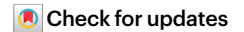


The CEPI centralized laboratory network for COVID-19 will help prepare for future outbreaks



In 2020, in response to the COVID-19 pandemic, the Coalition for Epidemic Preparedness Innovations (CEPI) established a Centralized Laboratory Network (CLN) of ten laboratories in order to standardize immunological assays, provide testing support to vaccine developers, identify the immune correlates of protection for vaccines, and facilitate approval and dissemination of the most effective vaccine candidates. The establishment of the CLN also assisted in capacity-building initiatives and technology-transfer programs.

Partnerships with laboratories in different countries facilitated the transfer of knowledge, techniques and technologies for medical countermeasures against the coronavirus SARS-CoV-2. These global laboratories were selected on the basis of their successful track record in testing clinical samples under high-quality systems, their willingness to collaborate and their ability to handle high volumes of samples from multiple geographical regions¹. In 2021, the CLN included the following partners: the International Centre for Diarrheal Disease Research (Bangladesh), Medicines and Healthcare products Regulatory Agency (MHRA; formerly the National

Institute for Biological Standards and Control, UK), Q² Solutions–Nexelis (Canada), Q² Solutions (USA), Q² Solutions (China), Translational Health Science and Technology Institute (India), UK Health Security Agency (formerly Public Health England; UK), Universidad Nacional Autónoma de México (Mexico), Viroclinics (Cerba Research; Netherlands) and Vismederi (Italy).

Six immunological assays – including three antibody-binding assays, a wild-type virus-neutralization assay, a pseudovirus neutralization assay and an immune-cell-based assay – have been developed and validated by two of the laboratories in our network: Q² Solutions–Nexelis and UK Health Security Agency. The assays have been transferred to the other laboratories in CEPI's CLN and have been qualified in each laboratory as suitable for use in clinical trials in accordance with regulatory guidelines.

CEPI partnered with MHRA and the World Health Organization to develop an international standard for assays of immunoglobulins directed against SARS-CoV-2, with an assigned quantitation value based on the results of an international collaborative study. All laboratories within the CLN use the same reagents, comparable materials and

equipment, parallel protocols and procedures and well-characterized standards and panels, to ensure the accuracy, reproducibility, and harmonization of assay results. Within approximately 2 years, the CEPI CLN provided preclinical to phase 3 clinical trial support to more than 50 vaccine developers (some funded by the COVAX initiative) and allocated more than 70,000 samples for testing.

CEPI's initial success in supporting the worldwide SARS-CoV-2 vaccine initiative will inform the establishment of systems to respond quickly to future outbreaks, minimizing potential disease burden and deaths². CEPI is focused on streamlining the vaccine development and evaluation process to allow faster roll-out of safe and effective vaccines to tackle future pandemic threats. CEPI's goal, which is embraced by the G7 and G20, is to compress the time taken to develop vaccines against new threats to within 100 days of a recognized outbreak and available genetic sequence^{3–5}. To meet this ambitious goal, CEPI is applying lessons learned from the COVID-19 pandemic. These include recognizing existing gaps to increase workforce capacity, building a diverse pipeline of talented professionals, developing multiple global interconnected

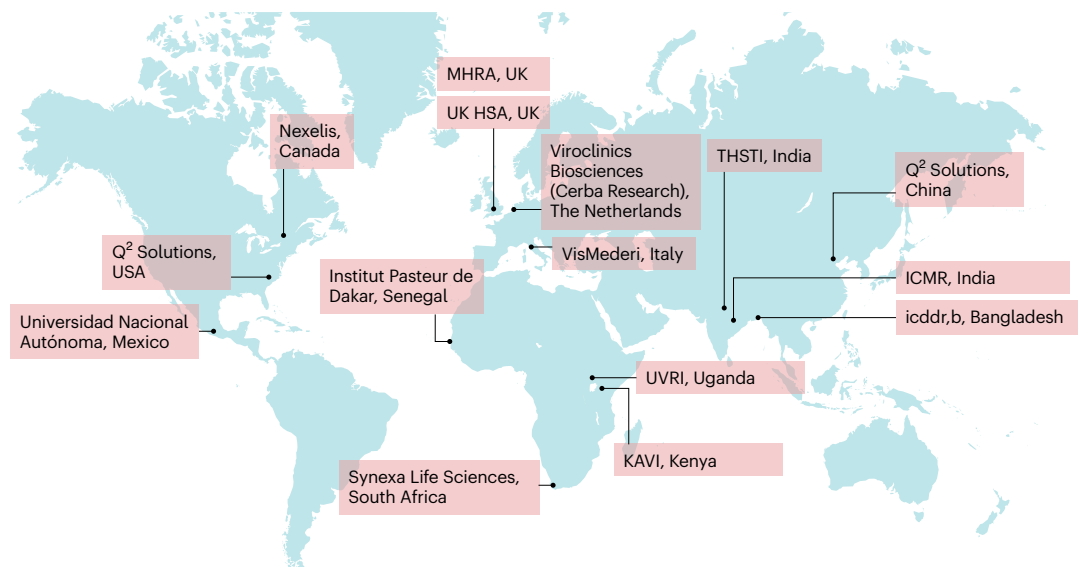


Fig. 1 | The CEPI CLN. Laboratories in the network (information correct as of June 2023).

partnerships, financing global-preparedness systems and improving equitable access to quality manufacturers and laboratories, particularly in low- and middle-income countries. CEPI is funding programs to build a library of prototype vaccines against potential pandemic pathogens selected through systematic review, predictive modeling, data science and reliable and verifiable information or data.

CEPI is also funding vaccine development for known threats for which no vaccines have yet been approved. CEPI's list of priority pathogens comprises Lassa virus, Nipah virus, Ebola virus, Marburg virus, mpox (formerly monkeypox) virus, Chikungunya virus, Rift Valley fever virus, Middle East respiratory syndrome (MERS) coronavirus, other pathogenic β -coronaviruses, and 'disease X' pathogen (an unknown pathogen with epidemic or pandemic potential).

To support the 100 Days Mission, the Laboratory Research and Innovations department within CEPI is enhancing global coverage and the workforce capacity of the laboratories within our CLN. Recently CEPI has [partnered with five additional high-quality laboratories](#), including four in Africa (the Institut Pasteur de Dakar in Senegal, the Kenya AIDS Vaccine Initiative, the Uganda Virus Research Institute, and Synexa in South Africa) and one in India (the Indian Council of Medical Research). The laboratories joined to CEPI's network by June 2023 are shown in Fig. 1.

We are planning to add more laboratories to the CEPI CLN in the coming months to ensure coverage on every continent. Having laboratories strategically located across different regions allows for faster detection of, and

response to, emerging diseases. With a distributed network, the time required to identify and diagnose an outbreak is reduced, which allows faster understanding of the disease and its characteristics. This also enables a prompt mobilization of resources, expertise and research capabilities to assess, diagnose and develop vaccines or other countermeasures for outbreaks. Increasing the number of laboratories within our network can also help us tap into diverse capabilities, such as specialized knowledge, technology and infrastructure. The network also promotes collaboration and knowledge sharing, fostering innovation and enhancing the chances of successful vaccine development.

The goal of the CEPI CLN is to develop and validate a battery of assays for the priority emerging diseases for which CEPI is developing vaccines. The CEPI CLN is offering research and scientific laboratory services and/or reagents to support scientific programs for responding to outbreaks, including sample testing for vaccine development projects funded by CEPI or its partners. We continue our partnership with the MHRA and the World Health Organization to develop international standards against priority diseases, authorized through the Expert Committee on Biological Standardization approval processes. In addition, we will ensure that assays and procedures developed by our laboratory network are reliable, standardized and easy to implement. We are providing support for the development of new platforms such as high-throughput approaches while ensuring that the procedures will be available to the public and could be used by any third parties on an open-access basis.

Vaccines are the most powerful tool in the fight against the next epidemic or pandemic, and the development of reliable standardized assays for assessment of vaccine efficacy is a crucial step on this path. Through partnership with key stakeholders, the CEPI CLN will ensure that the development of assays against future epidemic and/or pandemic threats is accelerated and can be accessible to anyone. The CEPI CLN also supports the strengthening of local research and development capabilities, fostering self-sufficiency and sustainability in epidemic and pandemic preparedness.

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Competing interests

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