
- *Filoviridae* (EBOV, SUDV, MARV, others)
  - Mouse (various KO), hamster, guinea pig, ferret, NHP (various)
- *Nairoviridae*
  - CCHFV: Mouse (KO)*
- *Orthomyxoviridae*
  - Influenza virus (various strains): Ferret



*Model(s) currently in development via PMN Service Orders

CEPI-Supported/Developed Models within the PMN

- *Paramyxoviridae*
  - Nipah virus: Hamster, Grivet monkey
  - Hendra virus: Mouse*
  - Salt Gully virus: Ferret*
- *Phenuiviridae*
  - SFTSV: Mouse*, ferret*
- *Poxviridae* (VARV, MPXV, BPXV, CPXV, others)
  - Mpox: Mouse*
- *Togaviridae*
  - CHIKV: Mouse (KO), macaque (cynomolgus)
- *In vitro / Ex vivo* systems
  - e.g., MPS, organ-on-a-chip, organoids, precision cut tissue slices, unique *ex vivo* cell models, etc.*



*Model(s) currently in development via PMN Service Orders

Vaccine development pathway – traditional

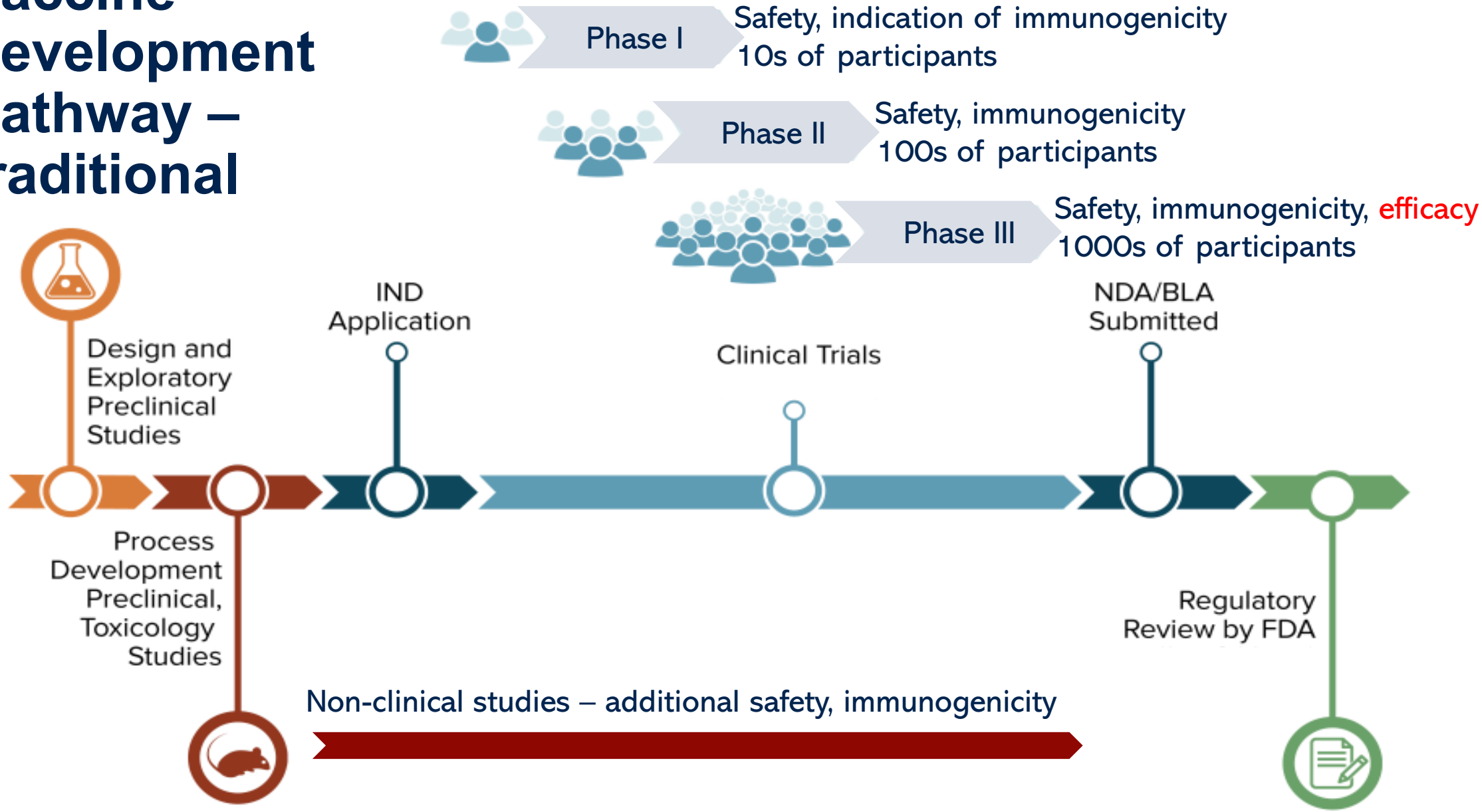


Figure adapted from www.cbo.gov/publication/57010

Vaccine development pathway – Animal Rule

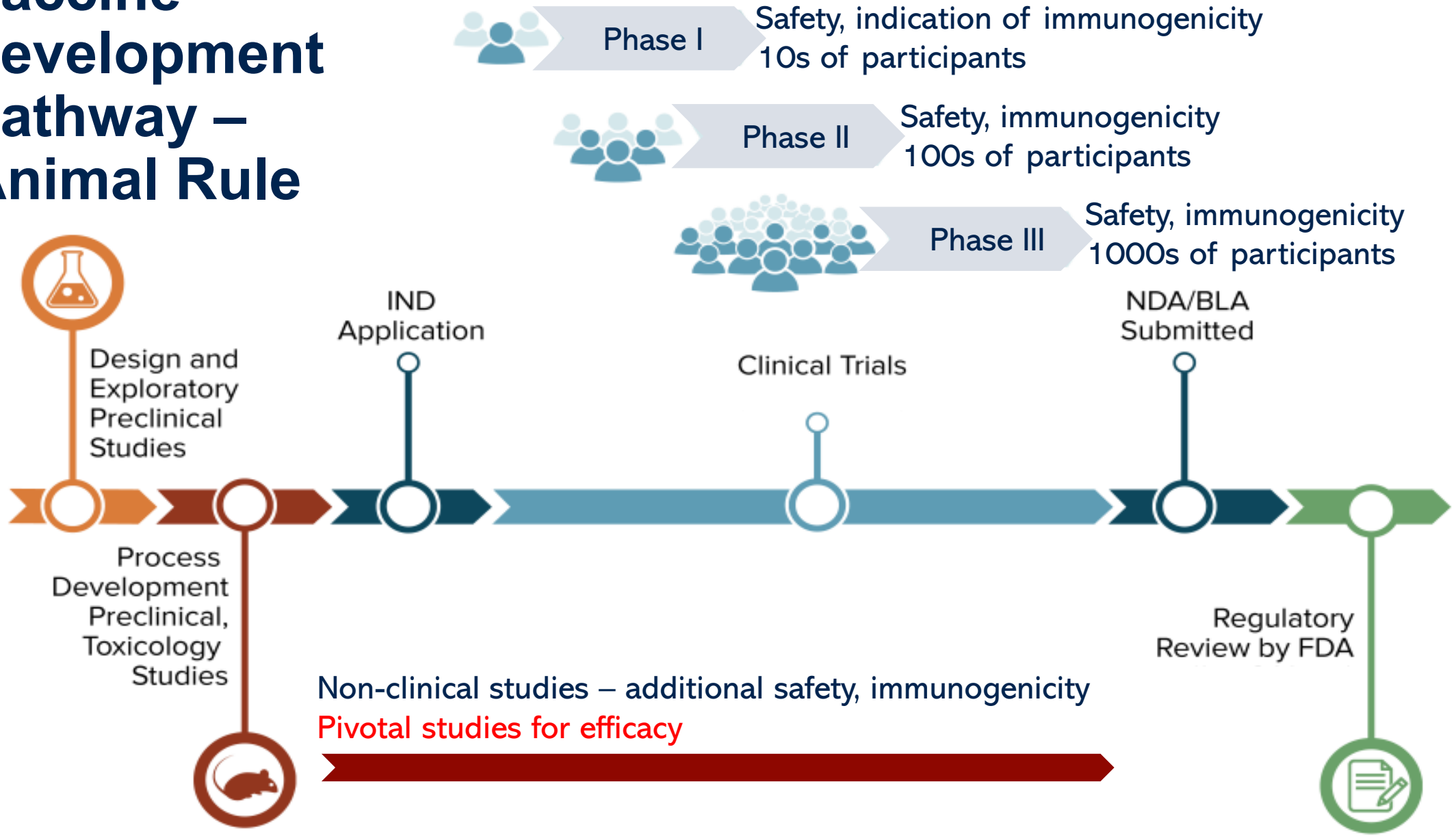


Figure adapted from www.cbo.gov/publication/57010

Why invest in establishing animal models for Nipah virus?

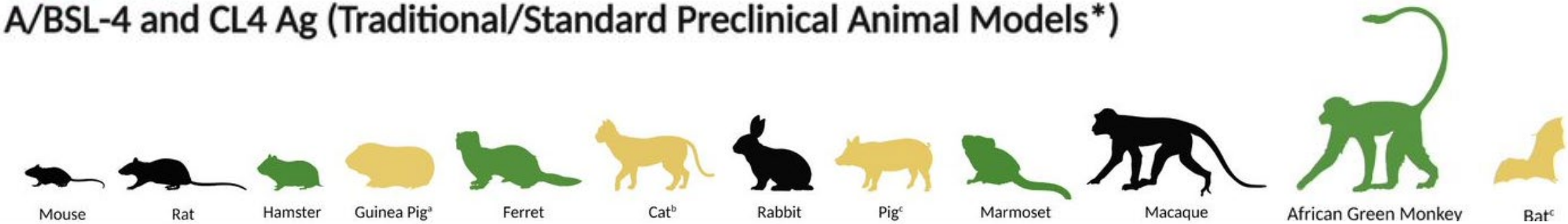
- Lack of harmonization across groups that have developed animal models of Nipah disease
  - Challenge stock
  - Challenge dose
  - Challenge route (IN vs. IN/IT vs. IP vs. others)
  - Clinical scoring
  - Humane endpoints

- Thus far, modelling efforts for Nipah have been predominantly research-grade rather than quality-driven for regulatory purposes
  - Regulated studies needed for regulatory rigor and for generating pivotal efficacy data
  - Need to be documented to the extent that the study can be completely reconstructed

- High quality natural history studies will define models that any developer can subsequently use
  - Thorough characterization of the course of disease in a model without any MCM intervention serves as baseline
  - MCM developers can then demonstrate the efficacy of their products compared to the baseline
  - Centralizing this effort saves developers from duplicating efforts, contributing to the 3Rs

Nipah Virus

A/BSL-4 and CL4 Ag (Traditional/Standard Preclinical Animal Models*)



Primary disease characteristics
(based on the available literature)

100% lethal 5-6 days pi 100 TCID50 or less (Malaysia > Bangladesh); IN and IP routes; labored breathing, nasal exudates; imbalance, muscle twitching, tremor, limb paralysis; gross pathology includes edema, hemorrhage, and congestion; virus in lung, CNS, heart, liver, spleen, kidney, bladder, urine

100% lethal 7-8 days pi 5,000 TCID50 (Malaysia = Bangladesh); IN and oronasal routes; dyspnea, cough, nasal discharge; depression, tremors, muscle twitching, hind limb paralysis; gross pathology includes edema and hemorrhage; virus in brain, lung, lymphoid organs, adrenal, kidney, testes/uterus, liver, and various swabs

100% lethal 8-11 days pi 6 x 10e4 TCID50 (Bangladesh); IN/IT routes; anorexia, hyperventilation; hindlimb tremors; gross pathology includes hemorrhage in lungs, fluid in lungs, lymph node enlargement, edema (including in brain); virus in lung, spleen, pancreas, liver, trachea, kidney, heart, bone marrow, spinal cord, brain, tonsil, lymph nodes

100% lethal 7-14 days (depending on strain) pi 1 x 10e5 TCID50 (Bangladesh > Malaysia); IN and IP routes; severe dyspnea, open-mouth breathing, nasal discharge; muscle twitches, seizures; gross pathology includes pulmonary consolidation, lung congestion, lymph node enlargement, congested liver, GI inflammation, brain congestion; virus in lung, lymph nodes, heart, liver, spleen kidney, adrenal gland, brain, urinary bladder, sex organs

[a] Disease in guinea pigs resembles human disease, but reduced pulmonary involvement

[b] Disease in cats resembles human disease, but no neurological involvement/encephalitis

[c] Intermediate amplifying host

*Animal models shaded in green represent optimal available models that recapitulate most aspects of human disease including respiratory and neurological involvement, gross and histopathological lesions, and tissue viral load; animal models shaded in yellow represent susceptible models in which some aspect(s) of human disease are recapitulated (e.g., disease presentation, viral shedding, seroconversion, etc.), but lack one or more critical aspects of the disease observed in humans - these models may be beneficial for vaccine/therapeutic screening studies and/or transmission studies; models shaded in black are suboptimal (i.e., not susceptible, develop only mild disease, or require adaptation to establish disease) and are not recommended for further development or product evaluation.

**Bangladesh and Malaysia strains (NiV_B and NiV_M, respectively)

Nipah animal modelling plan

- CEPI has partnered with the National Emerging Infectious Disease Laboratory (NEIDL) at Boston University to establish models of Nipah virus disease in two species:
  - Syrian Golden hamsters
  - Grivet monkeys (*presented herein*)

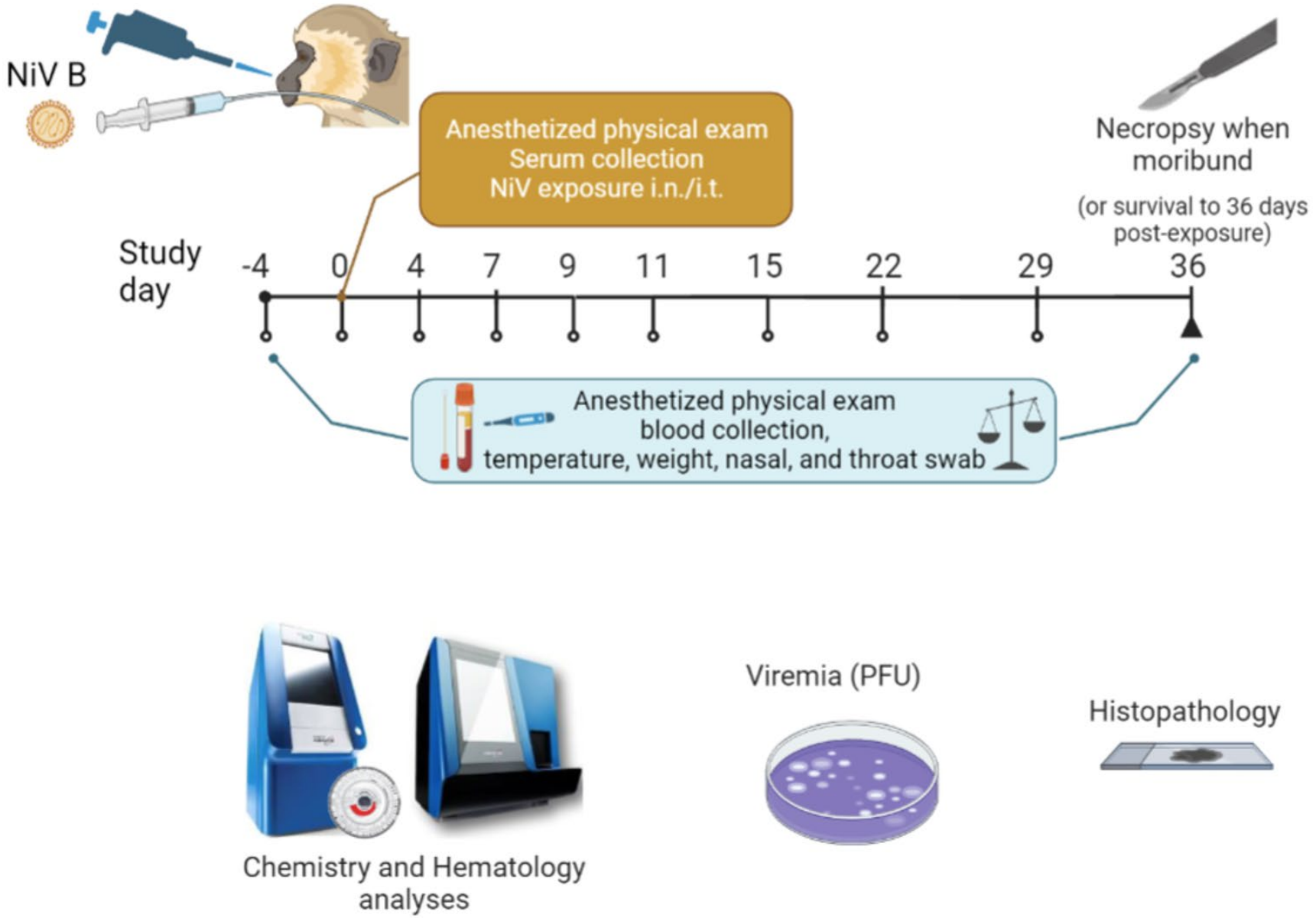
- Dose-finding studies
  - Determination of optimum challenge dose
  - Determination of optimum challenge route
  - Determination of ideal Nipah virus challenge strain
  - Determination of critical disease endpoints

- Model-defining Natural History studies
  - FDA guidance will be sought from CBER and CDER before initiation
  - Models will be regulatory-compliant and made available for developers with Nipah vaccines in advanced clinical development to conduct pivotal efficacy studies

Study Design:

Dose finding/refinement in Grivet monkeys

NiV-Bangladesh (NiV-B)

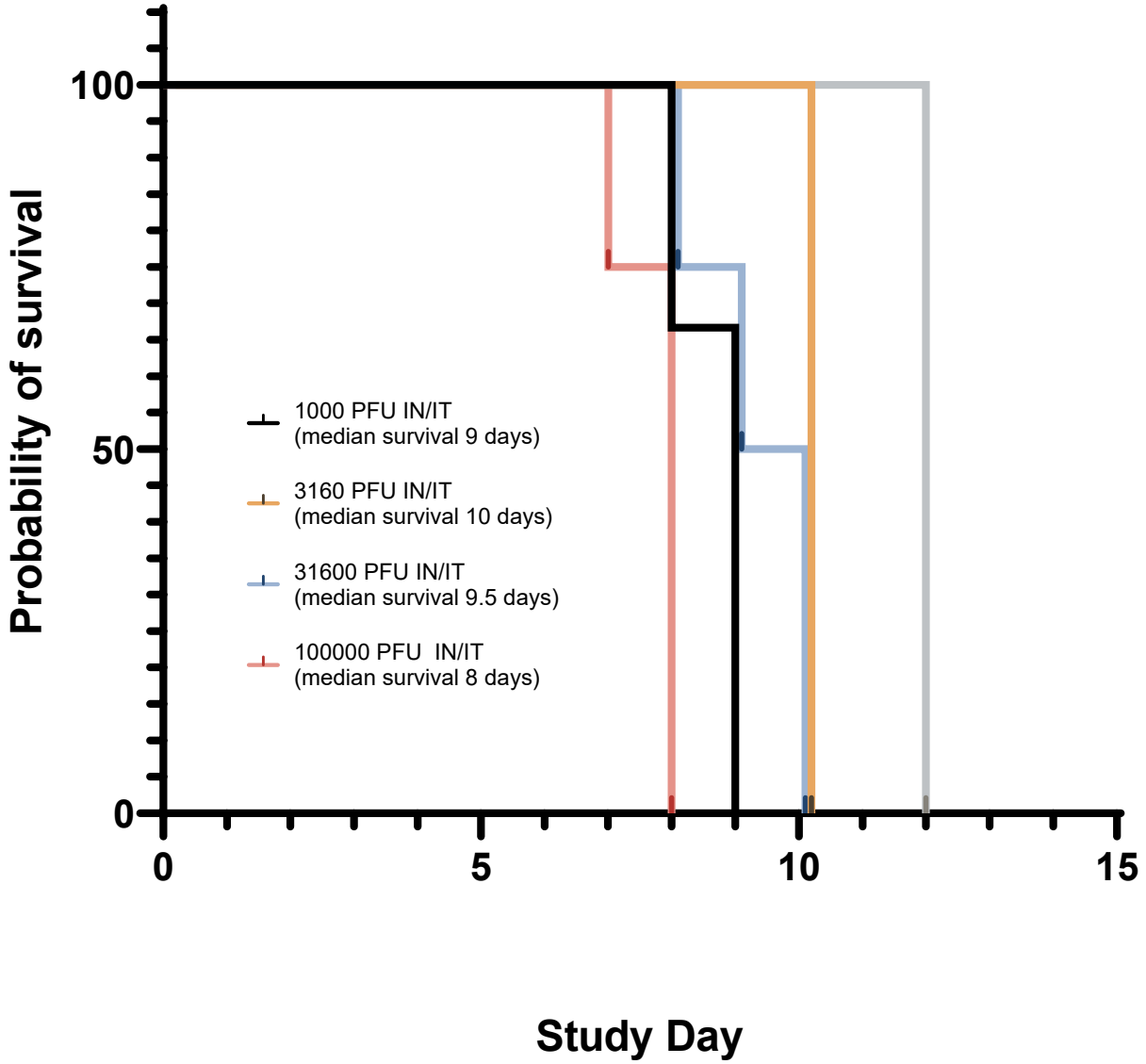


Slide courtesy of Dr. Nadia Storm, NEIDL

Survival: Grivet Dose Finding Study

Group	Number	Target Exposure Dose (PFU)	Route
1	4	1000	IN/IT
2	4	3160	IN/IT
3	4	31600	IN/IT
4	4	100000	IN/IT

- Limited infectious virus as determined via plaque assay in tissues and swabs
- No infectious virus in serum

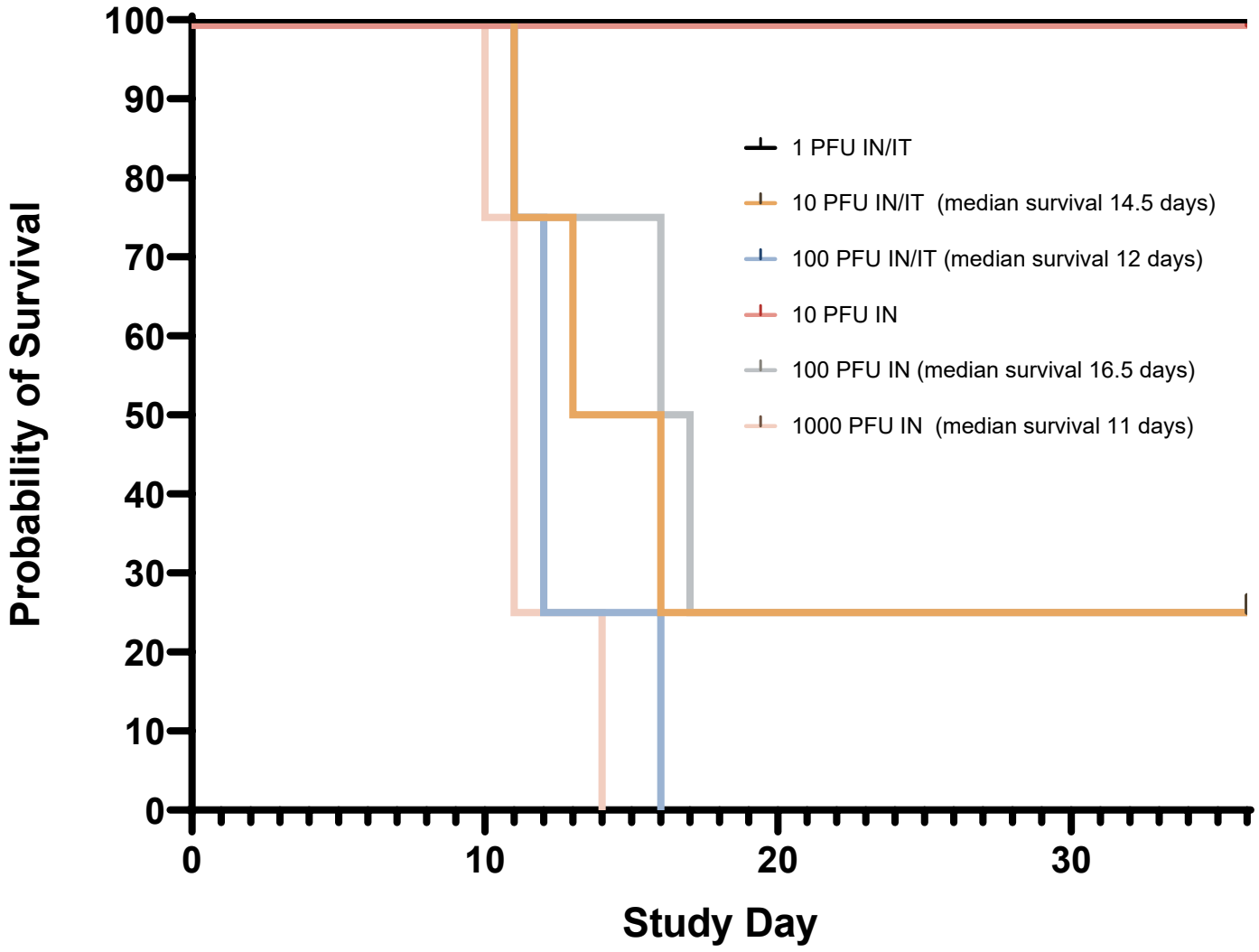


Slide courtesy of Dr. Nadia Storm, NEIDL

Survival: Grivet Dose Refinement Study

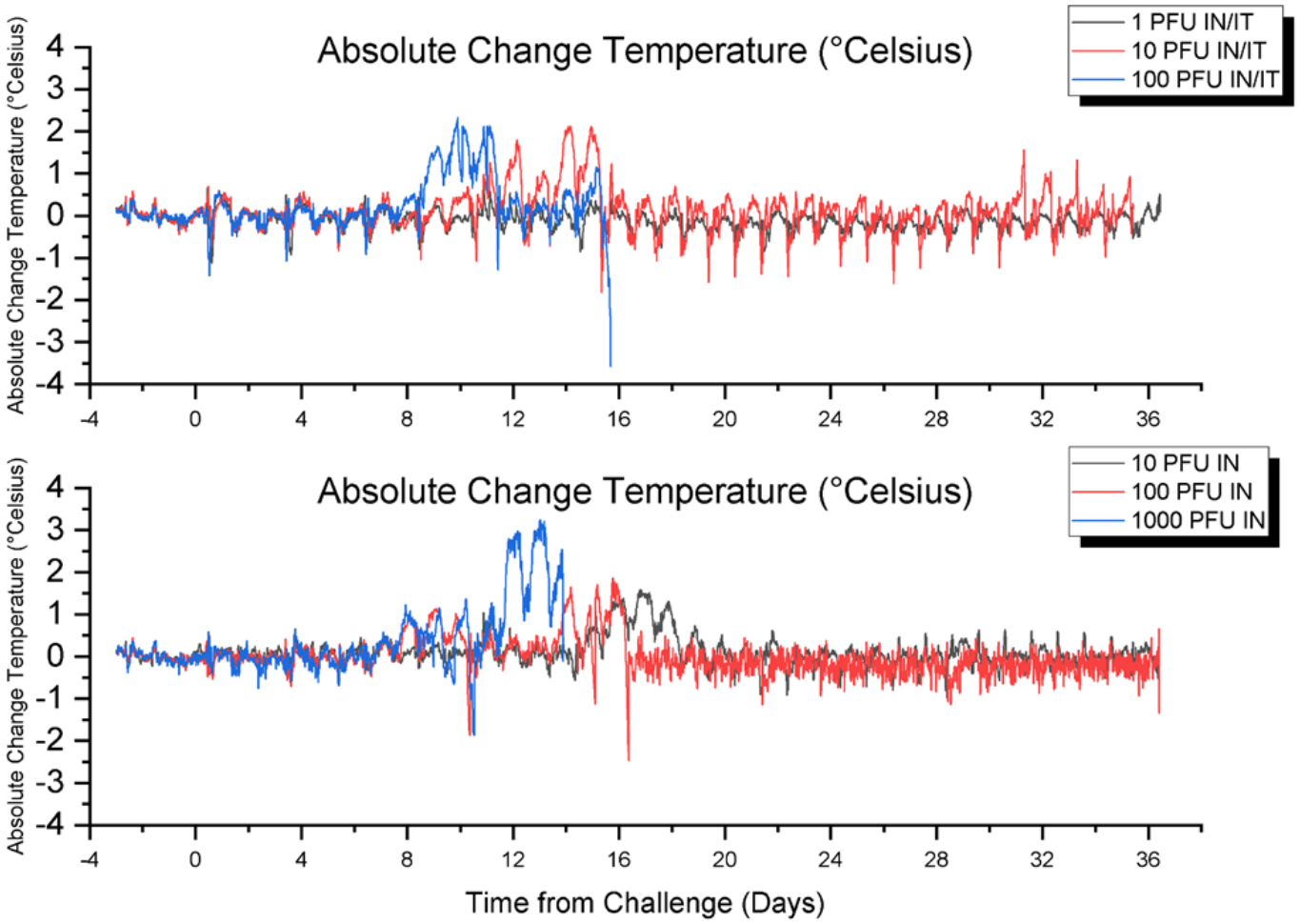
Group	Number	Target Exposure Dose (PFU)	Route
5	4	1	IN/IT
6	4	10	IN/IT
7	4	100	IN/IT
8	4	10	IN
9	4	100	IN
10	4	1000	IN

- Uniform lethality at 1,000 PFU IN and 100 PFU IN/IT
- Tendency toward more neurological signs at low dose
- RNA detected in blood of all animals except one of the 1 PFU IN/IT; most clear by Day 11
- RNA detected at late times from 10 PFU IN group (Study Days 22 and 29 survivors)



Slide courtesy of Dr. Nadia Storm, NEIDL

Telemetry: Core Body Temperature



- Temperature measured via implantable data loggers
- Data normalized to temperature values at equivalent time of day prior to virus challenge
- Observations:
  - Dose-dependent fever patterns
  - Fever observed at 10 and 100 PFU in IN/IT groups
  - Fever observed at 10, 100, and 1,000 PFU in IN groups
    - Note: all animals in 10 PFU group survived

Slide courtesy of Dr. Nadia Storm, NEIDL

Vaccine development pathway – Animal Rule

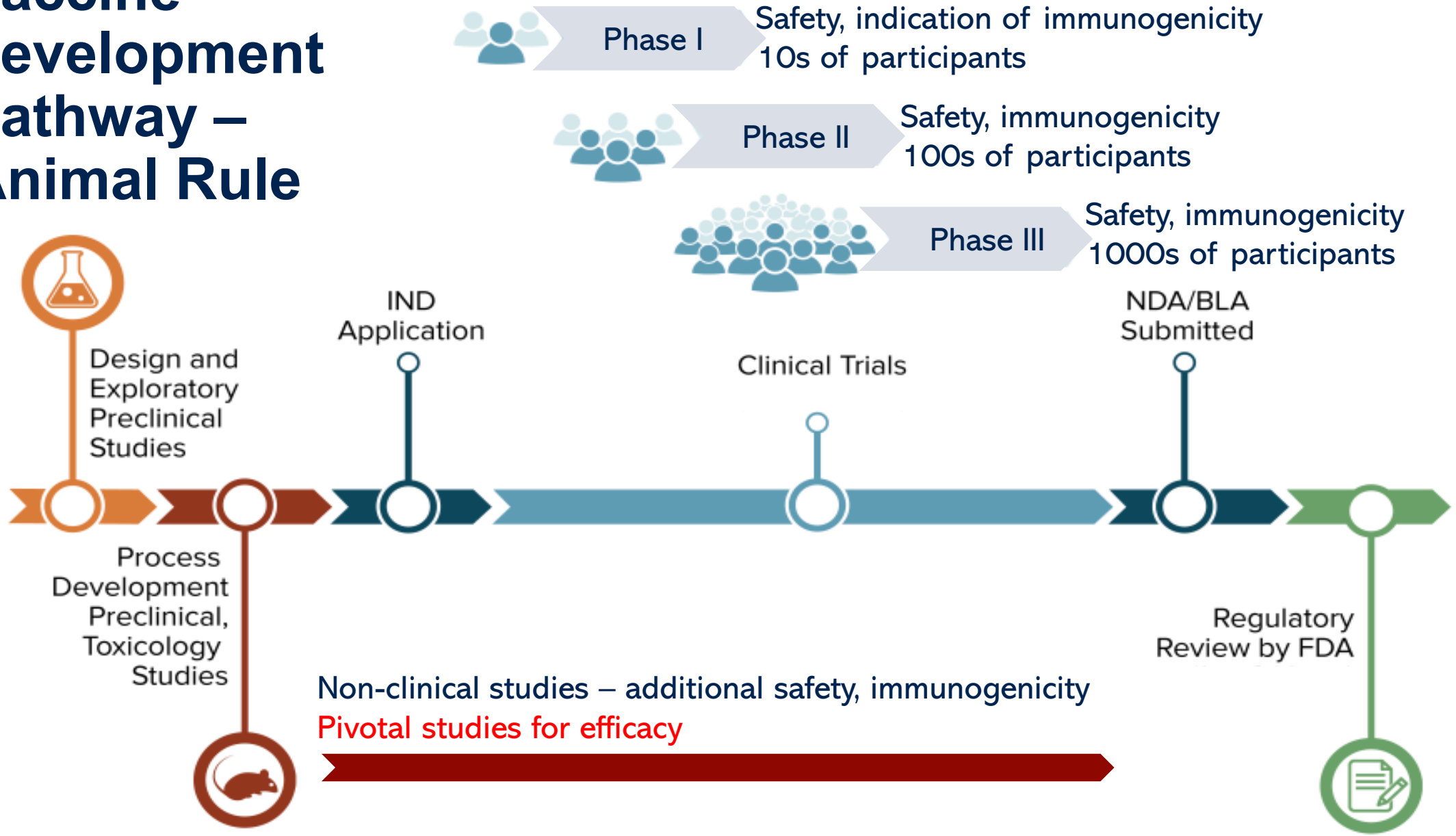


Figure adapted from www.cbo.gov/publication/57010

FDA Pre-IND Submission

- Cover letter
- Introduction, with references
- List of questions
- Animal sourcing and health documentation
- Study protocol for dose finding/refinement
- Telemetry report
- Assay qualification report
- CoA for challenge virus
- Sequence data for challenge virus
- Study protocol for planned Natural History study
- Statistical analysis plan for planned Natural History Study

CEPI

Overview of the Centralized Laboratory Network (CLN) and Support for Nipah Vaccines

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Technical Lead at Centralized Laboratory Network
Department of Laboratory Research & Innovations
Coalition for Epidemic Preparedness Innovations (CEPI)

PHO Microbiology Rounds
07 May 2026

Objectives of the Network

1) **Testing of samples** from (pre-clinical and) clinical trials
    a) subset to ensure comparability across programs to facilitate CEPI programmatic decision making with a set of standardized assays
    b) complete set - to facilitate rapid evaluation, approval, and dissemination of th most effective vaccine candidates

2) Preparedness

To align with the CEPI mission and enhance our ability to effectively respond to potential outbreaks

3) Capacity building

To establish hubs that enhance local capabilities, support global health security initiatives, and provide training for other labs and staff in standardized assay techniques

CEPI

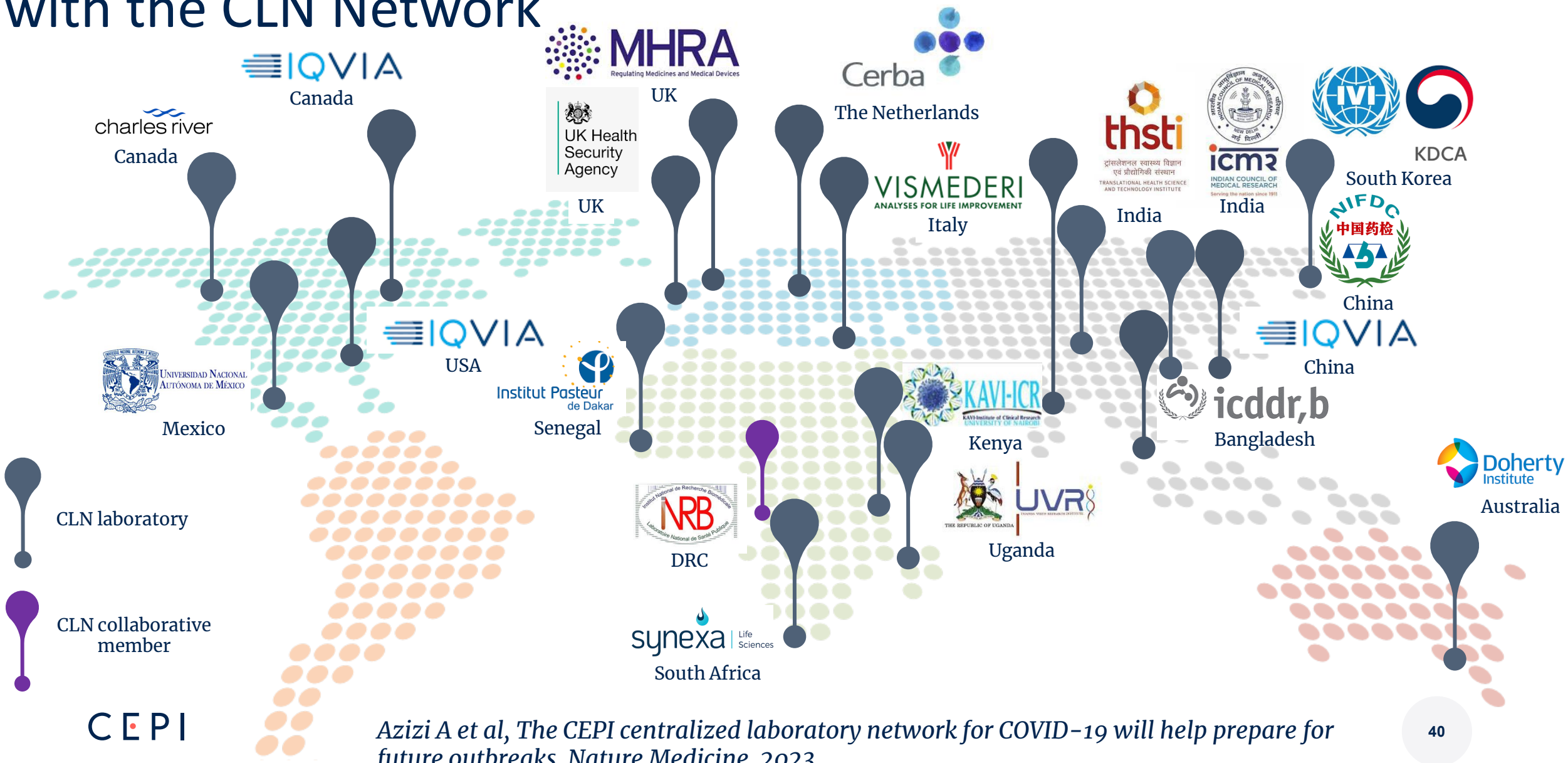
How to Improve Assay Standardization?

- **Reference reagents at NIBSC, a WHO Collaborative Center**
  - Research reagent and panels
  - WHO International Antibody Standard established by the ECBS (22/130_NT,https://nibsc.org/products/brm_product_catalogue/detail_page.aspx?catid=22/130_NT)

- **CEPI Centralized Laboratory Network**
  - Selection of laboratories with high quality standards worldwide
  - Selection of a core set of preclinical and clinical assays needed for key immunogenicity and efficacy endpoint evaluation
  - Harmonization of protocols and key reagents across the laboratories

CEPI

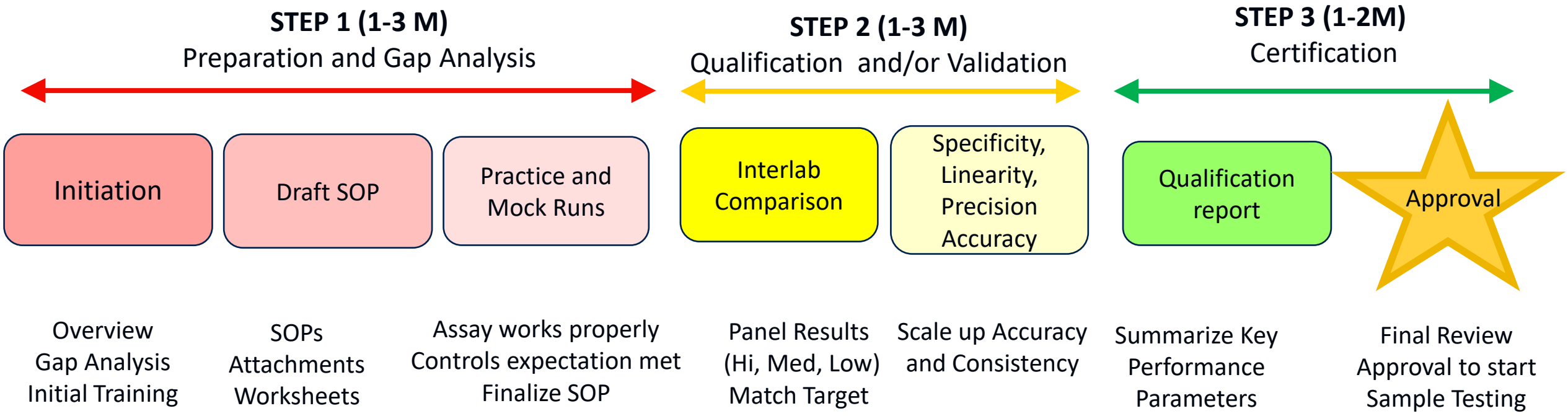
19 Laboratories and 1 Collaborative Member are Associated with the CLN Network



CEPI

Azizi A et al, The CEPI centralized laboratory network for COVID-19 will help prepare for future outbreaks, Nature Medicine, 2023

Assay Transfer Process



CEPI

Manak M et al., Standardised quantitative assays for anti-SARS-CoV-2 immune response used in vaccine clinical trials by the CEPI Centralized Laboratory Network: a qualification analysis. Lancet Microbe, 2024

Pathogens of Interest at CEPI-CLN

SARS-CoV-2
(terminating end of 2025)

IQVIA, UKHSA,
IPD, Icddr,b, THSTI, MHRA, Cerba, VisMederi, IQVIA China, UNAM

Nipah

Icddrb, ICMR, THSTI

Filoviruses

UVRI, UKHSA, CRL

Disease X

Flu

VismederiDo herty, IVI

Mpox

UKHSA, Vismederi,
UVRI, INRB

SARS-1, MERS, other coronaviruses

IQVIA,
KAVI, Synexa, NIFDC, Doherty

Lassa

MHRA,
IPD, Synexa

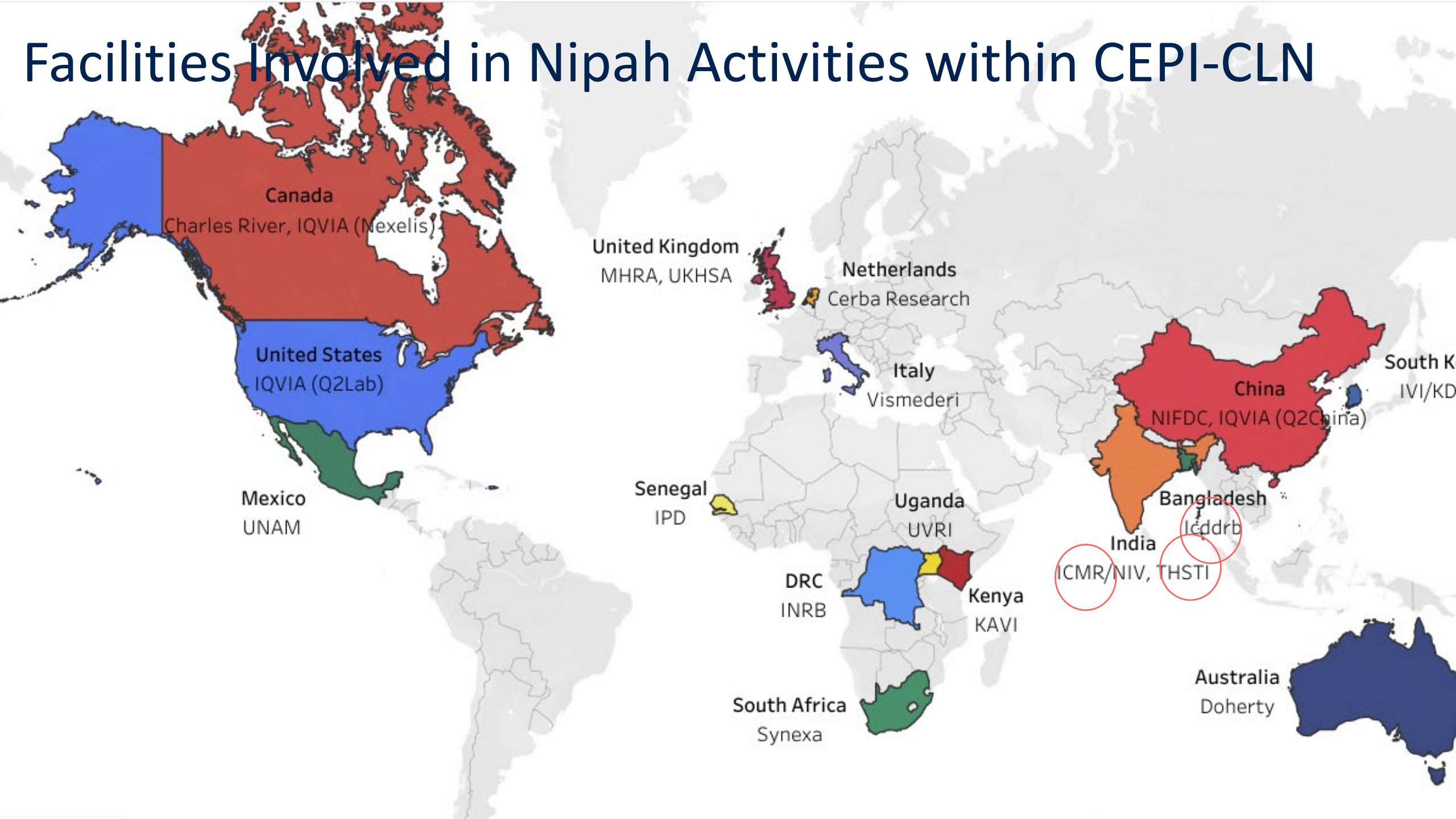
RVF
IPD

CHIK
IQVIA

CEPI

Azizi A et al., Unifying global efforts by CEPI's centralized laboratory network. Frontiers in Immunology, 2024

Facilities Involved in Nipah Activities within CEPI-CLN

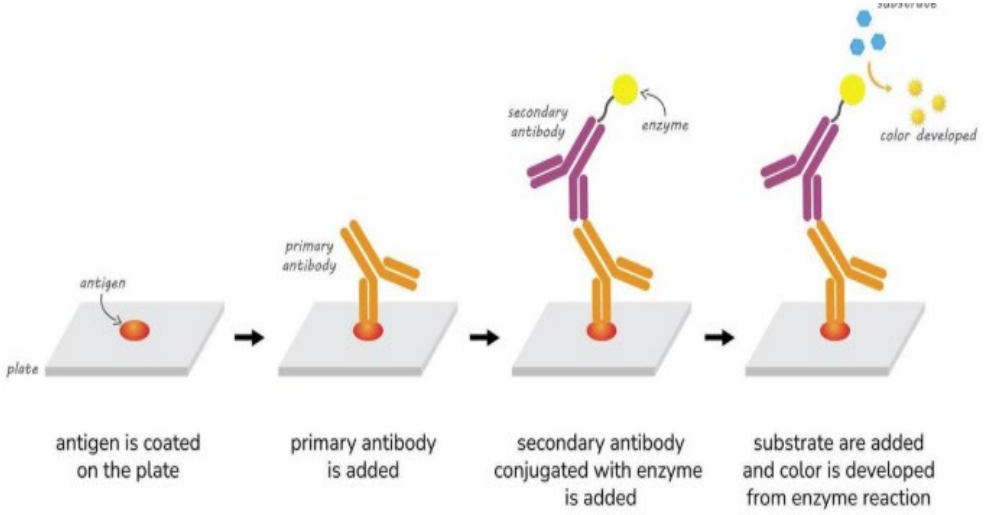


Humoral Immunity: Antibody titer & Neutralization

Binding Assay

ELISA (Binding)

Detects antibodies against G/F proteins
High throughput
Not functional
Output: Antibody level (e.g. IgG)



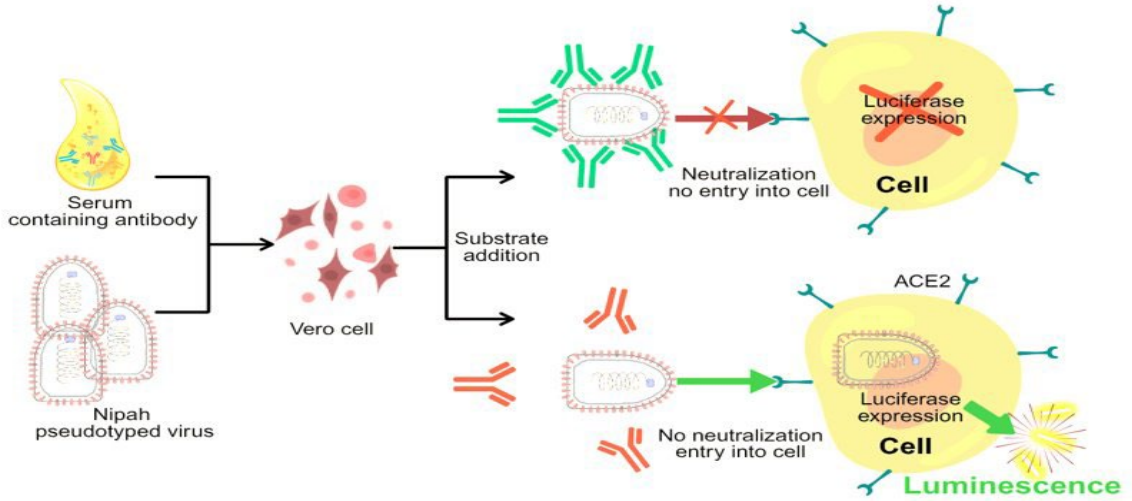
Neutralization Assay(s)

Live Virus Neutralization (MNA/VNA)

Gold standard
Requires BSL-4
Measures true protection
Output: Neutralization titers

PNA (Pseudovirus Neutralization)

Safer (BSL-2)
Uses pseudotyped virus
Measures neutralization
Output: Neutralization titers



Alam A et al,. Development and Validation of a Standardized Pseudotyped Virus based Neutralization Assay for Assessment of Anti-Nipah Virus Neutralizing Activity in Candidate Nipah Vaccines. *Vaccines*, 2025

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Cell-Mediated Immunity

Cellular Assay(s)

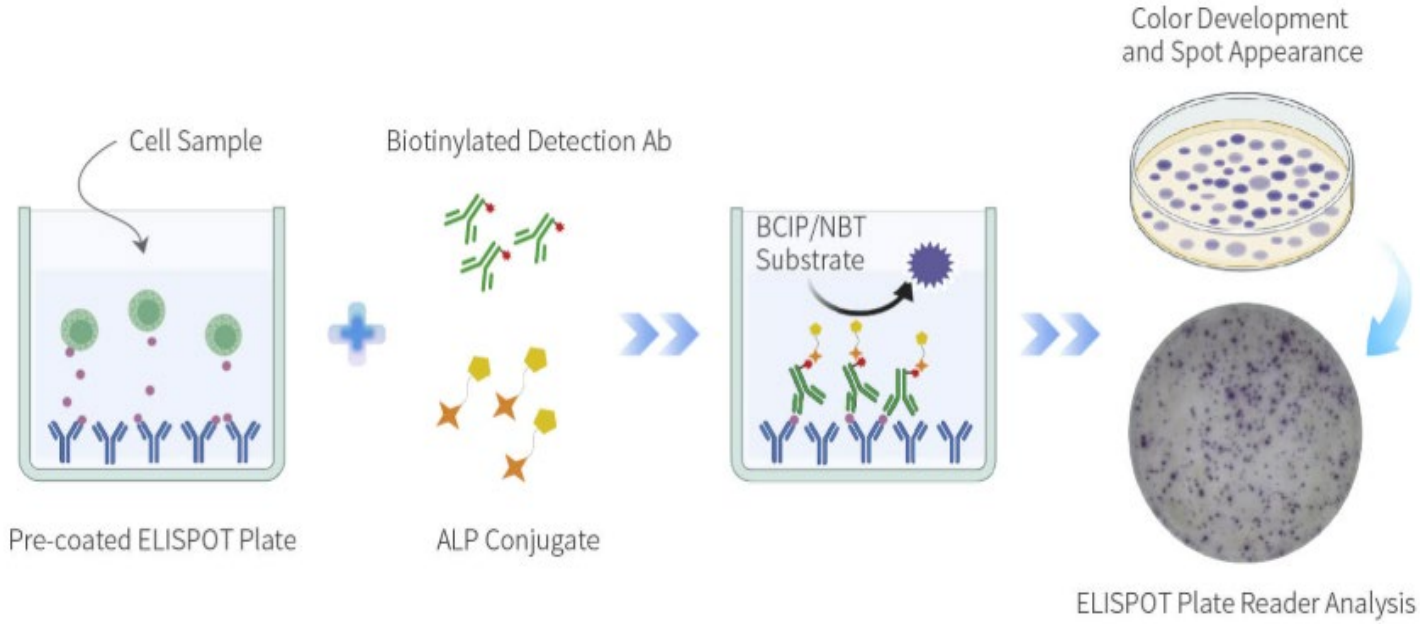
ELISpot Assay

Measures antigen-specific T cell responses

Typically detects:

Th1 response (IFN-γ) or Th2 cytokines (IL-5)

Uses PBMCs stimulated with Nipah peptides



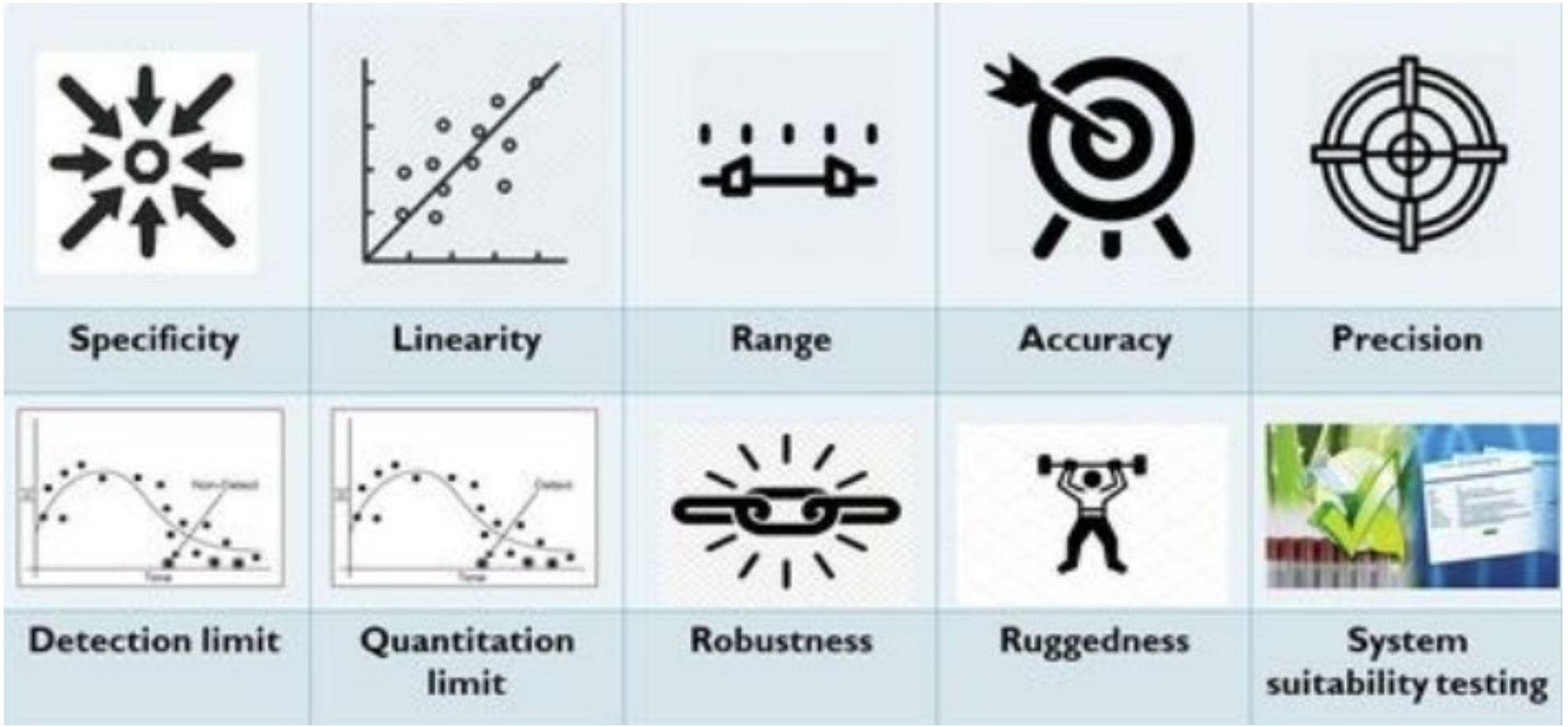
Why Important?

Critical for:

- Viral clearance
- Long-term immunity

Method Validation

- The word validation simply means assessment of validity or action of proving effectiveness. Validation is a team effort where it involves people from various disciplines of the plant. Method Validation if the process of ‘establishing documented evidence’ which provides high degree of assurance that the method will meet the requirements for the intended application.



Azizi A et al., Immunological Assays for Assessing COVID-19 Vaccines by the CEPI-Centralized Laboratory Network, *NPJ Vaccines*, 2024

Nipah Assays at CEPI-CLN

	Binding antibodies		Neutralizing antibodies			T cells
	ELISA		Pseudo-typed neutralization		Wild type virus neutralization	ELISPOT
	NiV-G Protein from creative diagnostics Total IgG in serum	NiV-G Protein NiV-F Protein Total IgG in serum	Pseudo particles with rVSV backbone NiV-G and NiV-F	Pseudo particles pNL4-3env.luc+ NiV-G and NiV-F	MNA	INFγ & Granzyme B Peptide pool of the whole G protein
Assay development	Completed at Icddr,b	Completed at THSTI	Completed at Icddr,b	Completed at THSTI	Completed at ICMR-NIV	Completed at Icddr,b
Assay qualification	Report drafting at Icddr,b	Ongoing at THSTI	Completed at Icddr,b	Ongoing at THSTI	Ongoing at THSTI	Completed at Icddr,b
Assay validation	–	Planned at THSTI (depending on sample availability&)	–	Planned at THSTI (depending on sample availability&)	Planned at ICMR-NIV (depending on sample availability&)	–
Strain	Malaysia	Malaysia Bangladesh Indian	–	Malaysia Bangladesh Indian	Indian	Malaysia
Tech transfer (timelines for completion)	–	Icddr'b ICMR-NiV (TBD)	–	Icddr'b ICMR-NiV (TBD)	ICMR-NiV (TBD)	ICMR-NIV

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Completed | Ongoing / Planned | – Not applicable | Sensitivity: Official Use | &: Access to Auro vaccine samples is underway

Sens

Call to Action

Global Health Threat

Nipah virus remains a serious health threat with high mortality and major societal impacts worldwide.

Advances and Gaps

Progress in vaccines, diagnostics, and standardization exists, but critical gaps still need urgent attention.

Collaboration and Preparedness

International cooperation and integrated scientific efforts are essential to strengthen preparedness for future outbreaks.

High Throughput Platforms

Implement high-throughput and more versatile platforms for new diseases to enhance our ability to test, monitor, and respond to new diseases effectively.

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We welcome questions and feedback. As needed, please contact us at ali.azizi@cepi.net, selorm.avumegah@cepi.net or trevor.brasel@cepi.net

Thank you!

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