BEBPA

CEPI
The Coalition for Epidemic Preparedness Innovations

Standardization of Immune Response Assays to COVID-19 Vaccines

A Year's Experience Transferring Assays to a Global Network of Labs



31st August 2021

Welcome & Opening Comments

Moderator:
Laureen Little

BEBPA President &
Principal Consultant
Quality Services
In Washington, USA

Hiking in
Southern California, USA

Who is BEBPA?

Located in the USA

A non-profit organization

Founded in 2008

International Board

Founded by Dr. Laureen Little

Biopharmaceutical Industry

Platform for communication

Hallway conversation with other scientists

What Does BEBPA Do?

Identify	Organize	Form	Publish
Identify common technical issues faced by the biopharmaceutical community.	Organize highly scientific not-for-profit conferences, to discuss these common technical issues.	Form white paper working groups to brainstorm and share problem solving approaches	Publish non-consensus white papers delineating various approaches to previously identified problems

Being Interactive!

Pre-Pandemic

Pandemic

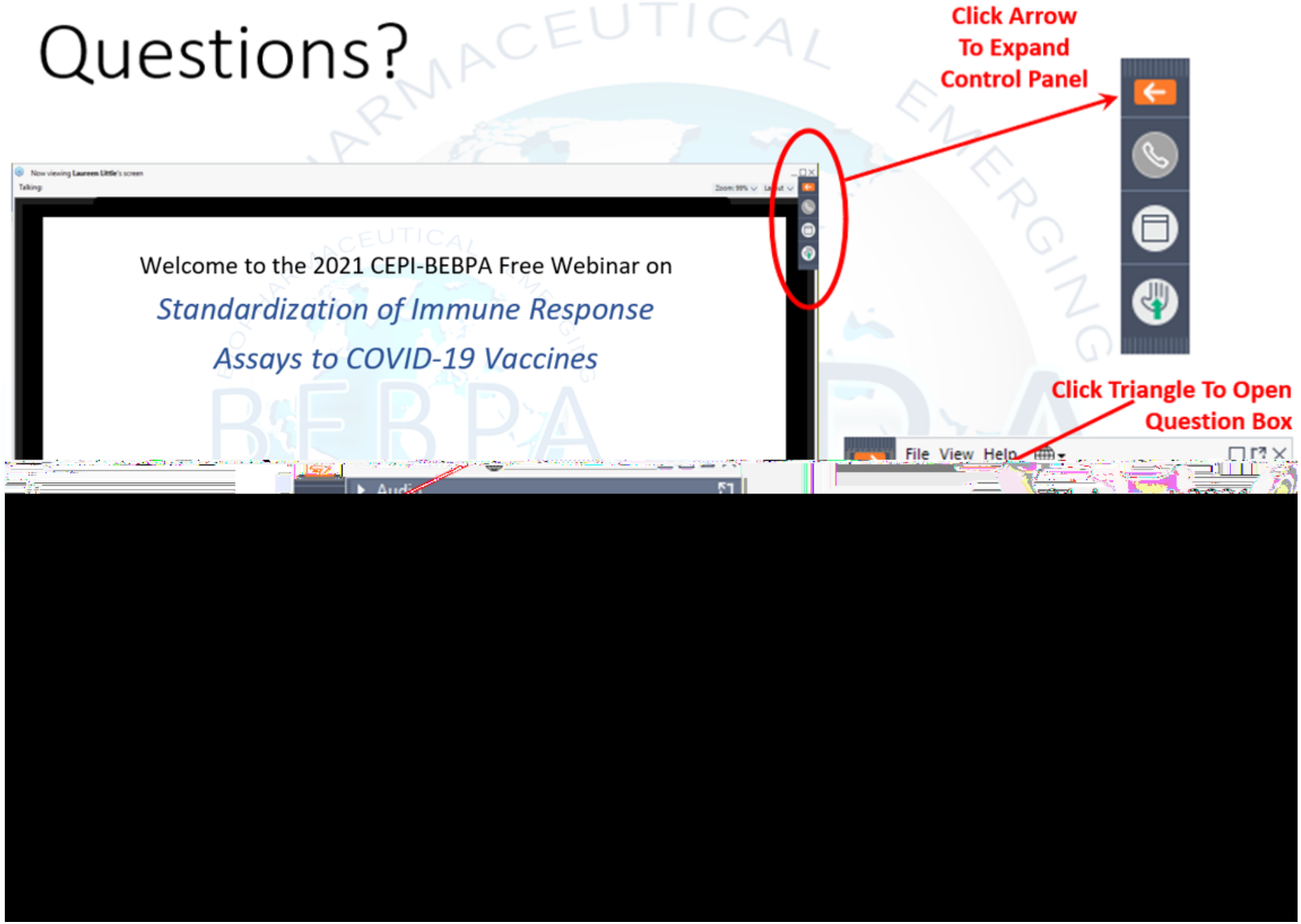
Let’s Keep it interactive…..

- Ask Questions
- Join our Social Media
- Answer our poll questions
- Download additional information

Questions?

All Attendees:

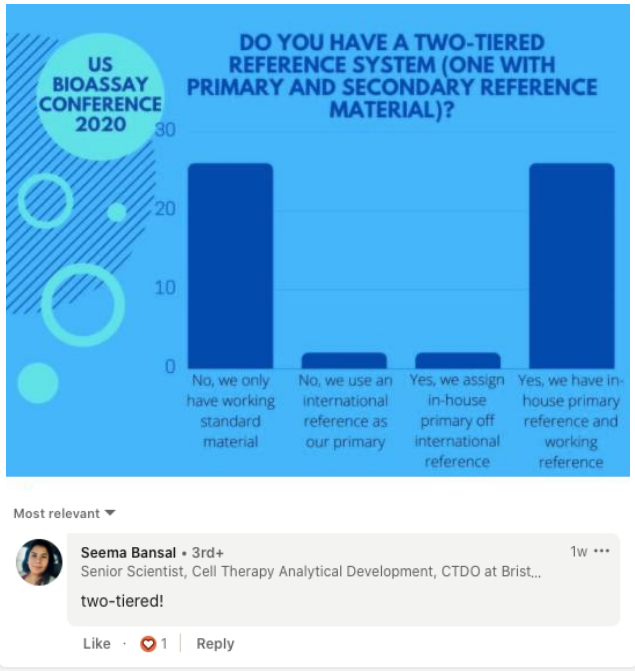
Please **type your questions at any time** into the Questions box! If we don't answer your question verbally during the session, we will answer it after the Webinar finishes and email the responses to all attendees. Thank you!

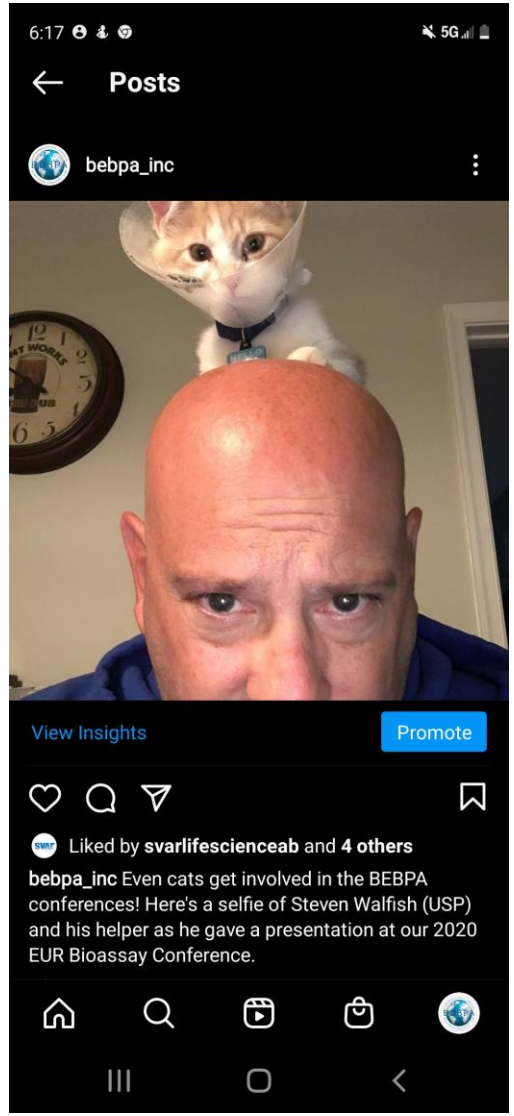


HOW TO DOWNLOAD HANDOUTS FROM CONTROL PANEL

BEBPA's Social Media

SCAN ME





www.cepi.net

@CEPIvaccines

2021 BEBPA/CEPI WEBINAR

Audience Survey

Distribution of the WHO International Standard for anti-SARS-CoV-2 immunoglobulin from Dec 2020 until July 2021.

More than 2400 units were shipped by NIBSC to 581 individual customers in 46 different countries worldwide

SESSION 1
A Year in Review

CHAIR:

Ivana Knezevic WHO, Team Leader, Norms and Standards for Biologicals, Quality, Safety and Standards; COVAX, Co-Lead of the Enabling Sciences SWAT Team

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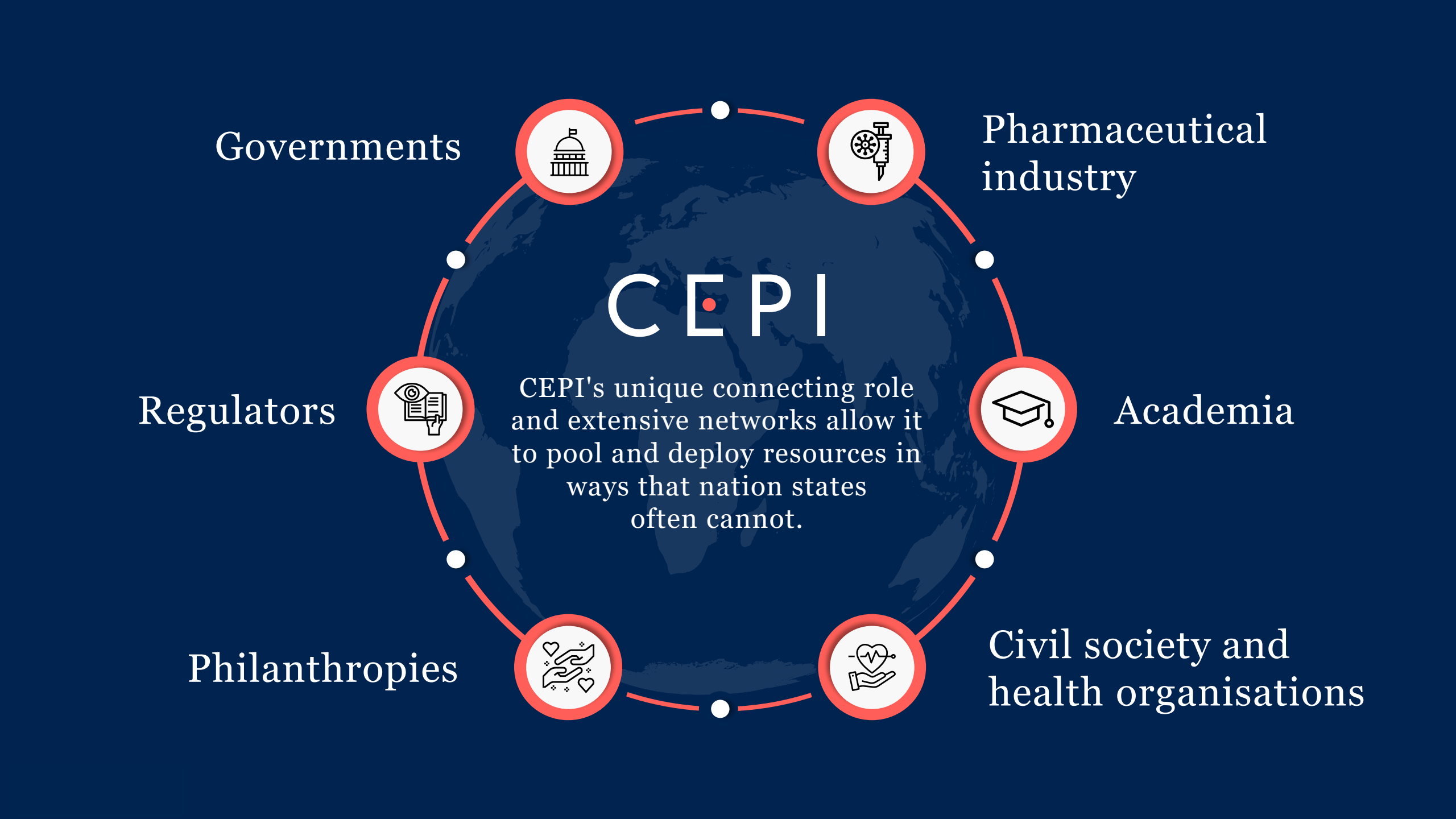
Overview on CEPI and COVAX

Paul Kristiansen CEPI, Head of Biological Standards & Assays, Preclinical Immunology; COVAX, Co-Lead of the Enabling Sciences SWAT Team


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 organisations

A global partnership

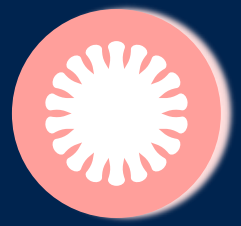
Vision

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

Mission

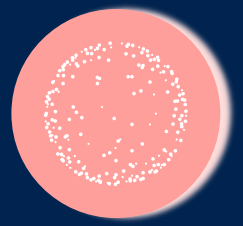
To accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need.

CEPI's vaccine portfolio



MERS

5 vaccine candidates

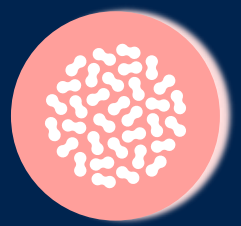


Lassa

6 vaccine candidates

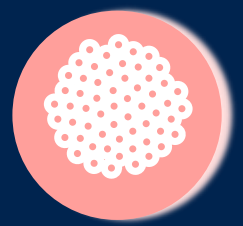
Nipah

4 vaccine candidates



Chikungunya

3 vaccine candidates

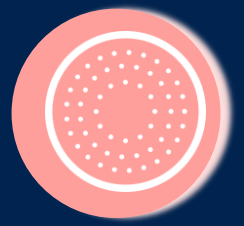


Rift Valley fever

2 vaccine candidates

COVID-19

12 vaccine candidates – 11 in active dev.



Disease X

3 platform technologies

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www.cepi.net/research_dev/our-portfolio/

CEPI and COVAX

- COVAX is the vaccines pillar of the ACT Accelerator, a collaboration between CEPI, Gavi and the World Health Organization, with key delivery partner UNICEF.

- COVAX provides countries access to the world's largest portfolio of vaccine candidates, actively managed by CEPI's R&D experts.
- Over 200 million COVAX doses delivered worldwide
- COVAX also provides cross-cutting support to vaccine developers through SWAT teams.
- This webinar is organized by the Enabling Sciences SWAT team, which supports COVID-19 vaccine developers in the area of standards, assays and animal models.

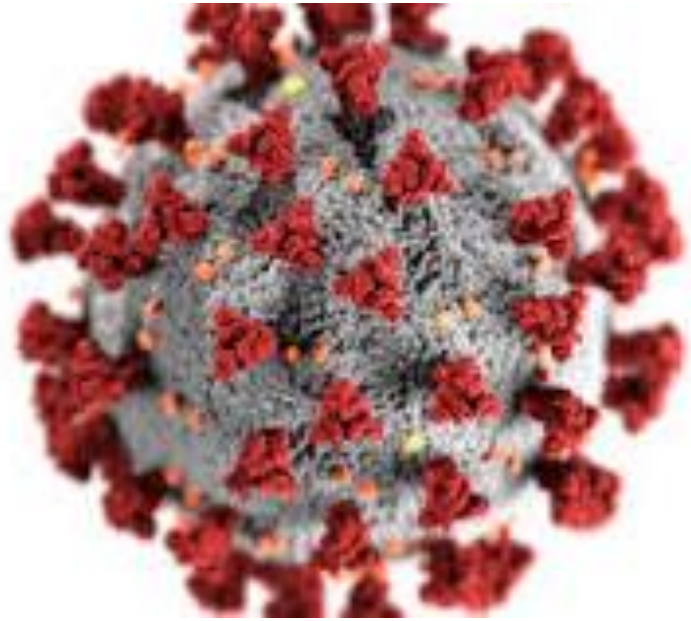
A sustainable partnership

CEPI Centralized Laboratory Network: key features

Valentina Bernasconi Scientist at CEPI, Project Leader of CEPI Centralized Laboratory Network

COVID-19 vaccine development landscape

- More than 400 vaccine developers worldwide
- Comparing immune responses against different vaccine candidates is challenging
    - Different stages of development
    - Biological variation
    - Technical differences (how and where specimens are collected, transported, stored, and analyzed)
    - Different technology platforms (e.g. recombinant viral vectors, inactivated vaccines, recombinant proteins and nucleic acids)
    - Lack of standardization among different assays and different testing laboratories



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How to improve immunological assay standardization?

- **Reference reagents at NIBSC, a WHO Collaborative Center**
  - Research reagent and panels
  - WHO International Antibody Standard established by the ECBS

  COVID-19-related research reagents available from the NIBSC

- **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

How to improve immunological assay standardization?

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Objectives of the Network

The CEPI Centralized Laboratory Network is open to **all** COVAX funded and non-funded vaccine developers:

- To test samples from pre-clinical to Phase III clinical studies for key immunogenicity and efficacy endpoint evaluation
- To support SARS-CoV-2 vaccine developers in the pathway towards licensure
- To help the identification of Immune Correlates of Protection
- To facilitate rapid evaluation, approval, and dissemination of the most effective vaccine candidates

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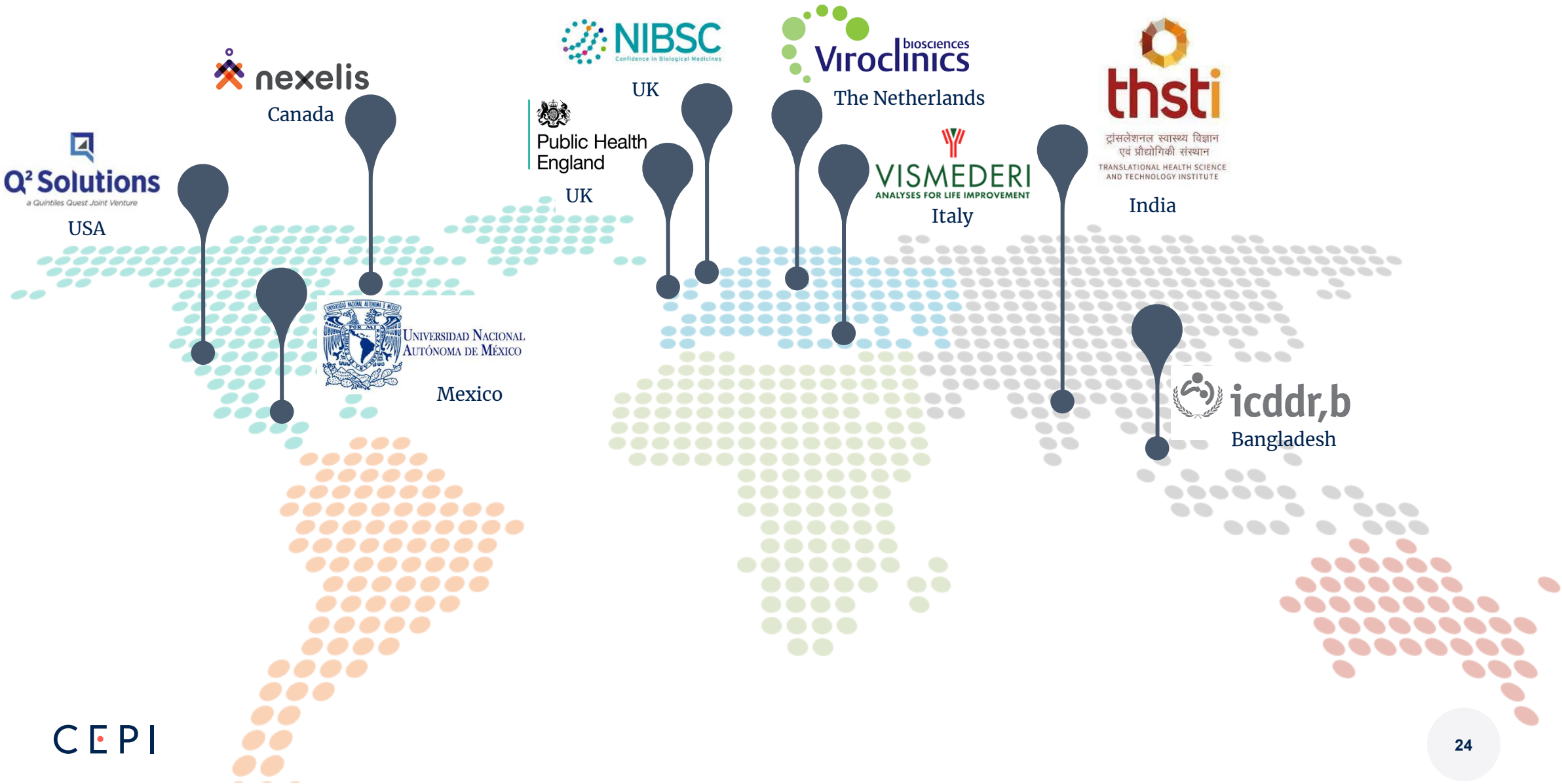
CEPI Centralized Laboratory Network



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Assays available within the Network

	Binding antibodies	*Neutralizing antibodies*		*T cells*
	ELISA	**Pseudo typed virus neutralization**	**Wild type virus neutralization**	**ELISPOT**
	• Stabilized pre-fusion full length S, RBD, N • Total IgG in serum	• Pseudo particles with VSV backbone • Safer testing alternative (no BSL3 required)	• Colorimetric microneutralization assay • Victoria virus isolate	• Peptide pool of the whole S protein • Cytokines: IFNy (Th1), IL-5 (Th2)
Qualification (Nexelis/PHE)	Completed	Completed	Completed	Completed
Tech transfer (receiving labs)	In progress (completed for some labs)	In progress (completed for some labs)	In progress (completed for some labs)	In progress
Validation (Nexelis/PHE)	Completed	Completed	Completed	NA
Average current capacity (samples per week)	2500	1500	500	500

- *Common key reagents are provided to all the Labs in the Network*
- *Scalable throughput*

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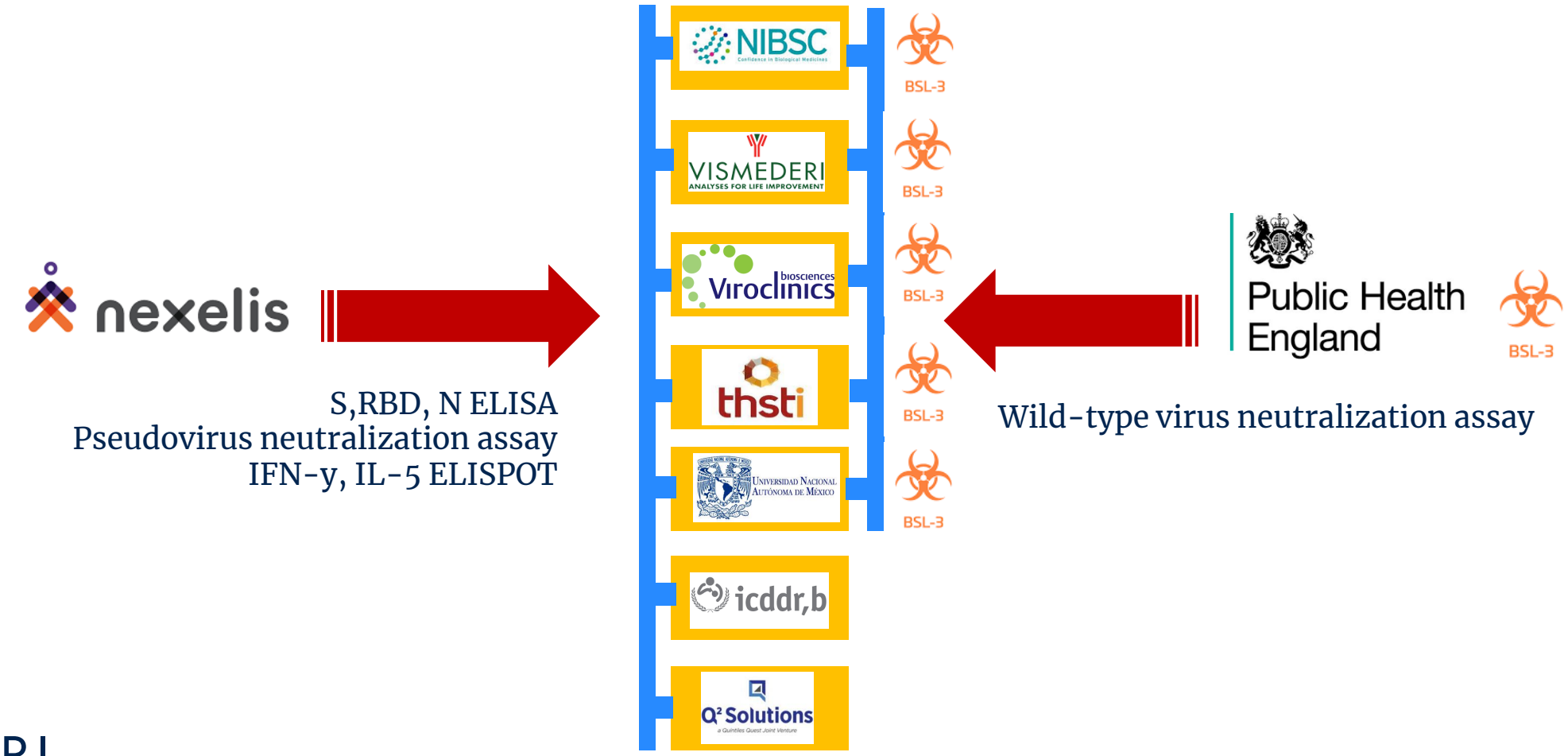
Assay harmonization and tech transfer

Common SOPs, Critical reagents, Controls and panels *



*Including bridging with WHO International Antibody Standard

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Elements for Assay Transfer Success (1)

❖ Key reagents

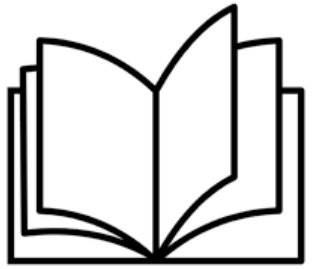
To reduce interlaboratory variability

- Serum/PBMC (controls, reference standards, panels)
- Coating antigens (S, RBD, N)
- Live viruses / Pseudoviruses (original strain and variants)

❖ Transfer protocol

To describe the steps to be performed for each type of assay

- Assay overview
- Gap analysis to highlight differences reference labs and recipient labs and mitigate the impact of the gaps
- Laboratory comparison assessment to ensure that comparable results can be obtained across laboratories
- Assay performance evaluation at recipient laboratories to ensure assay performances were not impacted by the transfer (precision, dilutional linearity, clinical specificity)
- QC charts and proficiency panel to assess the assay performance over time



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Elements for Assay Transfer Success (2)

❖ **Training and logistics**

To coordinate the tech transfer process

- Online training, videos, walk through method SOPs, ad hoc teleconferences
- Validated SoftMaxPro protocols for data analysis
- Management of shipments (Import permits/documentation, chain of cold , dry shipper)

❖ **Communication and teamwork**

To make sure all the participants to the program are aligned

- Monthly meetings and ad hoc teleconferences
- Joint network calls and lessons learned exercises

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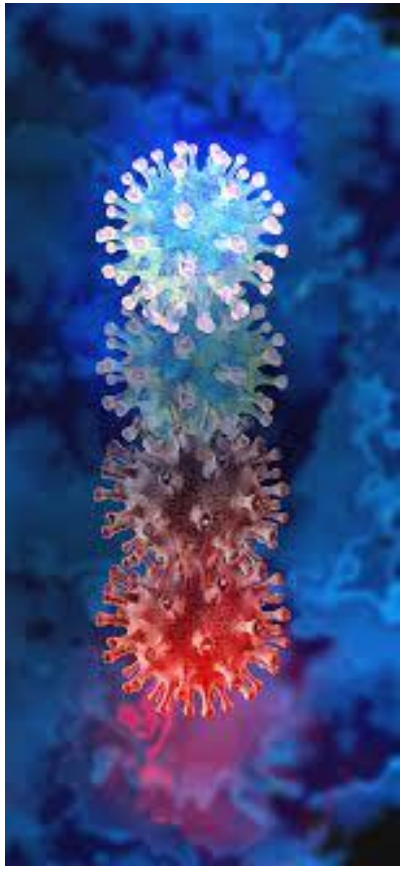
Tackling variants

- All viruses, including SARS-CoV-2, change over time
- CEPI Centralized Laboratory Network opens for testing of vaccines performance against SARS-CoV-2 variants:
  - Alpha, B.1.1.7, first identified in the UK
  - Beta, B.1.351, first identified in South Africa
  - Gamma, P.1, first identified in Brazil
  - Delta, B.1.617, first identified in India
- New circulating SARS-CoV-2 strains that might be tackled:
    - Lambda, C.37, first identified in Peru
    - Other variants that will potentially emerge in the future



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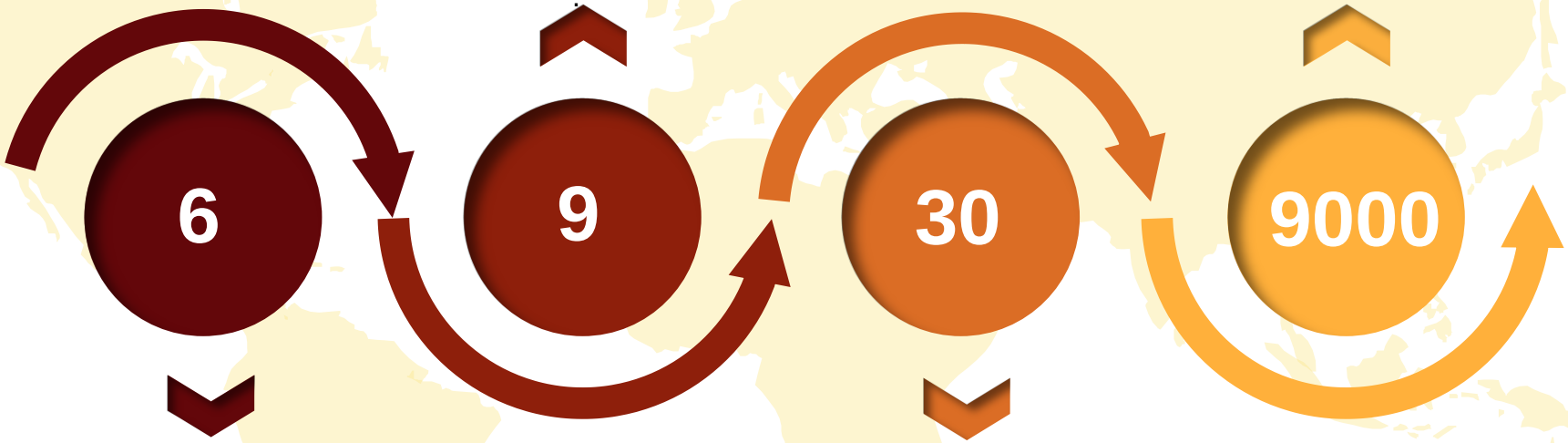
CEPI Centralized Laboratory Network

2020-21 achievements in numbers



Available assays

S,RBD,N ELISA assay
Pseudo virus neutralization assay
Wild type virus neutralization assay (including variants)
IFNy, IL-5 ELISPOT assay

Laboratories worldwide

Nexelis (Canada), Q2 Solutions (US), PHE Porton Down (UK), NIBSC (UK), VisMederi Srl (Italy), Viroclinics (The Netherlands), icddr,b (Bangladesh),THSTI (India), UNAM (Mexico)

COVID-19 vaccine developers engaged

In 3 continents among CEPI-funded and non CEPI-funded developers

Samples requested for analysis

Pre-clinical and clinical (Phase I-III) studies

Lessons learned from one year of transferring assays to a global network of laboratories

Arun Kumar Scientist at CEPI, Co-lead of CEPI Centralized Laboratory Network

Centralized Lab lessons learned in practice

- **Objectives**
  - to identify how to sustain strengths and improve weaknesses on the project
  - To define recommendations to improve future performance

- **Areas of focus**
  1) Agreements and contracts
  2) Communication, teams and project management
  3) Tech transfer process
  4) SOPs, instructions and training
  5) Supply of key reagents and consumables

- **Frequency**

Every 6 months since project initiation

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Agreements and contracts

1. **Frame the contract with the laboratories with a broader scope** to allow laboratory staff to be dedicated to the project 100%
   Procurement agreement does not allow labs to dedicate staff for the projects, properly support the labs with instruments and software

2. **Train the core staff on the legal basics**
   The project was managed by scientific staff with no legal background

3. **Give the labs all the information needed to estimate costing** for tech transfer and sample testing
   Some labs underestimated the work needed to complete the tech transfer process and the costs liked to it

4. **Prepare a Framework in advance and do not hurry contract negotiation**
   Contract negotiation took an average of 3 months per laboratory; despite this, many amendments were needed at later stages

Communication, teams and project management

1. **Define project governance** (roles and responsibilities, meeting frequency)
   Weekly calls were organized with transferring labs and monthly calls with receiving labs; list of team members was shared with everyone working on the project and periodically updated

2. **Identify appropriate points of contact with suitable expertise** (PM, legal/business, scientific lead, tech transfer expert) **in each lab**
   Delays in the response were due to lack of staff on the project and significant troubleshooting that was not taken into considerations

3. **Implement a "time rule" for feedbacks and encourage transparent communication**
   Technical questions and feedback on results took longer than expected and this delayed the completion of the transfer process

4. **Identify the risks related to the project and be flexible to adapt** to different situations, cultures and needs

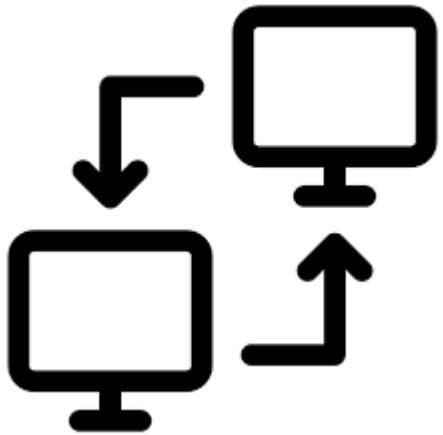
Tech transfer process

1. **Prepare a comprehensive tech transfer plan defining each step from the beginning, share the plan with the labs and support them through the process**
   More guidance was needed to go through the steps of the tech transfer as it was not clear from the beginning

2. **Allocate enough staff for each step of the transfer**
   The amount of work to complete the tech transfer was underestimated

3. **Complete assay qualification/validation prior to transfer**
   Assays validation was not completed before the tech transfer process started

4. **Develop a "Tech transfer FAQ"** available to new labs coming onboard
   Most of the time labs have the same questions related to the tech transfer process



SOPs, instructions and training

1. **Provide complete and approved SOPs, templates and instructions in advance and strictly follow them**
   Complete SOPs were shared only after the tech transfer start

2. **Create a common space** (e.g., SharePoint) **with appropriate structure to share SOPs and other documents among labs and a system to track documents versions**

3. **Define a process to approve documents** (e.g., lab-specific SOPs, tech transfer plan, qualification reports)

4. **Offer face-to-face training when possible and ad-hoc troubleshooting sessions**
   Due to the pandemic situations and travel restrictions online training only was provided

5. **Support the labs with up-to-date equipment and software licenses**

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Supply of key reagents and consumables

1. **Define critical reagents and develop a reagents inventory**

2. **Produce serum panels and pathogen-specific reagents** (e.g.: viruses, coating antigens) **prospectively** to increase the stocks and be able to cover any possible troubleshooting or issue during tech transfer/clinical testing

3. **Map the import/export process steps in advance** and share export/import permit requirements

4. **Pay attention to shipment for critical reagents** (use reliable shipment companies, don't ship during holidays, inform about shipping dates and tracking numbers)

5. **Create a central procurement system for supplies and reagents and identify alternative vendors**

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Lessons learned take-home

Teamwork

Defined framework

Competent stuff

Training

Reagents supply

Flexibility

Transparent communication

Break

CEPI

Expert Panel Discussion & Audience Q&A

CEPI

Valentina Bernasconi

CEPI

Moderator

Mark Manak

CEPI

Rubhana Raqib

icddr,b

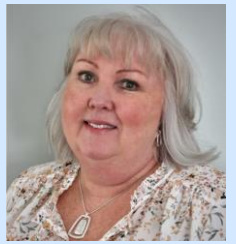
Mark Page

NIBSC

Confidence in Biological Medicines

Luc Gagnon

nexelis



Leslie Wagner

FDA

Pamela Proud

Public Health England

Robert Bailer

Q² Solutions

a Quintiles Quest Joint Venture

Guruprasad Medighesi

thsti

Ulrike Herbrand

charles river

Mabel Rodriguez

Universidad Nacional Autónoma de México

Angela Balgobind

Viroclinics biosciences

Silvia Grappi

VISMEDERI

ANALYSES FOR LIFE IMPROVEMENT

Siân Estdale

labcorp

To guide the discussion

1) What could have been done to better prepare for setting up of the Network?

2) What worked very well and should be kept in the future?

3) What could be improved?

SESSION 2
Moving to the Future

CHAIR:

Janet Lathey Program Officer, Office of Biodefense, Research Resources, and Translational Research, DMID/NIAID/NIH

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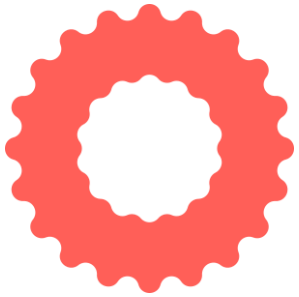
CEPI Centralized Laboratory Network: planning for the future

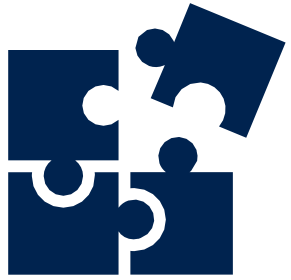
Valentina Bernasconi Scientist @CEPI, Lead of CEPI Centralized Laboratory Network

CEPI's aspiration: transform the R&D for preparedness and response – CEPI 2.0



Accelerate development of vaccines against emerging infectious diseases and enable equitable access to these vaccines for affected populations during outbreaks

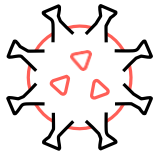
100 days from pathogen characterization to clinical data for deciding emergency use



Systematically reducing the risk of future epidemics and pandemics

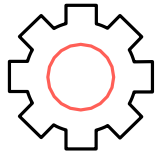
Strategic Objectives of CEPI 2.0

Prepare



For known epidemic and pandemic threats

Transform



The response to the next novel threat

Connect

To enhance and expand global collaboration

CEPI 2.0 Strategic Objectives

Prepare for known epidemic and pandemic threats

Develop vaccines and promising biologics against the most prominent known threats, building on COVID-19 achievements and CEPI 1.0

- End the COVID-19 pandemic
- Eliminate the risk of coronavirus pandemics
- Accelerate development of vaccines and other biologics against known high- risk pathogens

Transform the response to the next novel threat

Harness innovations in technology and systems to significantly reduce the global vulnerability to threats of novel pathogen outbreaks

- Use vaccine development innovations to give us a head-start on other novel threats
- Invest and scale critical research innovations which underpin rapid vaccine development
- Invest in innovations so vaccine manufacturing is cheaper, faster, and closer to an outbreak

Connect to enhance and expand global collaboration

Drive the development of a post-pandemic consensus and design a more robust and effective global preparedness and response architecture

- Build a strong, post-pandemic global coalition
- Push for collaboration and solutions which will enable a faster system-wide response
- Coordinate a scalable on-demand manufacturing network

CEPI Strategic Objectives and the Centralized Lab

Respond to outbreaks

Accelerate the research, development and use of vaccines during outbreaks for CEPI priority pathogens

- Create a Network of laboratories to accelerate testing of vaccines against SARS-CoV-2

Prepare for known epidemic and pandemic threats

Develop vaccines and promising biologics against the most prominent known threats, building on COVID-19 achievements and CEPI 1.0

- Use the Centralized Laboratory Network for the other CEPI priority pathogens from CEPI 1.0

Transform the response to the next novel threat

Harness innovations in technology and systems to significantly reduce the global vulnerability to threats of novel pathogen outbreaks

- Use the CL Network framework to give us a head-start on the same approach for other novel threats
- Invest and scale critical research innovations which underpin rapid vaccine testing
- Invest in innovations so vaccine testing is cheaper and faster

Connect to enhance and expand global collaboration

Drive the development of a post- pandemic consensus and design a more robust and effective global preparedness and response architecture

- Build a strong, post-pandemic global network
- Push for collaboration and solutions which will enable a faster system-wide response
- Coordinate a scalable on-demand testing network
- Align with other initiatives worldwide (for example G7)

Our aspiration for immunogenicity testing

100 days from pathogen characterization to clinical data for deciding emergency use

Reagents production

Assay development

Assay Qualification/Validation

reagent production and

transfer to the other labs of the

Sample testing

Final report

CEPI

Reducing bottle necks in immunogenicity testing

100 days

Reagents production	Assay development	Assay Qualification/Validation	Scale up of reagent production and shipment	Tech transfer to the other labs of the network	Sample testing	Final report
- Release of the virus sequence	- Trained staff - SOPs development	- Source of convalescent sera - Q/V protocol development	- Manufacturing capacity	- Tech transfer protocol development - BSL3/BSL4 facility	- Labs testing capacity	- QA - Secure data handling

- Lab selection and engagement
- Framework agreement in place between the labs and CEPI
- Supply of consumables and raw materials

CEPI

Reducing bottle necks in immunogenicity testing

100 days

Reagents production

- Release of the virus sequence

- Build partnerships with surveillance centers

Assay development

- Trained staff
- SOPs development

- Reserve staff
- Develop general SOPs for standard

Assay Qualification/Validation

- Source of convalescent sera
- Q/V protocol development

- Network of potential partners for sourcing serum
- qualify / validate assays for prototype

Scale up of reagent production and shipment

- Manufacturing capacity

- Rely on more than one lab

Tech transfer to the other labs of the network

- Tech transfer protocol development
- BSL3/BSL4 facility

- Develop general tech transfer protocol development

Sample testing

- Labs testing capacity

- sharing SOPs and reagents to labs outside the network

Final report

- QA
- Secure data handling

- Setting up data sharing system

- Lab selection and engagement
- Framework agreement in place between the labs and CEPI
- Supply of consumables and raw materials

- Early selection and contracting of laboratories with BSL3/4 capacity
- Work with different suppliers

Summary

1. Expand the CL network to include new labs
2. Tackle new diseases
3. Align with CEPI 2.0 objectives
4. Be prepared for the future!

Future pandemics – Are we better prepared?

Bassam Hallis Public Health England, Head of Pre-Clinical Dev & General Project Manager National Infection Service

CEPI

Public Health England

How did/are we responding?

- Globally
  - Scientific community collaboration on assays (WHO) and reagents (GHSI, PHE, BEI, EVAG etc)
  - WHO Solidarity Study - Global Platform trial
  - Centralised Laboratory Network (CEPI)

- Nationally
  - UK Vaccine Task Force – Standardised assays

Public Health England

Global collaborations - examples

NIBSC

1. Research Reagents – “a study”
2. Interlaboratory study
3. International Reference standard (…with CEPI and WHO)

https://nibsc.org/products/brm_product_catalogue/who_standards.aspx

https://www.european-virus-archive.com/

https://www.niaid.nih.gov/research/bei-resources-repository

Public Health England

WHO Solidarity and Bio-Hub

https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments

https://www.who.int/news/item/24-05-2021-who-and-switzerland-launch-global-biohub-for-pathogen-storage-sharing-and-analysis

WHO and Switzerland launch global BioHub for pathogen storage, sharing and analysis - The World Health Organization (WHO) and the Swiss Confederation today signed a Memorandum of Understanding to launch the first WHO BioHub Facility as part of the WHO BioHub System, which was announced in November 2020.

Public Health England

CEPI's Centralised Laboratory Network

https://cepi.net/news_cepi/cepi-establishes-global-network-of-laboratories-to-centralise-assessment-of-covid-19-vaccine-candidates/

Public Health England

UK Vaccine Task Force

https://www.gov.uk/government/publications/the-vaccine-taskforce-objectives-and-membership-of-steering-group

The Vaccine Taskforce (VTF) was set up to drive forward the development and production of a coronavirus vaccine as quickly as possible, bringing together government, academia and industry.

The Taskforce was asked to deliver 3 objectives:

1. Secure access to promising vaccine/s for the UK population
2. Make provision for international distribution of vaccines
3. Support industrial strategy by establishing a long-term vaccine strategy plan to prepare the UK for future pandemics

Public Health England

100 Days Mission – CEPI – G7

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/992762/100_Days_Mission_to_respond_to_future_pandemic_threats__3_.pdf

Sir Patrick Vallance and Melinda French Gates

A 100 Days Mission for Diagnostics, Therapeutics and Vaccines to respond to future pandemic threats.

Reducing the impact of future pandemics by making Diagnostics, Therapeutics and Vaccines available within 100 days - A report to the G7 by the pandemic preparedness partnership - 12 June 2021

“Vaccines ready to be produced at scale”

Public Health England

G7 Clinical Trial Charter

https://www.gov.uk/government/publications/g7-health-ministers-meeting-june-2021-communique/g7-therapeutics-and-vaccines-clinical-trials-charter

Principles 6 and 7

To expeditiously advance the development and testing of vaccines, as well as the investigation of correlates of protection and therapeutics, we will agree that as soon as novel pathogens or viral variants appear and become accessible to a G7 country, **the G7 will rapidly share testing methods, reference standards and testing materials (as they relate to the virus strain) with any other G7 country and beyond, via an open material transfer agreement.** We will take this forward through **the G7's national research bodies, and where appropriate contract research organisations, and will look to expand on the work of the Global Health Security Initiatives (GHSI), WHO and the Coalition for Epidemic Preparedness Innovations (CEPI).**

Public Health England

G7 Clinical Trial Charter

To make vaccine development faster, **we will work to develop a framework to coordinate testing methodology and share testing materials**, wherever possible, in response to pandemic threats. Where this is not possible, we will seek ways to compare the results of vaccine assessments in clinical trials. We will take this forward through the G7's national and international research bodies, and where appropriate contract research organisations, and will look to expand on the work of GHSI, WHO, and CEPI.

Public Health England

Were we adequately prepared?

1. Sufficient national and international plans in place?
2. Complex and bureaucratic international processes
3. Competition vs Collaboration
4. Role of National Labs vs CROs vs Academia
5. Regulatory Compliance - ‘Perfect was enemy of the good’

Public Health England

What's next?

WHO Bio-Hub and Reference Laboratories

International provision of critical reagents (BEI, EVAG, PHE, GHSI etc)

CEPI Centralised Laboratory Network

G7 Clinical Trial Charter

Bilateral Agreements

UK Vaccine Task Force

Expert Panel Discussion & Audience Q&A

CEPI

Valentina Bernasconi

CEPI

Moderator

Mark Manak

CEPI

Rubhana Raqib

icddr,b

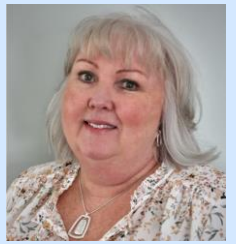
Mark Page

NIBSC

Confidence in Biological Medicines

Luc Gagnon

nexelis



Leslie Wagner

FDA

Pamela Proud

Public Health England

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Q² Solutions

a Quintiles Quest Joint Venture

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Angela Balgobind

Viroclinics biosciences

Silvia Grappi

VISMEDERI

ANALYSES FOR LIFE IMPROVEMENT

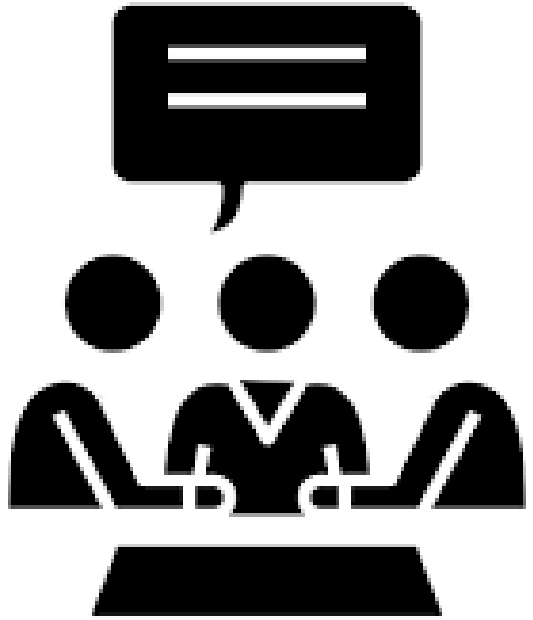
Siân Estdale

labcorp

To guide the discussion

1) *What's the major bottleneck we encountered and how to solve it in the future?*

2) *What's the most important step the Network can take to prepare for the next emerging pathogen?*



CEPI Centralized Laboratory Network: How to Become Involved?

Ana Paula de Almeida Aranha CEPI, Senior Project Manager of Centralized Laboratory Network

How to Become Involved?

1. If you are a vaccine developer

2. If you are a laboratory

1) Vaccine developers - apply today for sample testing

- **All** COVID-19 vaccine developers are invited to apply to use the Centralized Laboratory Network

- **To apply for sample testing, please complete and submit the Sample Analysis Request Form**

More info:
https://epi.tghn.org/covax-overview/enabling-sciences/#ref1

Any further question? Reach out to centralizedlab@cepi.net

CEPI

1) Vaccine developers - Practical info

Step 1: Complete the Sample analysis request form.

Please note incomplete applications will not be considered.

Step 2: Your requests will be reviewed by a CEPI internal committee.

We commit to get back to each Vaccine Developer applicant within two weeks.

Step 3: If your request is approved, CEPI will connect you with one of our partner labs.

Note 1: CEPI will fund the approved sample testing. Sample shipment costs and documentation related to the shipment of the samples is the Vaccine Developer's responsibility.

Note 2: Each Vaccine Developer owns the data generated by the analysis of its samples and should commit to share results with the broader research community

2) Laboratories - keep an eye on CEPI open CfPs

- **All** Laboratories are invited to apply to the next open Call for Proposals (CfPs) in autumn 2021
- CfP will be published on CEPI website: Calls for Proposals – CEPI

Eligibility criteria:

- Ability to perform one or more vaccine-relevant immunological assays for preclinical and/or human samples against SARS-CoV-2 and other CEPI priority pathogens
- Ability to perform studies under GLP/GCLP conditions or a quality system that assures data quality and integrity

Evaluation criteria:

- Applicant competencies, experience and track record
- Adequate capacity for the studies
- Appropriate quality systems in place
- Proven ability to maintain sufficient reagent stocks
- Appropriate project management capabilities
- Proven record of receiving samples from multiple geographical locations
- Ability to work in a network of international labs to harmonize protocols, reagents and data
- Competitive pricing

CEPI

Any further question? Reach out to centralizedlab@cepi.net

Webinar closure

Paul Kristiansen CEPI, Head of Biological Standards & Assays, Preclinical Immunology; COVAX, Co-Lead of the Enabling Sciences SWAT Team

CEPI

Read about us

THE LANCET

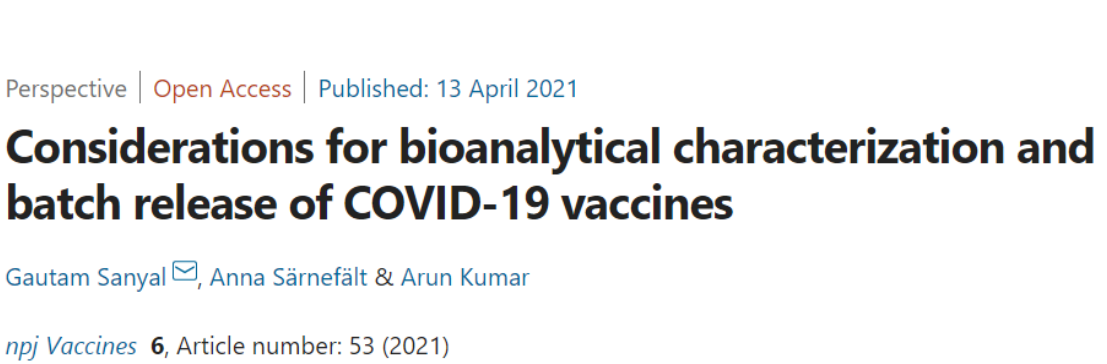
www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00982-X/fulltext#articleInformation

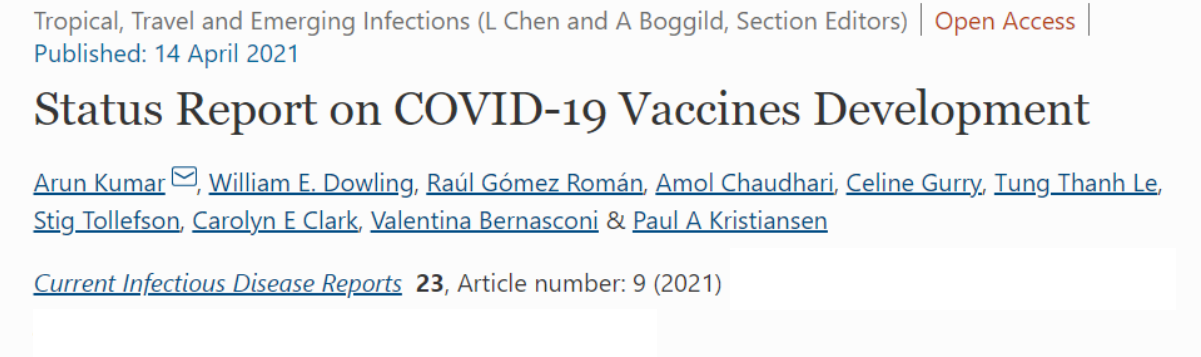
npj | vaccines

www.nature.com/articles/s41541-021-00317

Springer Link

www.link.springer.com/article/10.1007/s11908-021-00752-3





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www.cepi.net

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Patricia Koutz
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Catherine Pritchett

And the rest of the teams

Thank you for your participation

CEPI

Any further question?
Reach out to
centralizedlab@cepi.net