

NIBSC selected by CEPI to test coronavirus vaccines globally

We are delighted to announce that the National Institute for Biological Standards and Control (NIBSC) will play a key role in evaluating vaccines that have been developed for COVID-19.

The institute is one of seven partner laboratories that have been selected by CEPI (the Coalition for Epidemic Preparedness Innovations) to form a centralised laboratory to standardise the measurement of immune responses generated by multiple COVID-19 vaccine candidates. Samples from volunteers participating in phase I and phase II clinical trials will be tested in our labs as well as samples from preclinical studies.

Our scientists will be evaluating antibody responses and T-cell responses alongside other partner laboratories that are all using the same methods and biological reference materials. This will ensure that data are obtained in a consistent way so that the results for different vaccine candidates can be directly compared.

Additionally, as the world's leading producer of biological reference materials, the NIBSC has received funding from CEPI to develop an International Standard for COVID-19 antibody. This will consist of a sample of antibody with a defined amount of biological activity. It will act as the 'gold standard' that can be used by regulators and vaccine manufacturers all over the world to calibrate their own tests.

This work will be crucial – both for enabling the most promising vaccine candidates to be identified quickly and accurately and for determining the key procedures that are required to assure vaccine quality.

Dr Nicola Rose, Head of Virology at the NIBSC, said:

Standardisation of assays in vaccine development and more centralised measurement of vaccine responses is key for the robustness of the data obtained. The NIBSC is well placed to deliver this for the benefit of public health in the fight against the pandemic.

Dr Mark Page, Principal Scientist leading this work at the NIBSC adds:

This is an important initiative providing a service to vaccine developers globally and permits accurate evaluation of candidate vaccines for this pandemic.

Dr Melanie Saville, Director of Vaccine R&D at CEPI, further adds:

We are delighted that NIBSC will be joining CEPI's centralised lab network for the standardised assessment of COVID-19 vaccine candidates. With our global group of testing laboratories now in place, samples from COVID-19 vaccine clinical trials can be shipped to one of seven sites around the world for uniform evaluation, allowing us to evaluate candidates in high quality assays and identify which vaccine candidates may be performing well, in terms of immune response, in clinical trials.

Health and Care Secretary Matt Hancock said:

The UK is leading the way in developing a safe and effective vaccine for COVID-19 which will be absolutely crucial to saving lives and starting our return to normality.

We have one of the best medical regulators in the world and I'm delighted the NIBSC will play a crucial role in developing international standards to help ensure all vaccines are of the highest quality, safety and effectiveness.

Further information on the centralised laboratory network and how to apply to use the network to assess your COVID-19 vaccine trial samples is available on the [CEPI website](#).

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About NIBSC

The National Institute for Biological Standards and Control (NIBSC) is a centre of the Medicines and Healthcare products Regulatory Agency. The institute plays a major national and international role in assuring the quality of biological medicines. The NIBSC is the leading producer and distributor of WHO International Standards and biological reference materials, supplying over 90% of International Standards used worldwide. The NIBSC also acts as the UK's Official Medicines Control Laboratory and conducts independent batch release testing of biological medicines.

In addition to its standardisation and control activities, the NIBSC hosts several expert research and resource centres. The institute is a WHO Collaborating Centre for Reference and Research on Poliomyelitis and a WHO Essential Regulatory Laboratory for Influenza. The NIBSC is also home to the UK Stem Cell Bank and the Centre for AIDS Reagents.

About CEPI

CEPI is an innovative partnership between public, private, philanthropic, and civil organisations, launched at Davos in 2017, to develop vaccines to stop future epidemics. CEPI has moved with great urgency and in coordination with

WHO in response to the emergence of COVID-19. CEPI has initiated nine partnerships to develop vaccines against the novel coronavirus. The programmes are leveraging rapid response platforms already supported by CEPI, as well as new partnerships. Alongside Gavi and the World Health Organization (WHO), CEPI is co-leading COVAX to develop, manufacture and fairly allocate two billion doses of vaccine by the end of 2021.

Before the emergence of COVID-19, CEPI's priority diseases included Ebola virus, Lassa virus, Middle East Respiratory Syndrome coronavirus, Nipah virus, Rift Valley Fever and Chikungunya virus. CEPI also invested in platform technologies that can be used for rapid vaccine and immunoprophylactic development against unknown pathogens (Disease X).

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