COVAX

CEPI
The Coalition for Epidemic Preparedness Innovations

CEPI Centralized Laboratory Network

Zoom Webinar



12th March 2021

Instructions

Throughout the webinar, please ask any question in the Q&A function.

If you see that your question is already asked, you can click "like".

We'll respond to the questions during the Q&A session.

This webinar will be recorded.

The slide deck will be shared with participants after the meeting.

Agenda

Time (CET)	Topic	Speakers
15:00-15:05	Opening remarks	*Ivana Knezevic (WHO) & Paul Kristiansen (CEPI)*
15:05-15:10	About CEPI and COVAX	*Paul Kristiansen (CEPI)*
15:10-15:20	Centralized Laboratory key features	*Valentina Bernasconi (CEPI)*
15:20-15:30	Technical information on assays available	*Arun Kumar (CEPI)*
15:30-15:40	How to apply & practical info	*Ana Paula de Almeida Aranha (CEPI)*
15:40-15:55	Q&A session	*Valentina Bernasconi & Arun Kumar (CEPI)*
15:55-16:00	Closing remarks	*Ivana Knezevic (WHO)*

Opening remarks

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

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

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

  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

Use of the International Standard

Primary calibrant for:

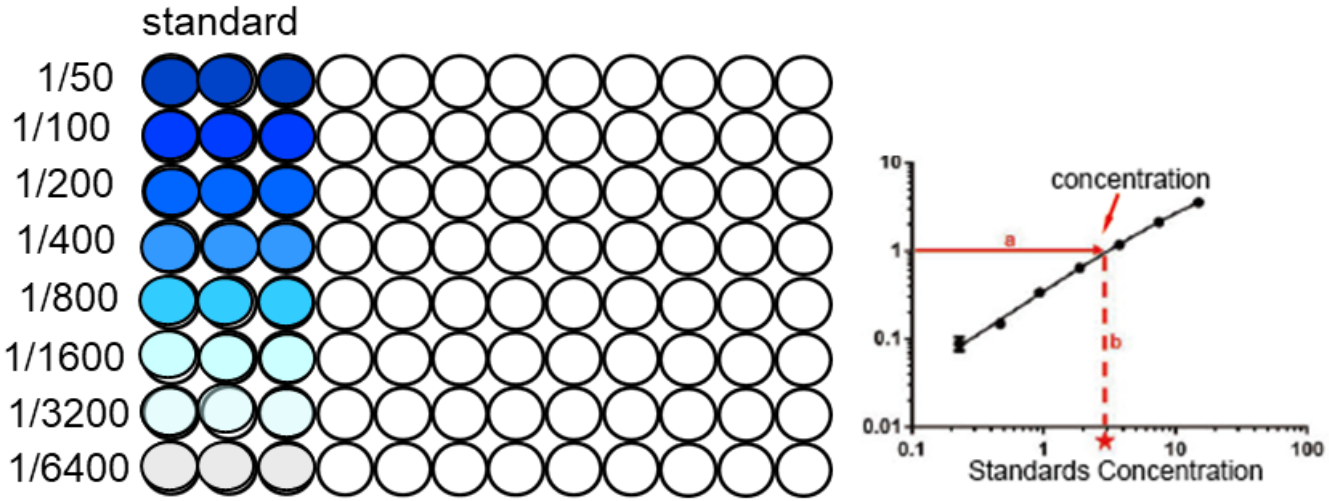
- National and other secondary standards

  calibration through small collaborative studies (e.g. 20/130)

	GM	95% CI	
Neut Ab	1300	981-1719	**IU/mL**
anti-RBD IgG	502	382-660	**BAU/mL**
anti-S1 IgG	588	398-870	**BAU/mL**
anti-Spike IgG	476	418-542	**BAU/mL**
anti-N IgG	747	214-2606	**BAU/mL**

- In house/assays standard

  each lab will calibrate its own standard by running in parallel with IS in their assays



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About CEPI and COVAX

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

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.

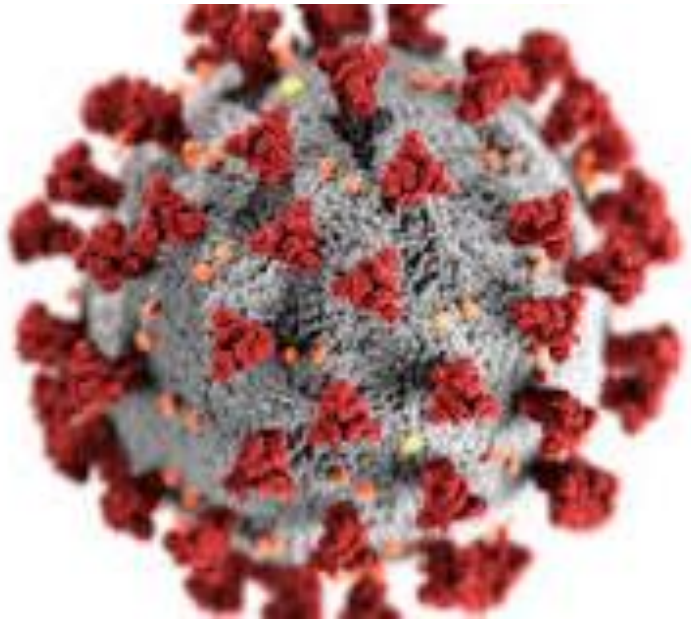
- COVAX is the only solution that will deliver fair, equitable access to vaccines for every country that participates.
- COVAX provides countries access to the world's largest portfolio of vaccine candidates, actively managed by CEPI's R&D experts.
- COVAX also provides cross-cutting support to vaccine developers through SWAT teams.
- This webinar is organized by the Enabling Sciences SWAT team, which supports COVID-19 vaccine developers in the area of diagnostics, standards, assays and animal models.

Centralized Laboratory Network
Key features

Valentina Bernasconi Scientist @CEPI, Lead 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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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 II 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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Technical information on assays available

Arun Kumar Scientist @CEPI, Co-lead of 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	Planned in Apr 2021
Tech transfer (receiving labs)	In progress; to be completed by Mar 2021	In progress; to be completed by Mar 2021	In progress; to be completed by Mar 2021	Planned in May 2021
Validation (Nexelis/PHE)	Ongoing	Ongoing	Ongoing	NA
Average throughput at Nexelis/PHE (samples per week)	480 (per analyst)	240 (per analyst)	450	150 (TBD) (per analyst)

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

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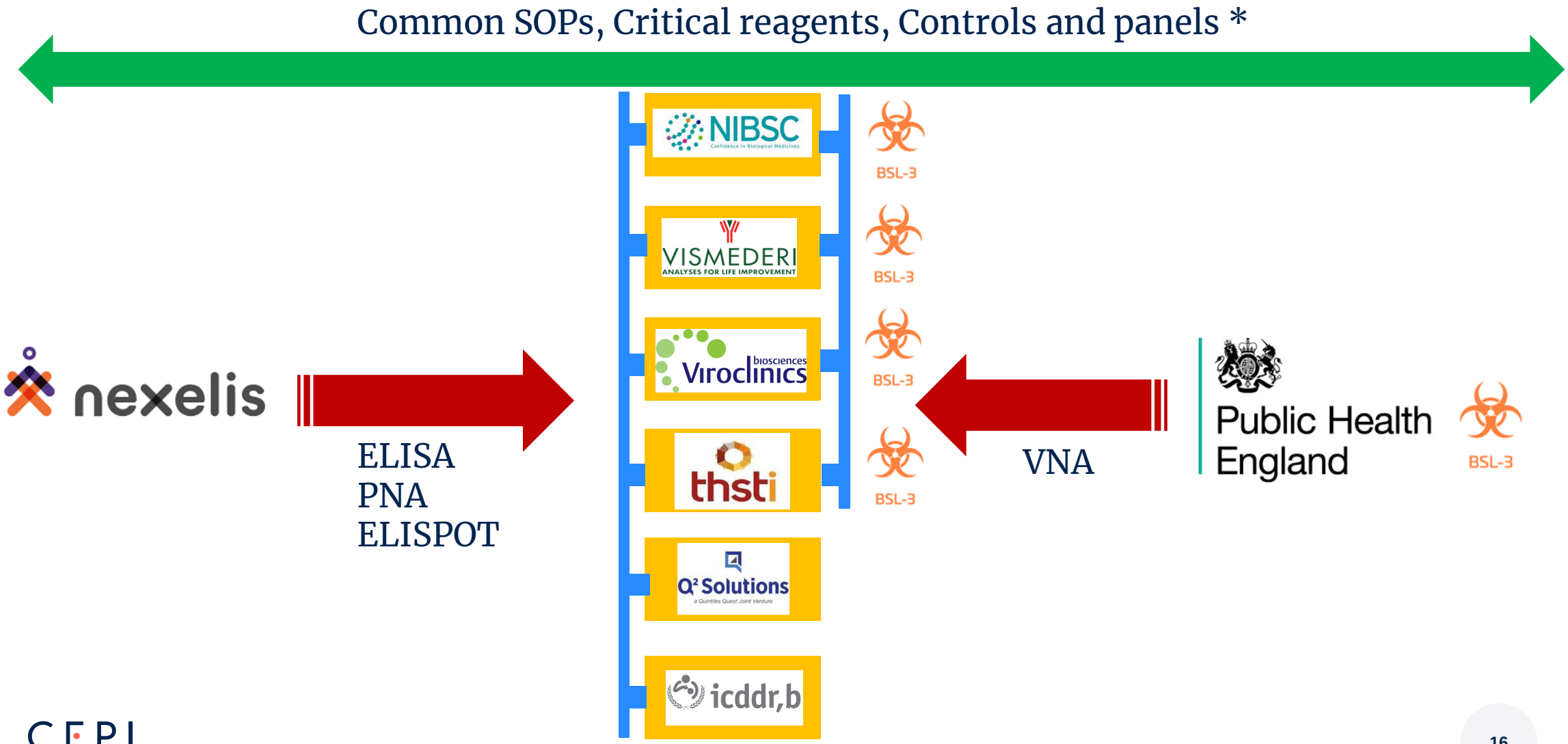
Assay harmonization and tech transfer



*Including bridging with WHO International Antibody Standard

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How to apply & practical info

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

Apply today for sample testing at the CEPI Centralized Laboratory Network

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

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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

What's coming next?

1. Inclusion of clinical Phase III samples
2. Inclusion of SARS-Cov-2 virus variant testing
3. Expansion of the global footprint of the Network

Q&A session

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Closing remarks

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

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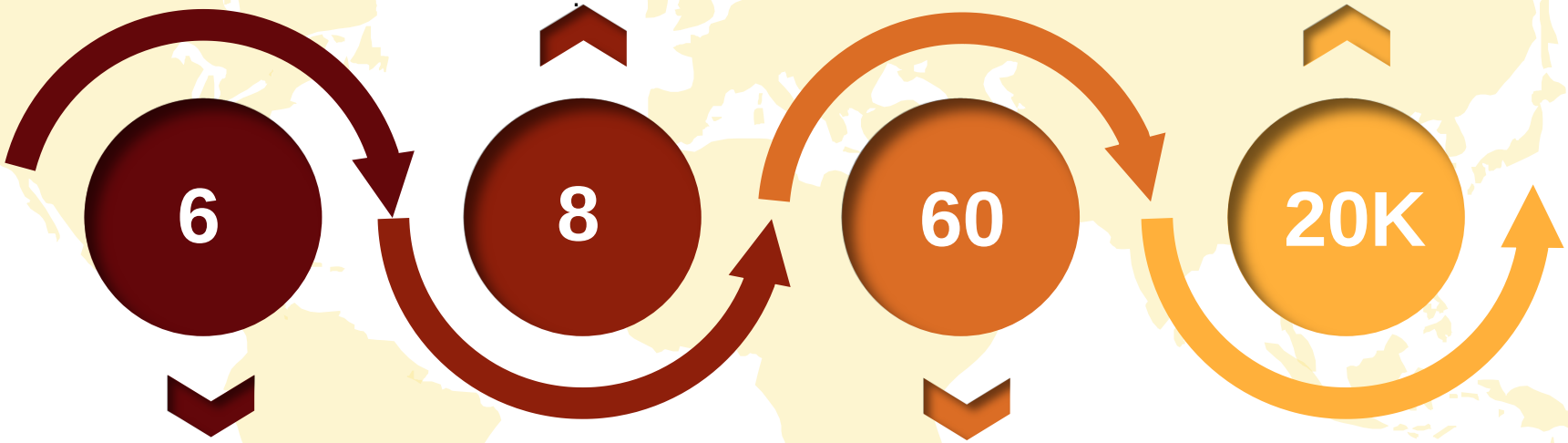
2020 achievements in numbers



Available assays

S,RBD,N ELISA assay
Pseudo virus neutralization assay
Wild type virus neutralization assay
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)

Covid-19 Vaccine developers engaged

In 4 continents among CEPI-funded and non CEPI-funded developers

Samples requested for analysis

From Preclinical, Clinical Phase I and Clinical Phase IIa studies

Thank you for your participation

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