MHRA approves COVID-19 vaccine trial in 7 working days

In our commitment to prioritising potential treatments for COVID-19, the Medicines and Healthcare products Regulatory Agency (MHRA) approved the COVID-19 Oxford Vaccine Trial request to trial a vaccine to prevent COVID-19 in a little over one working week.

The application was made on 18 March, and on 26 March the MHRA gave the COVID-19 Oxford Vaccine Trial the green light. The procedures for tailored scientific advice and guidance, and a speedy approval process, are part of MHRA's pledge to prioritise clinical trial applications submitted for COVID-19.

Scientists in Oxford started working on designing a vaccine early in January 2020, and have now identified one to start the first clinical testing phase. If the vaccine is proven to be safe and effective in this and larger trials, it could protect people and help save lives.

The project is supported by a joint funding scheme between the UK Research and Innovation (UKRI) and National Institute for Health Research (NIHR).

The MHRA is dedicated to supporting researchers and all those who are working on a response to COVID-19. We are providing scientific advice and informal guidance for all aspects of product development.

Science Minister, Amanda Solloway, said:

> "The government is doing all it can to support the science and research community who are working tirelessly to identify a vaccine to combat coronavirus.
>
> "Accelerating UK vaccine development, including clinical testing, will ensure that any successfully developed vaccine can be made available to people as soon as possible.

Dr June Raine, Chief Executive for the MHRA, said:

> "The dedicated scientific advice and rapid approval of this important clinical trial demonstrate our commitment to working together to find a vaccine for this pandemic.
>
> "We support the development and expedite authorisation of clinical trials for COVID-19 treatments, whilst maintaining our high

> regulatory standards to ensure the safety of people involved in the trials.
>
> “Protecting health and saving lives is at the forefront of our work, and we are committed to enabling the development of safe and effective vaccines and treatments for this virus.‘

MHRA prioritises trial applications for COVID-19

Clinical trials applications can be submitted directly to the MHRA Clinical Trial Helpline by emailing clintrialhelpline@mhra.gov.uk, in parallel to the normal Common European Submission Portal (CESP) route, so we can begin work as soon as possible. We then liaise closely with any applicants to ensure it’s managed as efficiently as possible.

More information on clinical trials applications for coronavirus (COVID-19).

We are currently offering an expedited review and approvals process for COVID-19 clinical trials, aiming to complete our review in a week.

We are also able to provide advice on any aspect of a clinical trial. Manufacturers, researchers and other regulators who are working on a response to COVID-19 can email or call our Clinical Trials Unit on clintrialhelpline@mhra.gov.uk or 020 3080 6456.