



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

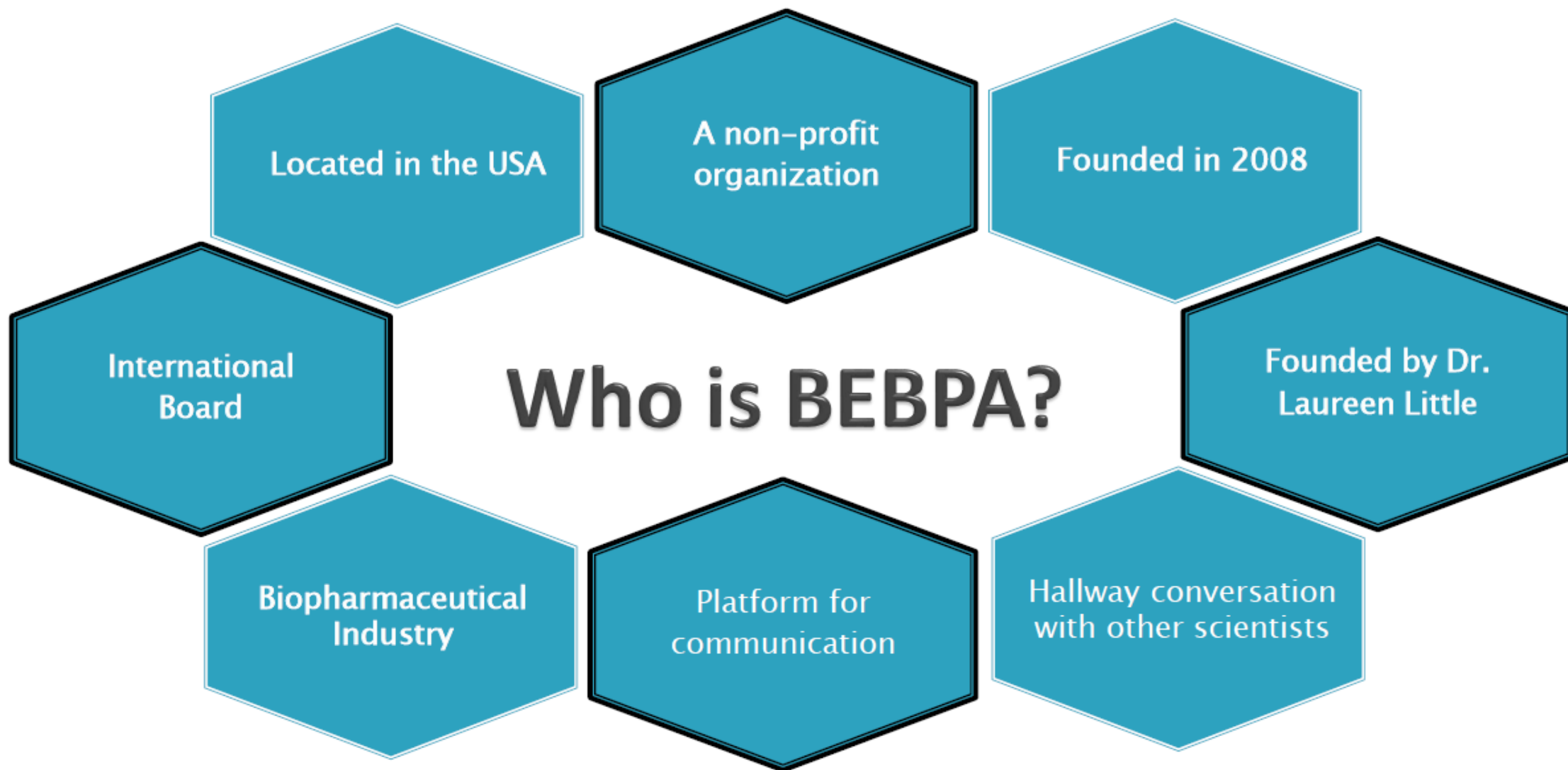


Moderator:
Lauren Little

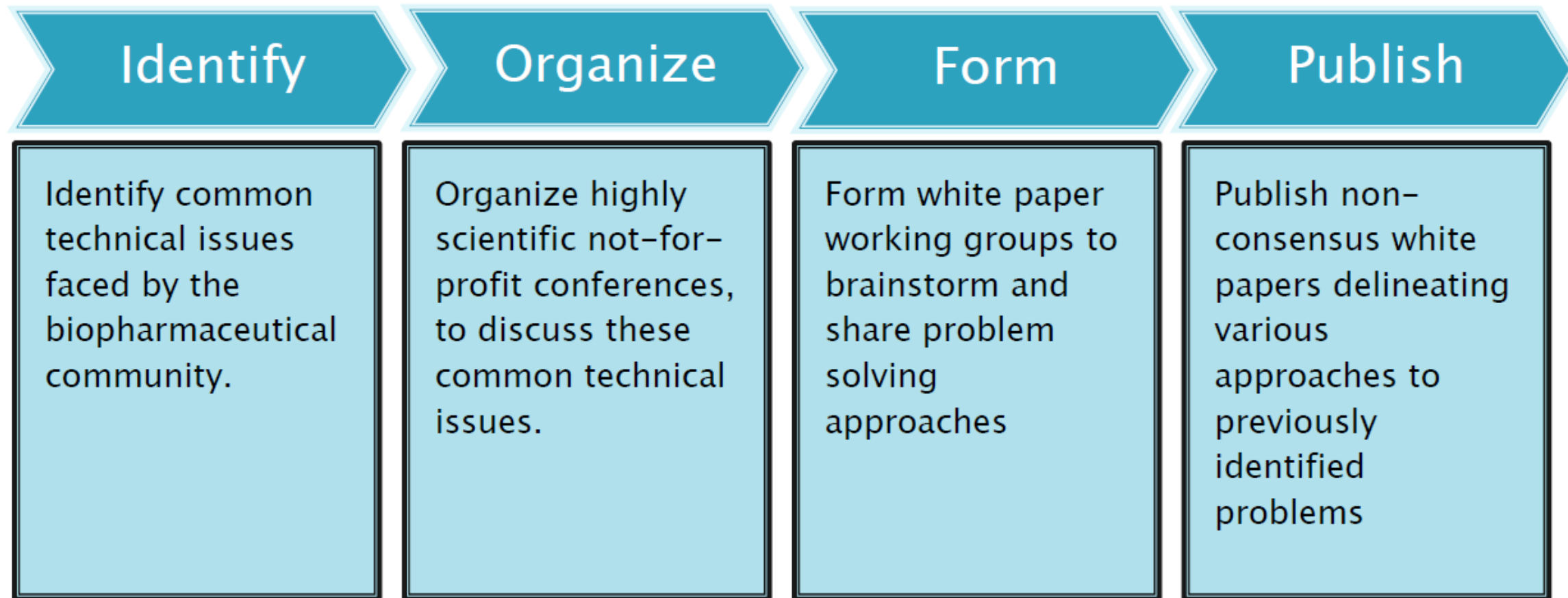
BEBPA President &
Principal Consultant
Quality Services
In Washington, USA



Hiking in
Southern California, USA



What Does BEBPA Do?



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!

The screenshot shows a Zoom webinar window titled "Now viewing Lauren Little's screen". The main content area displays a slide with the text: "Welcome to the 2021 CEPI-BEBPA Free Webinar on *Standardization of Immune Response Assays to COVID-19 Vaccines* 31 August 2021". A red circle highlights the Zoom control bar at the bottom of the window. A red arrow points from this circle to a vertical toolbar on the right, which contains icons for back, chat, phone, screen share, and a hand icon. Another red arrow points from the hand icon to a "Questions" panel on the right. This panel has a menu bar with "File", "View", and "Help". Below the menu bar, there are two expandable sections: "Audio" and "Questions". The "Questions" section is expanded, showing a text input field with the placeholder text "[Enter a question for staff]". A red circle highlights this input field, and a red arrow points to it with the text "Type Questions HERE!!". Below the input field is a "Send" button. At the bottom of the panel, there is a list of items: "2021 CEPI-BEBPA Webinar" and "Webinar ID: 225-664-611". The GoToWebinar logo is at the bottom right of the panel.

Click Arrow To Expand Control Panel

Click Triangle To Open Question Box

Type Questions HERE!!

GoToWebinar

HOW TO DOWNLOAD HANDOUTS FROM CONTROL PANEL

The screenshot shows a Zoom webinar interface. The main display area shows a "Welcome to BEBPA Conferences" slide with a large, faint BEBPA logo in the background. The Zoom control bar is visible at the bottom of the screen. A red circle highlights the control bar, with an arrow pointing to a detailed view of the control panel on the right. This panel includes icons for chat, mute, video, and hand raise. A red arrow points to the "Handouts" section, which is expanded to show a list of handouts. The first handout is "2021 USB - Zoom Login Info Handout.pdf". A red arrow points to the PDF icon next to the handout name. Another red arrow points to the "Questions" section, which is also expanded. The "Questions" section shows "BEBPA Conferences" and "Webinar ID: 977-798-667". The "GoToWebinar" logo is visible at the bottom right of the interface.

Click Arrow to Expand Control Panel

Click Triangle to Open Question Box

Click on Handout To Download PDF

New viewing Patty Koutz's screen
Talking
Zoom: 60%
Screenshot

Welcome to
BEBPA Conferences

File View Help

- ▶ Audio
- ▼ Handouts: 1
 - 2021 USB - Zoom Login Info Handout.pdf
- ▶ Questions

BEBPA Conferences
Webinar ID: 977-798-667

GoToWebinar



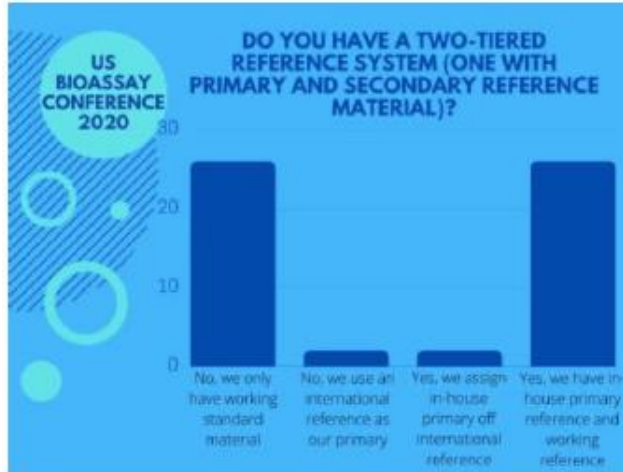
BEBPA's Social Media



BEBPA

312 followers
3mo · 🌐

Happy Holidays from our President Laureen Little! Looking forward to seeing you all at our 2021 conferences!



Most relevant ▾



Seema Bansal • 3rd+
Senior Scientist, Cell Therapy Analytical Development, CTD/O at Brist...

1w · 🌐

two-tiered!

1 Like · 1 Reply



🌐 27

6:17 📶 5G

← Posts

bebpa_inc



View Insights

Promote



🌐 Liked by svarlifescienceab and 4 others

bebpa_inc Even cats get involved in the BEBPA conferences! Here's a selfie of Steven Walfish (USP) and his helper as he gave a presentation at our 2020 EUR Bioassay Conference.



CEPI

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:

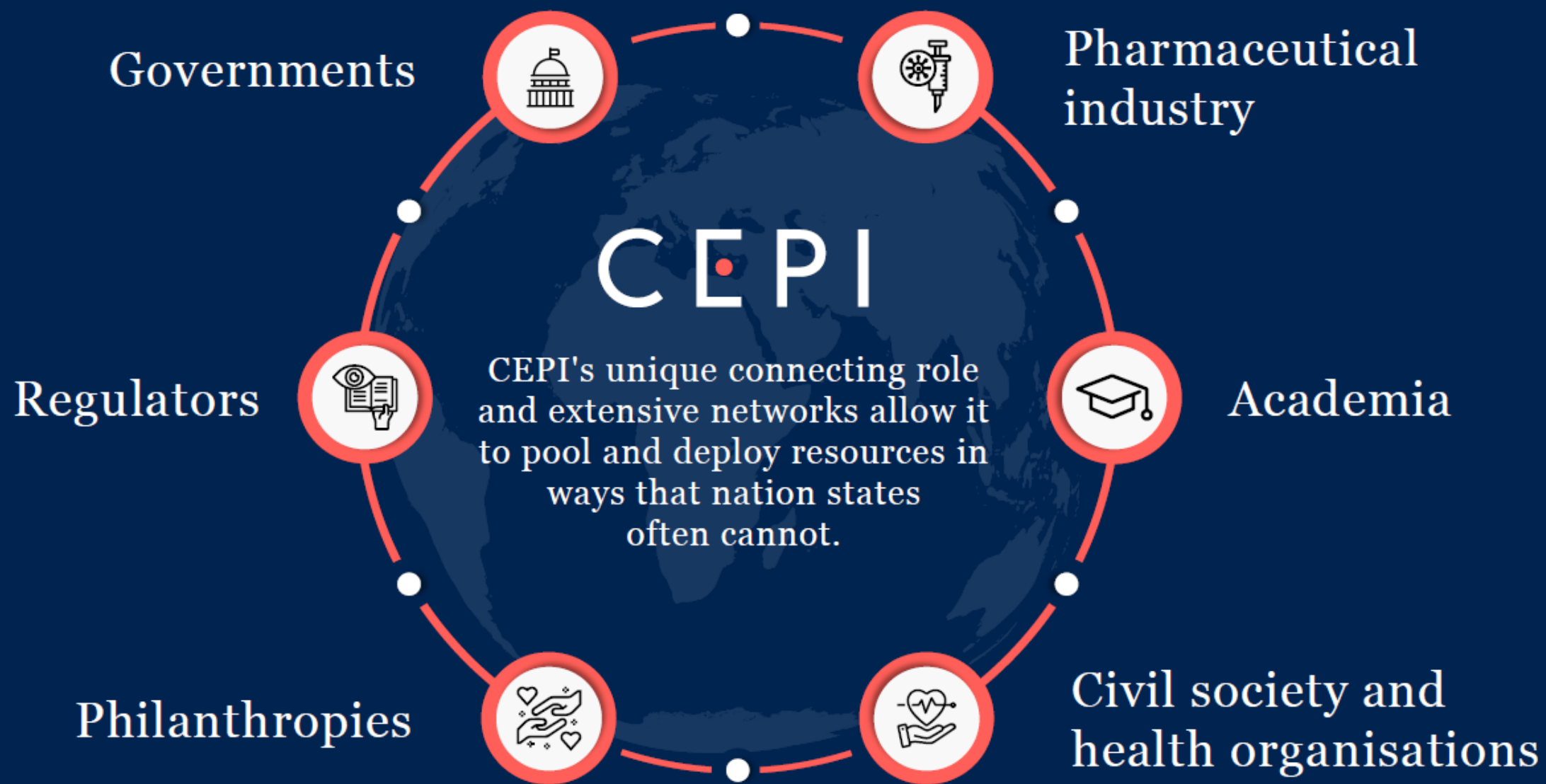
Ivana Knezevic WHO, Team Leader, Norms and Standards for Biologicals, Quality, Safety and Standards; COVAX, Co-Lead of the Enabling Sciences SWAT Team

Overview on CEPI and COVAX

CEPI



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



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.

A sustainable partnership

CEPI's role as a facilitator



The diagram consists of two horizontal bars above a sequence of five circular nodes. The top bar is dark blue and spans the entire width of the five nodes, labeled 'CEPI's role as a facilitator'. The bottom bar is light gray and also spans the entire width, but it features a red segment that covers the second and third nodes, labeled 'CEPI's role as a funder'.

CEPI's role as a funder

1
DISCOVERY

2
DEVELOPMENT /
LICENSURE

3
MANUFACTURE

4
DELIVERY /
STOCKPILING

5
LAST MILE

CEPI's vaccine portfolio



MERS

5 vaccine candidates



Lassa

6 vaccine candidates



Nipah

4 vaccine candidates



Chikungunya

3 vaccine candidates



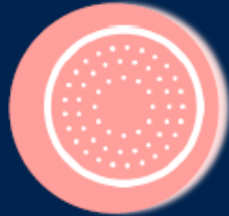
Rift Valley
fever

2 vaccine candidates



COVID-19

12 vaccine candidates
– 11 in active dev.



Disease X

3 platform technologies

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.

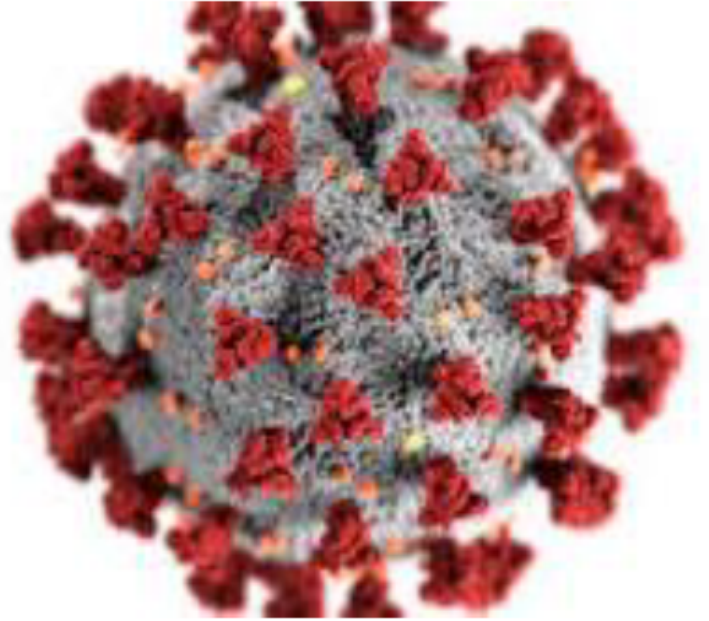


CEPI Centralized Laboratory Network: key features

CEPI

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



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?

❖ 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



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



CEPI Centralized Laboratory Network

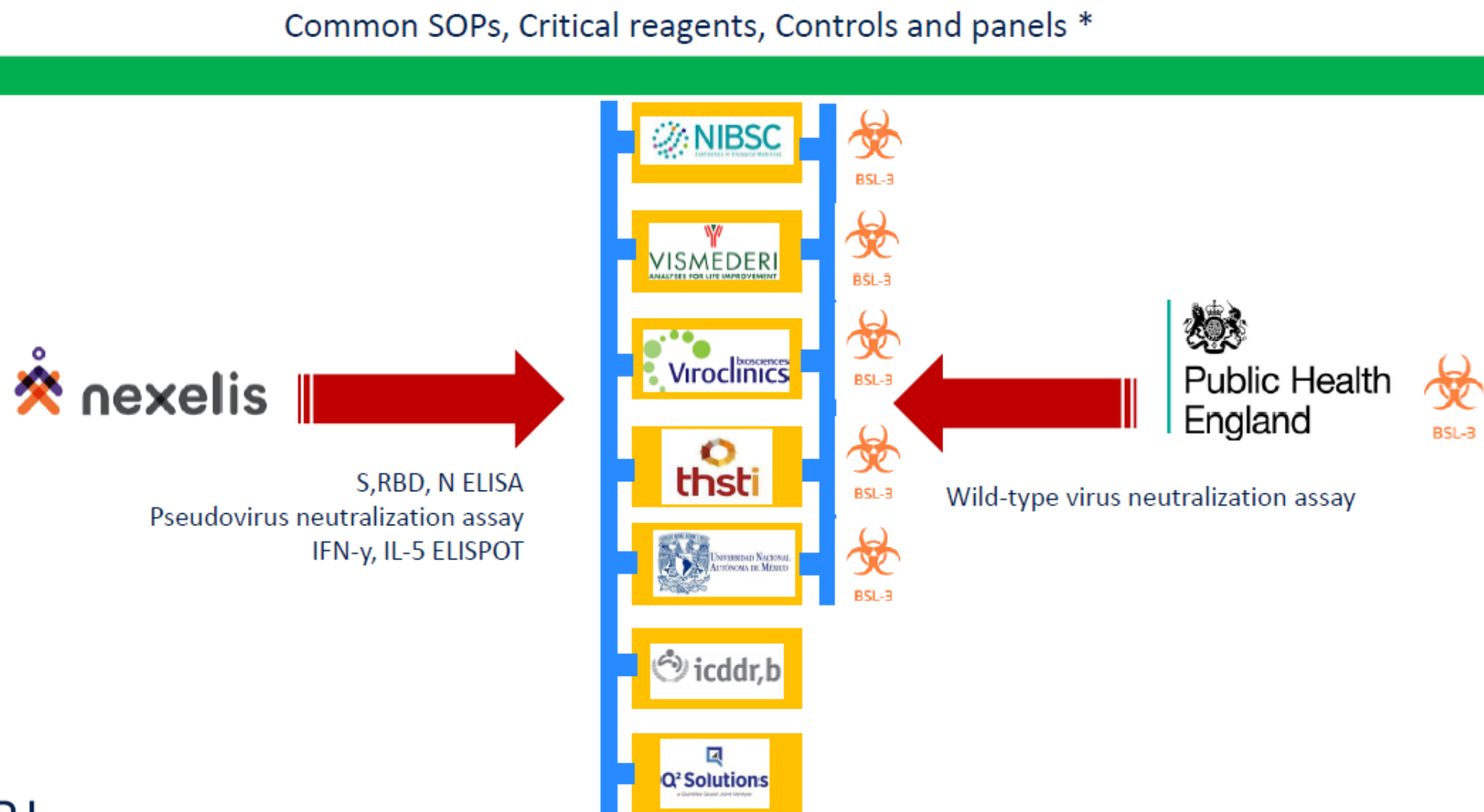


Assays available within the Network

	Binding antibodies		Neutralizing antibodies		T cells
	ELISA	Pseudo typed virus neutralization	Wild type virus neutralization	ELISPOT	
	<ul style="list-style-type: none">Stabilized pre- fusion full length S, RBD, NTotal IgG in serum	<ul style="list-style-type: none">Pseudo particles with VSV backboneSafer testing alternative (no BSL3 required)	<ul style="list-style-type: none">Colorimetric microneutralization assayVictoria virus isolate	<ul style="list-style-type: none">Peptide pool of the whole S proteinCytokines: IFNγ (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

Assay harmonization and tech transfer



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

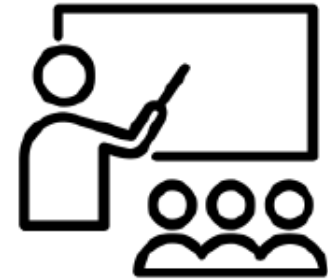


Elements for Assay Transfer Success (2)

❖ 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



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



CEPI Centralized Laboratory Network

2020-21 achievements in numbers

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)

Samples requested for analysis

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

6

9

30

9000

Available assays

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

COVID-19 vaccine developers engaged

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

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



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 linked 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**

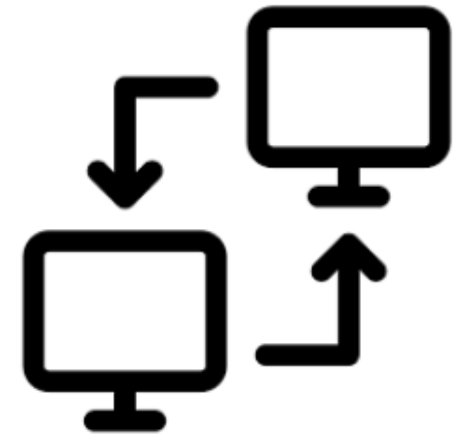
The amount of work to complete the tech transfer was underestimated

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**

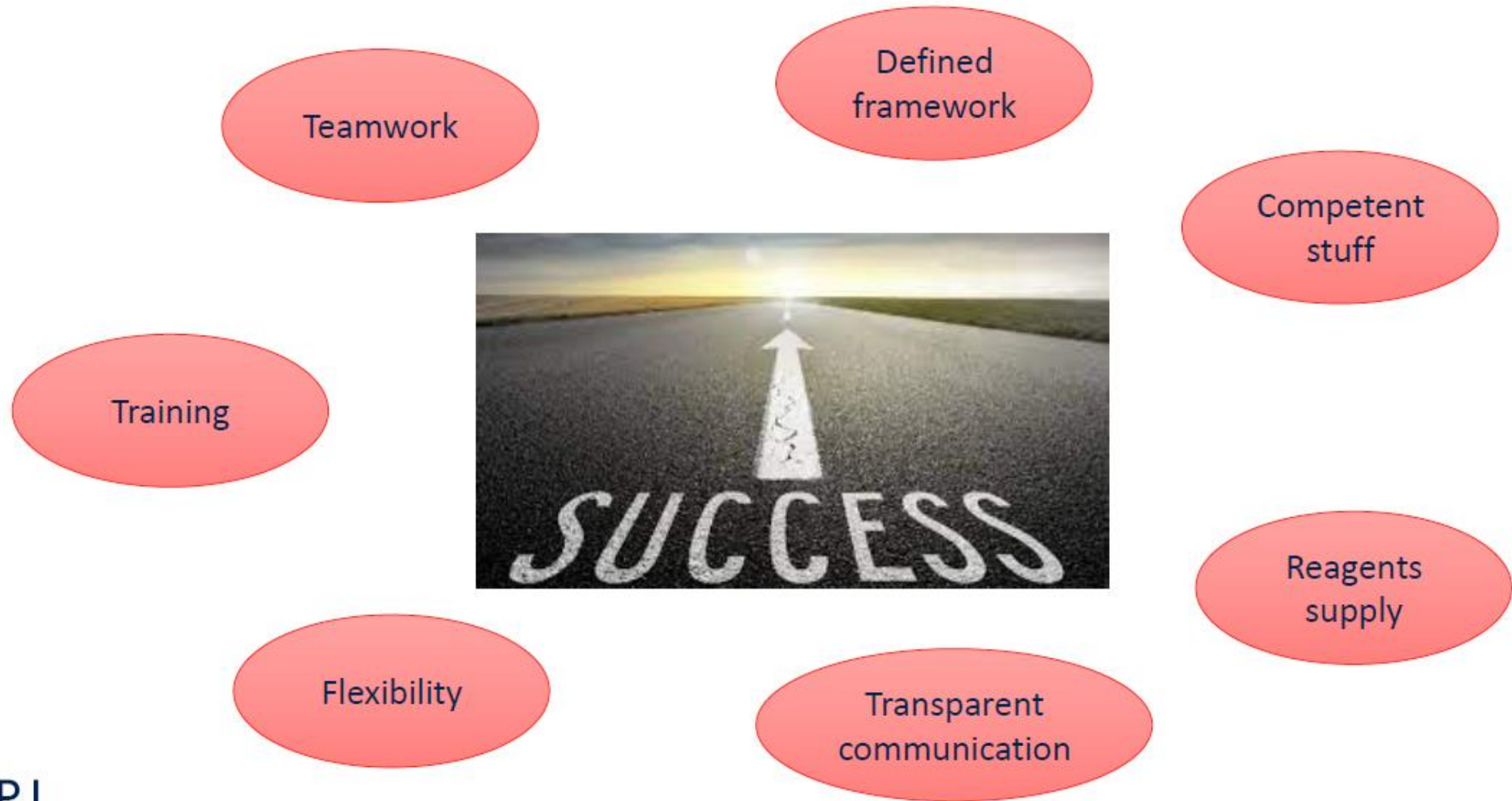


Supply of key reagents and consumables

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**



Lessons learned take-home



Break

Expert Panel Discussion & Audience Q&A



Valentina Bernasconi

CEPI

Moderator



Mark Manak

CEPI



Rubhana Raqib



Mark Page



Luc Gagnon



Leslie Wagner



Pamela Proud



Robert Bailer



Guruprasad Medighesi



Ulrike Herbrand



Mabel Rodriguez



Angela Balgobind



Silvia Grappi



Siân Estdale



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

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



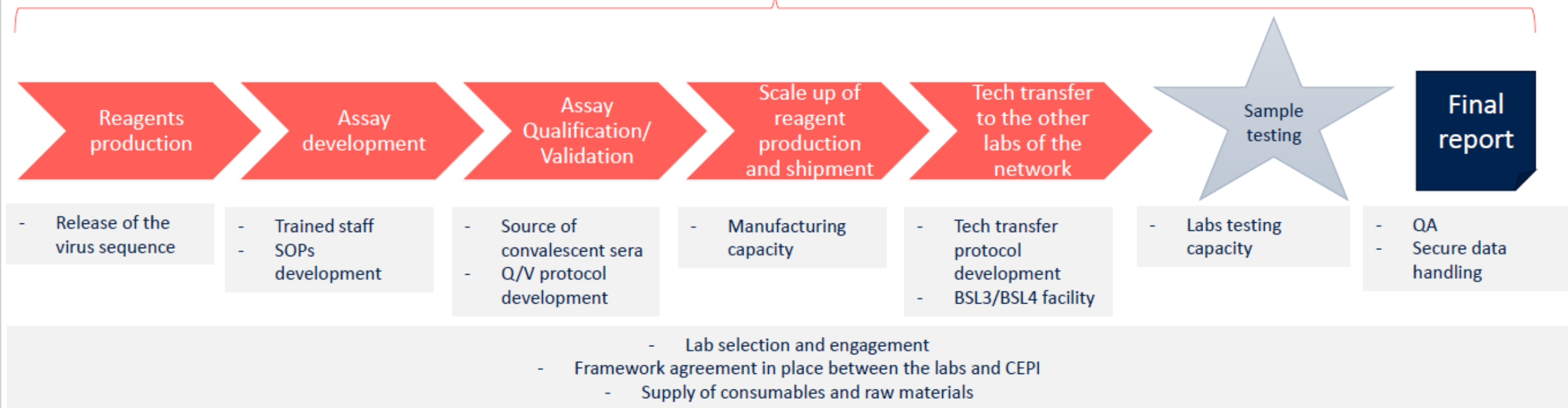
**100 days from pathogen
characterization to clinical data for
deciding emergency use**



Reducing bottle necks in immunogenicity testing



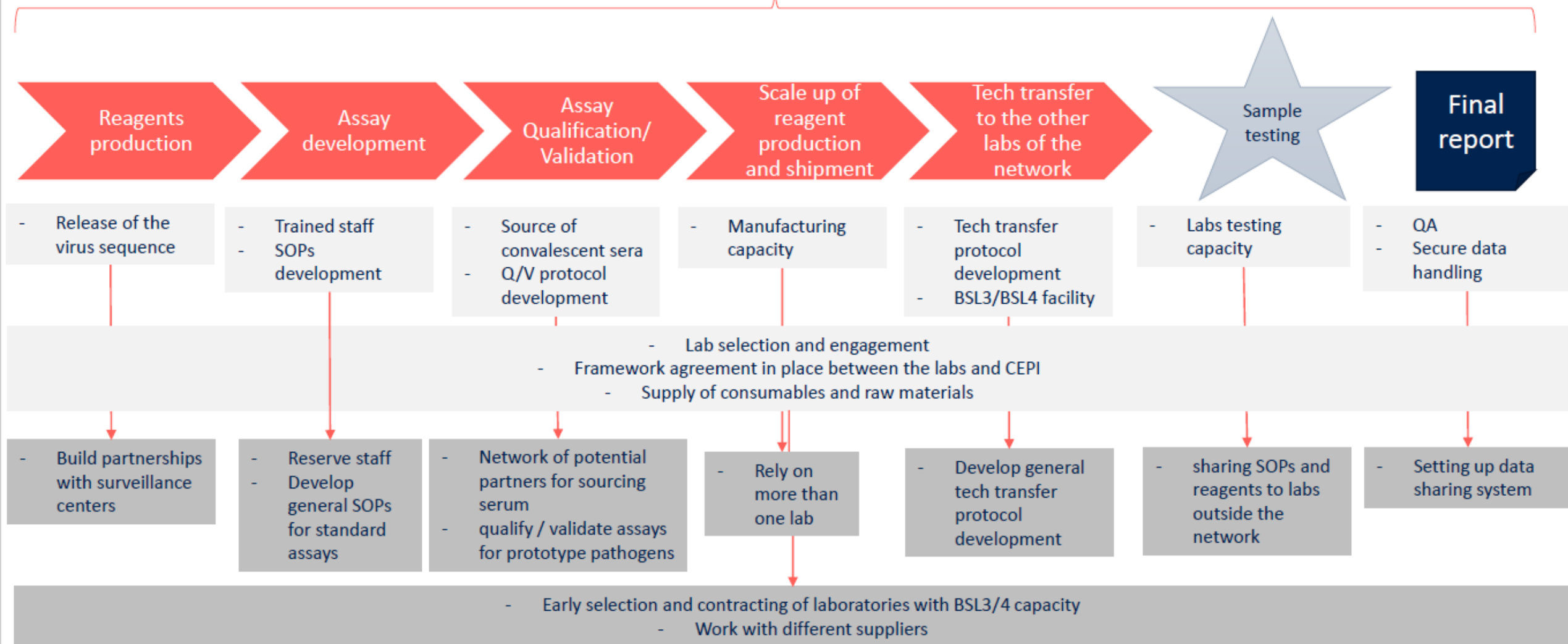
100 days



Reducing bottle necks in immunogenicity testing



100 days



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



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



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>



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.



CEPI's Centralised Laboratory Network

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



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



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”



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).**



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.



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'



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



Valentina Bernasconi

CEPI

Moderator



Mark Manak

CEPI



Rubhana Raqib



Mark Page



Luc Gagnon



Leslie Wagner



Pamela Proud



Robert Bailer



Guruprasad Medighesi



Ulrike Herbrand



Mabel Rodriguez



Angela Balgobind



Silvia Grappi



Siân Estdale



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

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

Webinar closure



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

Read about us

THE LANCET

[www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)00982-X/fulltext#articleInformation](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00982-X/fulltext#articleInformation)

CORRESPONDENCE | VOLUME 397, ISSUE 10290, P2148-2149, JUNE 05, 2021

The CEPI centralised laboratory network: supporting COVID-19 vaccine development

Arun Kumar ✉ • Valentina Bernasconi • Mark Manak • Ana Paula de Almeida Aranha • Paul A Kristiansen

Published: June 05, 2021 •

npj | vaccines

www.nature.com/articles/s41541-021-00317-4

Perspective | Open Access | Published: 13 April 2021

Considerations for bioanalytical characterization and batch release of COVID-19 vaccines

Gautam Sanyal ✉, Anna Särnefält & Arun Kumar

npj Vaccines 6, Article number: 53 (2021)

CEPI

www.cepi.net

Springer Link

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

Tropical, Travel and Emerging Infections (L Chen and A Boggild, Section Editors) | Open Access |
Published: 14 April 2021

Status Report on COVID-19 Vaccines Development

Arun Kumar ✉, William E. Dowling, Raúl Gómez Román, Amol Chaudhari, Celine Gurry, Tung Thanh Le, Stig Tollefson, Carolyn E Clark, Valentina Bernasconi & Paul A Kristiansen

Current Infectious Disease Reports 23, Article number: 9 (2021)

Acknowledgements



Paul Kristiansen
Valentina Bernasconi
Arun Kumar
Ana Paula De Almeida Aranha
Mark Manak



Ivana Knezevic



Janet Lathey



Rubhana Radiq
Mustafizur Rahman
Protim Sarker



Greg Kulnis
Luc Gagnon
Marie-Pierre Tonietto
Mary Osei-Twum
Steven-Phay Tran
Hellen Fassoulas



Mark Page
Dianna Wilkinson
Sandra Prior
Yann Le Duff



Pamela Proud
Sue Charlton
Bassam Hallis



Joanna Zmurko
Brent Seaton
Robert Bailer
Richard Guarino
Charles Zogzas



Prof Pramod Garg
Guruprasad Medigeschi
Abitha Murali
Neha Garg
Tanvi Agrawal



Isabel Garcia
Mabel Rodriguez
Laura Palomares
Laura Cobos
Octavio Tonatihu



Ivo Ploemen
Angela Balgobind
Rienk Jeeninga
Danny Duijsings
Marta Murreddu



Alessandro Torelli
Silvia Grappi



Leslie Wagner

charles river
Ulrike Herbrand



Siân Estdale



Laureen Little
Patricia Koutz
Anastasia Kozorezova
Catherine Pritchett

And the rest of the teams

Thank you for your participation

CEPI



Any further question?

Reach out to centralizedlab@cepi.net

In the absence of the WHO International Standard (now exhausted), an interim standard is now available:

https://nibsc.org/products/brm_product_catalogue/detail_page.aspx?catid=21/234

