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CEPI's collaborative task force to assess COVID-19 vaccines on emerging viral strains

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Collaboration fills a key gap in the global outbreak response by acting as a mechanism to both monitor and test emerging viral strains and evaluate whether these circulating strains may impact COVID-19 vaccine development

To rapidly monitor the emergence of new COVID-19 viral strains and evaluate their impact on vaccine candidates in development, CEPI, the Coalition for Epidemic Preparedness Innovations, has announced the launch of a first-of-its-kind collaboration with the GISAID Initiative, Public Health England (PHE) and the National Institute for Biological Standards and Control (NIBSC) to further strengthen real-time global tracking and testing of SARS-CoV-2 sequences– the virus behind COVID-19. The announcement follows recent attention to a mutant strain of the virus detected in mink and human populations in Denmark.

Monitoring emerging viral strains

As part of the new cross-cutting taskforce, CEPI will strengthen the work of GISAID, a global science initiative and the primary source of virological data of SARS-CoV-2 virus. GISAID is an essential component of COVID-19 R&D that enables real-time progress in the understanding of the geographical spread, circulation, and evolution of the SARS-CoV-2 virus and the new COVID-19 disease it causes.

Since the first SARS-CoV-2 viral genomes were shared via GISAID on 10 January 2020, **over 200,000 SARS-CoV-2 viral sequences** have since been made available with unprecedented speed on its publicly accessible platform. CEPI's support will bolster GISAID's global operations to meet growing user demands and technical enhancements to facilitate not only data submission, but also the enablement of solutions to strengthen reporting by public health laboratories.

GISAID will produce for CEPI regular reports on genomic diversity which will be openly shared by CEPI, to support analyses on the diversity of the spike protein sequence—a key target for COVID-19 vaccine development. Tracking viral mutations and diversity is important to ensure current COVID-19 vaccine candidates can be tested against circulating strains of the virus.

Testing the impact of a new viral strain on the immune response

If a newly emerging SARS-CoV-2 strain with a potentially significant sequence mutation is reported by GISAID, CEPI will inform its two laboratory partners, Public Health England (PHE) and the National Institute for Biological Standards and Control (NIBSC), both based in the UK. The laboratories will be asked to conduct tests, known as neutralisation assays, on laboratory-grown stocks of the new viral strain to determine whether, compared to current SARS-CoV-2 strains, antibodies are still able to effectively respond to ('neutralise') the new strain.

The neutralisation tests will be performed using the **NIBSC's antibody standard**. Developed with CEPI-support, the NIBSC antibody standard is a pool of samples from patients who have been infected and recovered from SARS-CoV-2 infection, and is currently in use by R&D partners worldwide. Both laboratories will conduct the tests to confirm the reliability of results.

Should the tests detect changes in the ability for antibodies to neutralise the new SARS-CoV-2 viral strain, preclinical testing will then be performed to evaluate whether there are any changes in pathogenesis (disease progression) and virulence (severity of infection) associated with the new strain. Findings will be immediately communicated to the global research community via the World Health Organization (WHO) and CEPI networks. As a result, the rapid sharing of key data should help guide vaccine developers to determine if their vaccine candidates are protective against current circulating strains of SARS-CoV-2.

This new collaboration extends CEPI's existing partnerships with **PHE** and the **NIBSC**, which are also part of CEPI's centralised laboratory network to standardise the assessment of COVID-19 vaccine candidates undergoing clinical testing.

A total of $1.3 million in funding will be provided by CEPI to GISAID to enhance their global operations. Up to an additional US $1.3 million funding will also be provided to PHE and the NIBSC to carry out the neutralisation tests to provide information on the effectiveness of vaccine candidates in development against newly circulating SARS-CoV-2 strains.