

UKHSA Presents

The power of vaccine development and global partnerships

Chair: Dr Bassam Hallis, Head of Vaccine Development and Evaluation Centre, UKHSA

#UKHSAPresents



Agenda:

- UKHSA's response to vaccine development and importance of global partnerships
 Yper Hall and Sue Charlton, UKHSA
- Working with Academia
 Oxford Vaccines Group
- Working with Not-for-Profit and Industry
 Adam Hacker, Coalition for Epidemic Preparedness Innovations (CEPI)
- Q&A and discussion

UKHSA Presents: The power of vaccine development and global partnerships Thursday 10 July 2025

UKHSA: Who we are

The UK Health Security Agency (UKHSA) is an executive agency of the UK government, responsible for protecting every member of every community in the UK from the impact of a range of health risks.

The threats we protect against range in type, scale and intensity, and include:

- Biological threats: Infectious diseases from new and emerging infections including pathogens with pandemic potential to endemic infections
- Environmental threats radiation, chemical, and other environmental hazards such as extreme weather events

We provide intellectual, scientific and operational leadership at national and local level, as well as on the global stage, to make the nation's health secure.



Science at UKHSA: Securing Health and Prosperity

We protect health and prosperity by rapidly identifying and addressing threats to health, preventing costs associated with major outbreaks and incidents, and reduces the burden on the National Health Service (NHS)

Our Science underpins our work to protect health in the UK and globally, including our efforts to reduce inequalities and protect the most vulnerable

We develop and strengthen our skills and capabilities to deliver the governments ambition for the UK to be a science superpower, working in partnership with industry and academia, for better outcomes in saving lives and contribute to prosperity

We protect health and livelihoods by rapidly identifying and addressing health threats

JKHSA Scientists generate new knowledge, evidence and provide a range of scientific services.

We bring together operational capabilities, data analytics and work leading science

Protect health and livelihoods from current and future health threats

Science at UKHSA Securing **Health and Prosperity**

Develop and strengthen our scientific capabilities

to deliver UKG's Science as

a Superpower aim

Our science aligns to our health security mission and underpins our work to protect health in the UK and globally

Reduce sickness and prevent spread of infection, reduce the

burden and cost to NHS.

Health threats such as new and emerging infections, antimicrobial resistance, climate and environmental change, air pollution and chemical and radiological incidents

Reducing sickness is fundamental to health and prosperity. Our scientific work supports the development of tools and strategies to control the spread of infection and reduce the burden on and costs to the NHS

VDEC - facilitating the development of new vaccines and therapeutics

Capabilities



World-leading expertise with multiple high consequence pathogens

High Containment capabilities at BSL 2,3&4, Select Agent accreditation, Schedule 5 compliant facilities



Unique capabilities in preclinical model development & testing Approved partner for BARDA, part of NIAID's network & CEPI's Central Lab Network Implementing partner CEPI preclinical models network



Comprehensive assay development & clinical testing for vaccine evaluation studies for regulators and industry



Expert business partners focused on delivering to appropriate quality standards



Two new buildings, with state of the art laboratories with over 200 highly trained scientistS

VDEC is UKHSA's specialist capability for the development and evaluation of vaccines & therapeutics.

Prepare We work with partners to develop the tools we need to protect health from infections of major public health consequence and support preparedness for future threats including against disease X contributing to the delivery of the 100 Days Mission.

Respond: We work in partnership, supporting and enabling vaccine developers to ensure we have the vaccines needed to save lives. We work with policy makers to optimise the benefits from vaccines and ensure the most effective vaccinations programmes

Build: We maintain and build specialist capacity and capabilities to protect heath against vaccine preventable disease

Partnerships







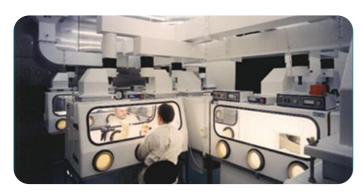


VDEC Pre-Clinical Evaluation Dr Yper Hall

Pre-Clinical Evaluation



Ability to handle a wide range of species; from small rodents up to non-human primates (NHP)



Accreditation to perform infectious disease research at high-containment biosafety levels 3 and 4 for ACDP and SAPO



An enhanced quality management system suitable for good laboratory practice (GLP) and good manufacturing practice (GMP) compliance

Pre-Clinical Evaluation Facilities





- Biological Services Group of >50 staff
- Rhesus and Cynomolgus macaque breeding colonies
- Flexible laboratory complex for housing/procedures
 - 9 clean rooms
 - 8 BSL2 laboratories
 - 30 BSL3/SAPO laboratories
 - 1 BSL4/SAPO4 suite
- Wide range of species
 - Rats, guinea pigs, hamsters, mice
 - Rabbits, ferrets
 - Farm animals
 - Non-human primates



Range of Pre-Clinical Models

BSL2 Pathogens	BSL3 Pathogens	BSL4 Pathogens	
Seasonal influenza	LPAI (H7N1)	HPAI (H5N1) *BSL3/SAPO4	
Zika	SARS-CoV-2	Ebolavirus	
Clostridiodes difficile	Bacillus anthracis	Lassa	
	Burkholderia pseudomallei	CCHF	
	Coxiella burnetii	Nipah	
	Mycobacterium tuberculosis	Marburg	
	Rift Valley Fever		
	Yersinia pestis		
	Monkeypoxvirus		

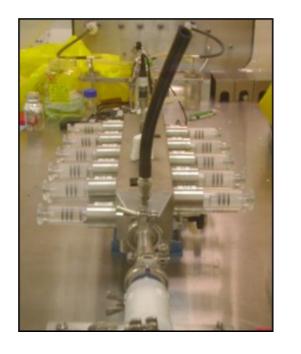
Additional Capabilities







- Aerobiology expertise for controlled pathogen exposure
- Surgery and telemetry





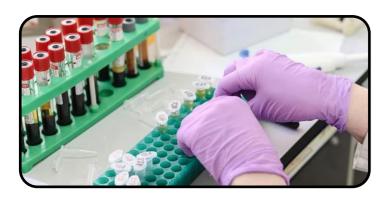
MRI, CT and PET-CT, inc. NHPs infected with BSL3 pathogens

ISO9001:2015 accredited

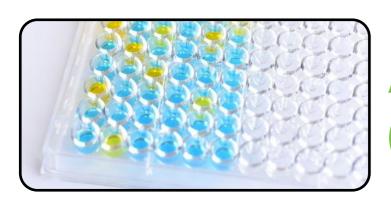
Pathology Department; board certified veterinary pathologists

VDEC Clinical Evaluation Dr Sue Charlton

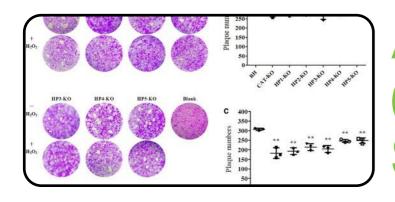
Clinical Evaluation



Develop and validate analytical methods to support clinical trial testing (Phases I-IV)



Assays to quantitate antibody responses (ELISAs, multiplexed assays)



Assays to measure functional immune responses (virus neutralisation, toxin neutralisation, HAI, SBA)

VDEC's clinical testing facilities





- Team of approx. 60 staff
- Purpose built BSL2 and BSL3 laboratories part of the GXP testing facility
- Flexible laboratory complex
- 11 BSL2 laboratories
- 6 BSL3 laboratories
- Dedicated ULT freezer rooms & sample reception areas
- Equipment monitored 24/7 by Eurotherm systems
- Dedicated GXP QA and validation teams

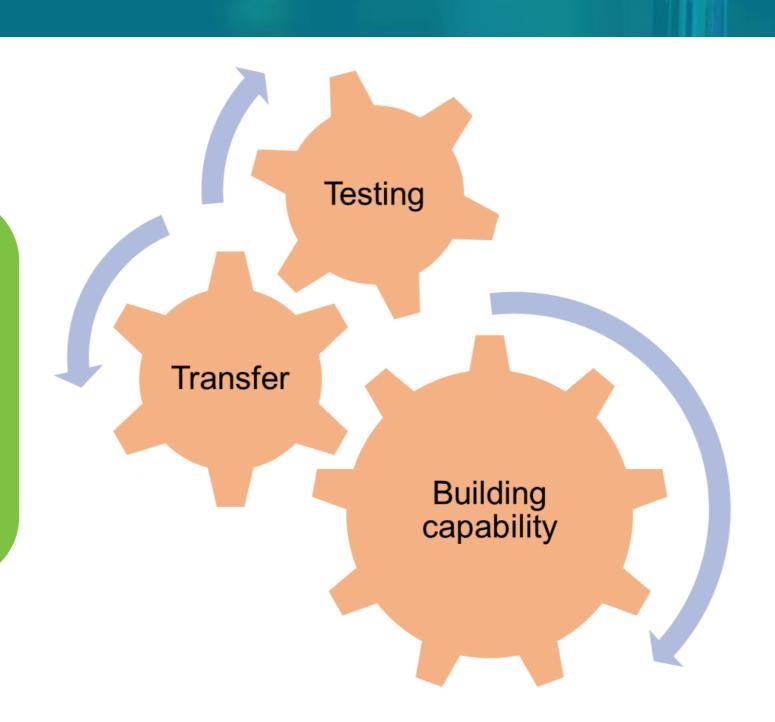
Range of methods

Target	Binding assays	Functional assays	PV assays	T cell
SARS-CoV-2	\checkmark	\checkmark	\checkmark	
SARS-1		✓		
MERS		✓		
Seasonal Influenza	✓	√ *		✓
HPAI	✓	√ *	\checkmark	✓
Paediatric schedule	✓			
RSV	\checkmark	\checkmark		
B anthracis	✓	✓		
Mpox	✓	✓		\checkmark
EBOV Sudan			✓	*HAI, MNA

VDEC Global Partnerships Dr Sue Charlton and Dr Yper Hall

Global Partnerships

- Models
- Analytical methods
- Materials



- Supporting clinical trials around the world
- Evaluation of vaccines & therapeutics in Preclinical models

- Training provision (GCP/ analytical methods)
- Establishment of labs
- Sharing expertise

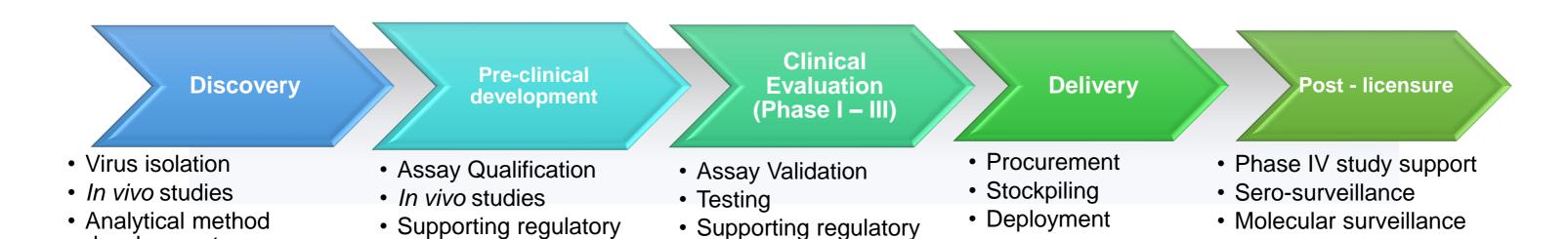
VDEC's Global Partnership Network

development

Antigen discovery

submission

Academia / NGOs / Industry / Governments Worldwide



Work is performed in compliance with the appropriate regulatory framework:

Supporting regulatory

submission

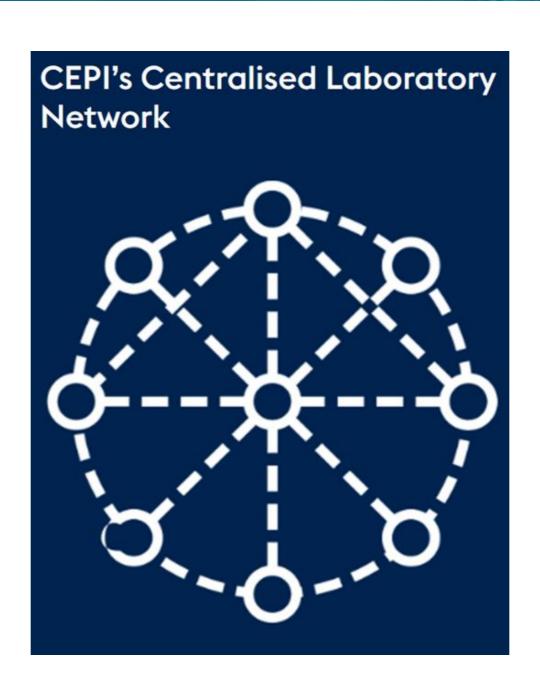
Batch release

ISO9001:2015 **GLP** GCP **GMP**

VDEC and the CEPI Centralised Laboratory Network

CLN is the largest global network of vaccine testing labs

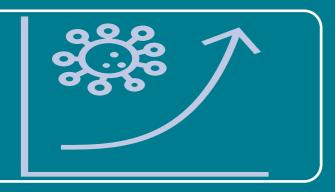
- Use of standardised protocols & shared reagents supports the 100DM:
- reduced sample shipping times
- harmonised analysis
- global capacity



UKHSA's contribution

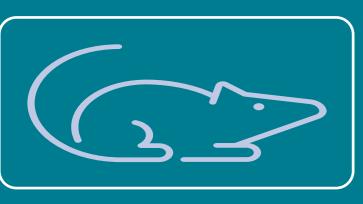
- •Clinical (& pre-clinical) sample testing
- •Transfer of validated assays to labs in the network, supporting development of COVID vaccines
- Proficiency testing of network labs
- •Qualification of assays to support vaccine development (Mpox, Lassa, Marburg, Sudan, MERS, SARS1)
- •Cross validation of live virus assays to PV assays

VDEC and the UK Vaccine Network



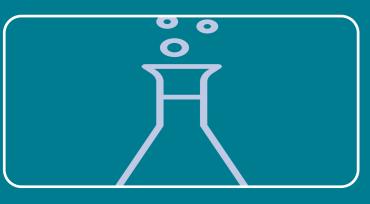
Analytical methods

- Live virus neutralisation assays
- PV assay capability
- Novel assay technologies



Pre-clinical Models

- Pathogenicity studies
- Defined end-points for countermeasure development



New technologies

- Novel vaccine candidates
- Whole virus vaccine development





Endemics & Pandemics – collaborations to strengthen vaccine preparedness

Prof Teresa Lambe OBE FMedSci



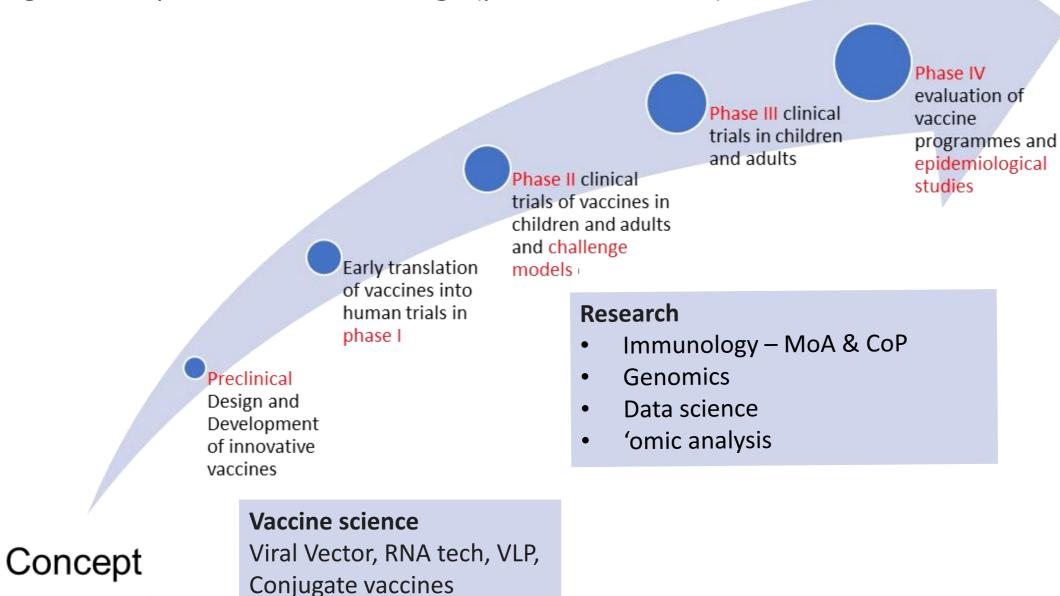


Bench to Bedside - since 1994



In excess of **140,000** volunteers recruited, across **8** countries **170** clinical trials/studies

Ranging from **26** phase 1 to **52** late stage (phase III or above)





Policy

Proactive Vaccinology

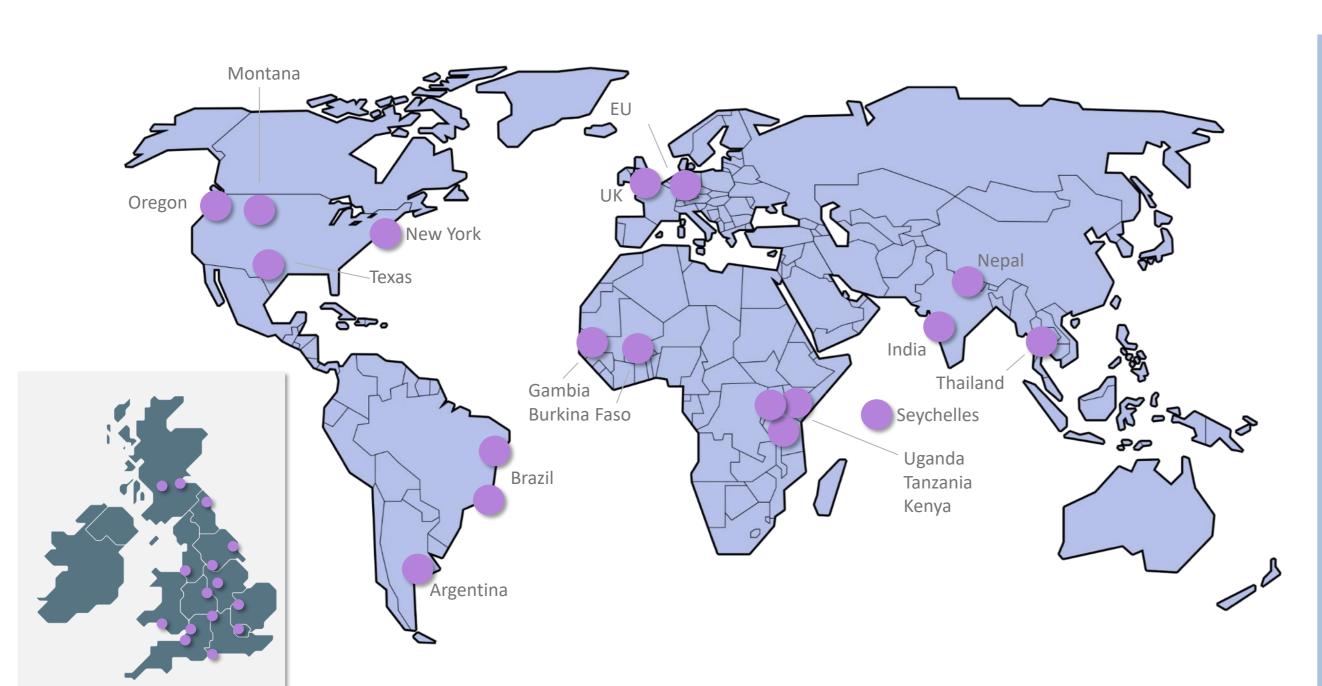
Induce an effective long-lasting immune response that confers protection against disease

- How do early signals shape long-term memory?
- How is protective immunity maintained?
- How is protective mucosal immunity generated and maintained?
- What do correlates of protection reflect in the periphery and the mucosa?
- What goes awry in at-risk groups?



Global network





To impact human health, largescale scientific collaborations & programmes are needed

You can't be expert on everything!

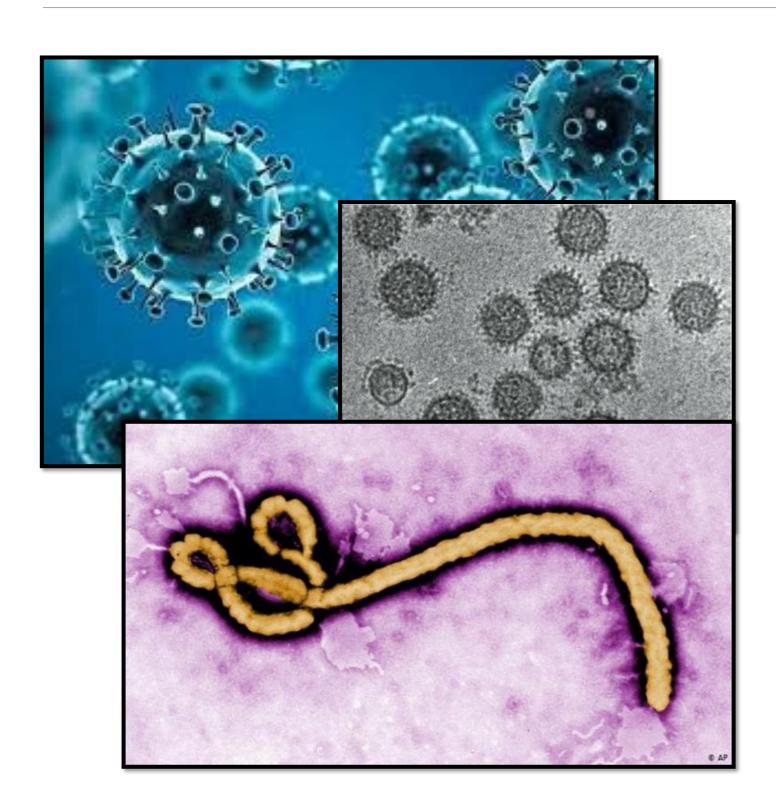
Inclusive not exclusive practices

- Basic science
- Translation Research
- Clinical trials
- Manufacturing
- Regulators
- Govt Bodies
- Right people
- Right place
- Right attitude



Activities....





Respiratory infections

- Respiratory Syncytial Virus
- Influenza
- COVID19
- Pneumococcus
- Meningococcus
- Pertussis
- Measles

Challenge models

- Respiratory Syncytial Virus
- Influenza
- COVID19
- Typhoid
- Paratyphoid

Other

- Clostridium difficile
- Non-typhoidal salmonella

- Malaria
- TB

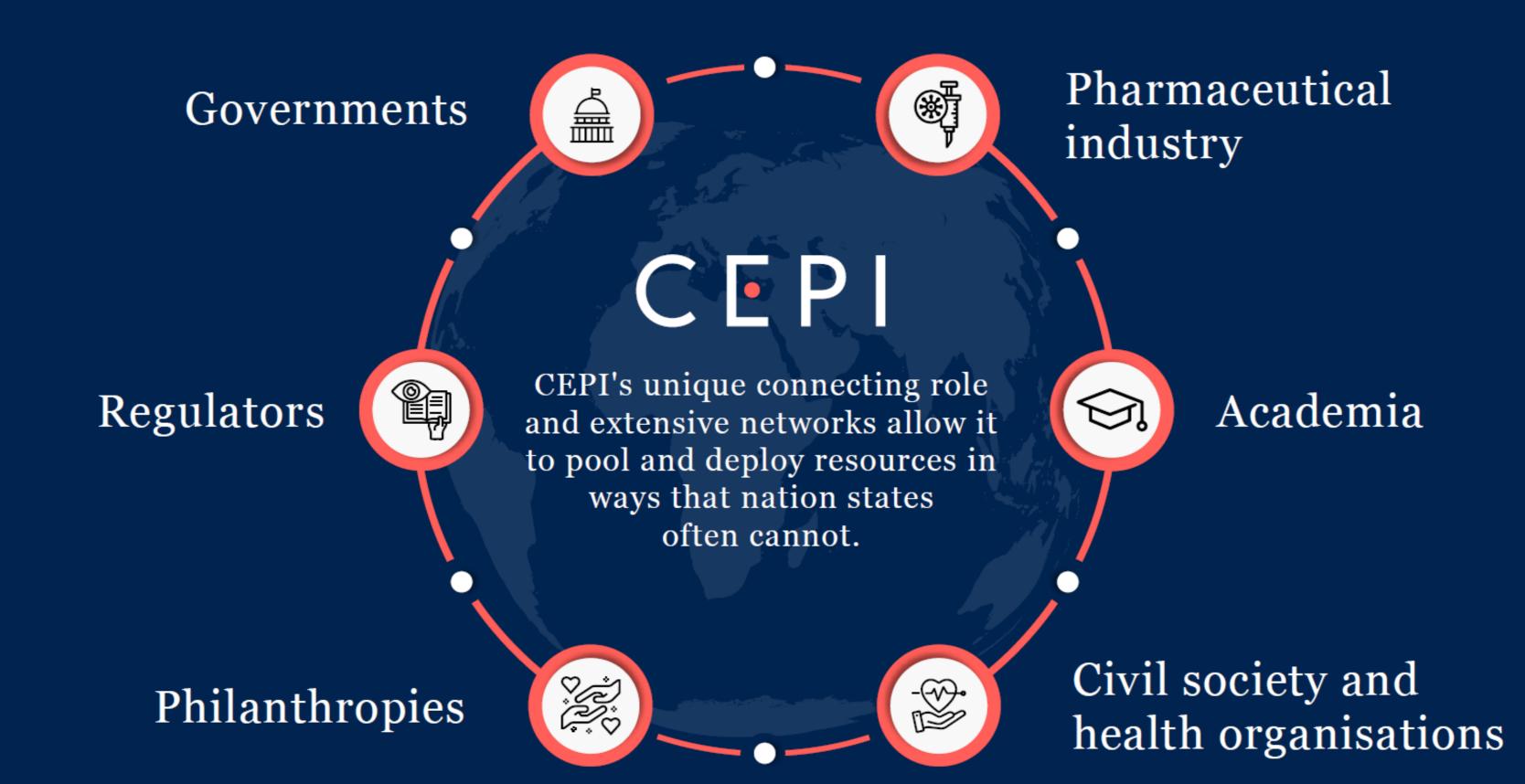
Outbreak Pathogens

- Q Fever
- Plague
- Congo-Crimean Haemorrhagic Fever
- Marburg virus
- Ebolavirus (sudan)
- Lassa virus
- Nipah virus
- Middle East Respiratory syndrome
- Junín virus
- Hantavirus
- Chikungunya virus
- Mayaro virus
- Oropouche virus



An introduction to CEPI

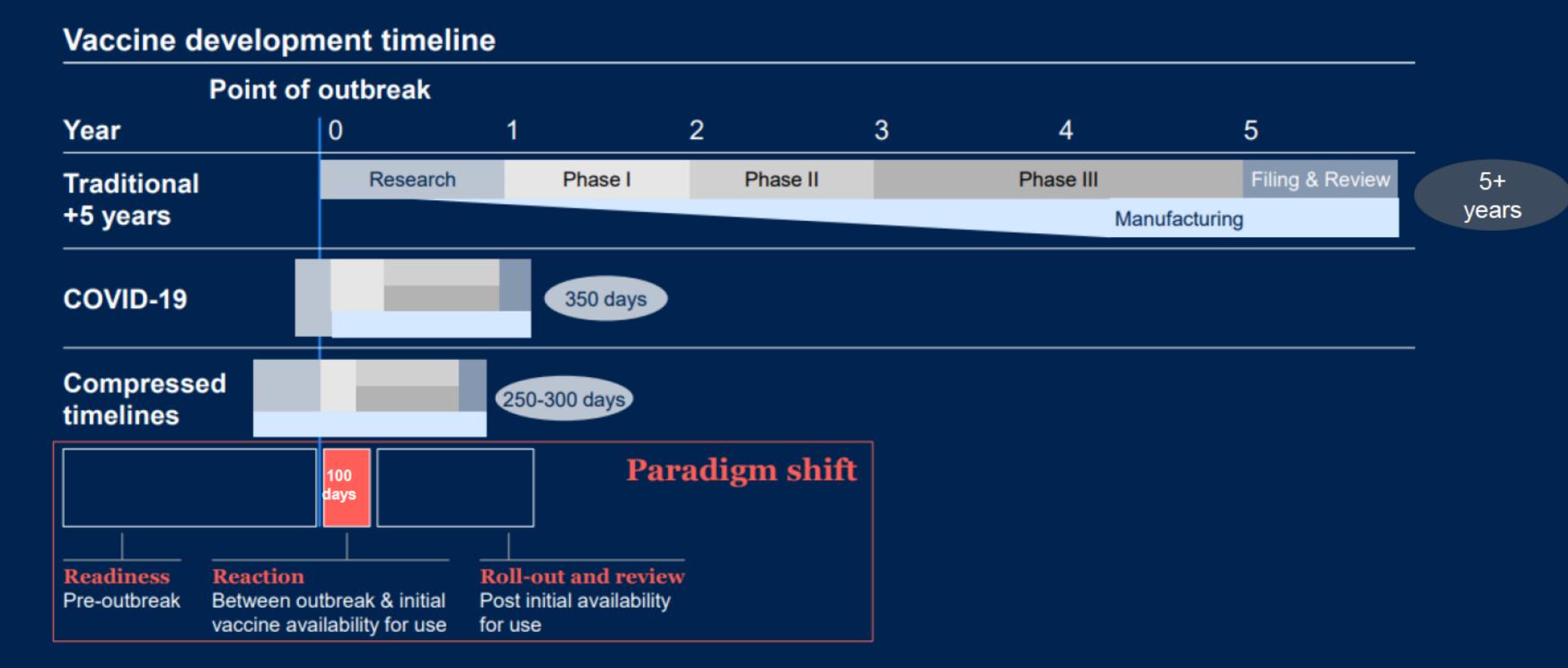
UKHSA Presents Adam Hacker PhD, Valentina Bernasconi PhD 10 July 2025



CEPI Regulatory network



Paradigm shift towards preparedness



CEPI's vaccine portfolio and networks



platform technologies

5 Chikun

Chikungunya 2 active

6

Lassa Fever 3 active

4

MERS-CoV 2 active

4

Nipah Virus 3 active

14

SARS-CoV-2 4 WHO EUL. 3 approved for domestic use 13

Broadly protective CoV vaccines 10 active 3

Rift Valley Fever **15**

Disease X platforms

5

Vaccine Manufacturing Network 18

Centralized Laboratory Network Labs 19

Preclinical Models Network Labs

The CEPI Centralized Laboratory Network (CLN)

CEPI CL Network: Standardized and validated clinical immunogenicity assays

- CEPI network of clinical immunogenicity labs for performance of immunology assays in support of global clinical trials
 - Leveraging International Standards usage
 - Standardized and harmonized lab testing methods across network
 - Technology Transfer and assay validations
- 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

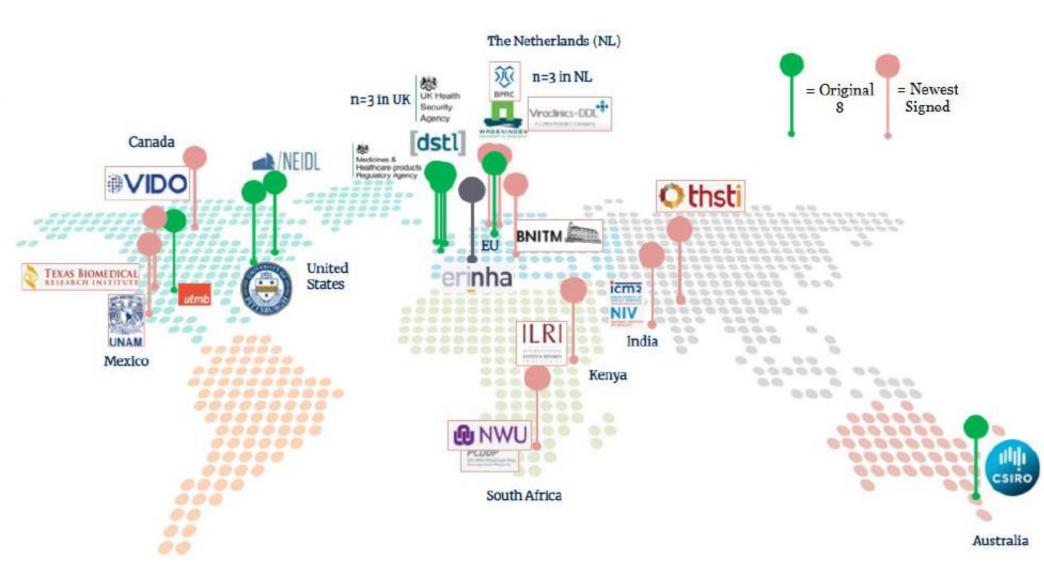


The CEPI Preclinical Model Network (PMN)

CEPI PM Network: Preclinical animal model development and vaccine candidate testing

- 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, and other Disease X approaches (+ SARS-CoV and SARS-CoV-2)
 - Small and large species, including NHP
- Compliance with high animal ethics standards; partnership and reviews by https://www.nc3rs.org.uk/
- High-quality research supported by established quality systems or well-documented through protocol-specified methods





CEPI's Experience with UKHSA

Highly responsive contract work filling specific UK Gov and CEPI research needs and meeting 100 Days Mission Objectives

- Preclinical assay development/optimization/qualification/validation
 - Leading tech transfer and performance of SARS-CoV-2, MPOX, Influenza and other assays
 - Assay training to other recipient organizations
- Preclinical sample analysis for vaccine developers
 - Assay data collection for regulatory packages
- Proof of concept model development studies for CEPI Pathogens and for vaccine testing
 - Virus stock acquisition, production, and characterization; disease modeling
- Model refinement studies, including improved endpoints to address ethical vaccine efficacy testing
 - Incorporation of telemetry or remote monitoring strategies, defining biomarkers and correlates of immune protection, defining best immunoassays

Contact:

Vaccine Development and Evaluation Centre



VDEC@ukhsa.gov.uk

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