



Covid 19 Vaccine trials

Event Chronology

Live document - updated September 2020

Event Chronology In Reverse Date Order

– Latest Updates At The Top Of This Document Oldest Updates At The Foot Of The List.

18 September 2020

Human Medicine Regulation

End date for public consultation on changes to human medicine regulations. Britain is preparing to revise its laws to allow the emergency use of any effective coronavirus vaccine before it is fully licensed: but only if it meets required safety standards.

17 September 2020

Imperial College London trial

Researchers at Imperial have developed a candidate which, when injected, will deliver the genetic instructions to muscle cells to make the SARS-CoV-2 spike surface protein. This should provoke an immune response and create immunity to the virus. Rather than giving people a weakened form of the illness, the Imperial vaccine instead uses synthetic strands of genetic code based on the virus' genetic material. The following information has been requested from the Home Office on advice from "Medicines and Healthcare Products Regulatory Agency" [MHRA] who do not hold the information.

1. a copy of the **project licence** granted under UK Home Office Animals [Scientific Procedures] Act 1986 in respect of "animal trial" of Covid 19 candidate vaccine LNP-n CoV saRNA or, alternatively, copy of letter of authorisation from Home Office if a licence is not required, and
2. a copy of the **project licence** granted authorising progression from "animal trial" to "human trial" in respect of Covid 19 candidate vaccine LNP-n CoV saRNA or, alternatively, copy of letter of authorisation from Home Office if a licence is not required .

17 September 2020

University of Oxford vaccine trial

Vaccinations resume in South Africa.

15 September 2020

University of Cambridge vaccine trial

Another vaccine candidate is being developed by the University of Cambridge which hopes to start clinical trials in the autumn after it received £1.9 million in funding from the UK Government. The Cambridge candidate, DIOS-CoVax2, is DNA based. Computer-generated antigen structures are

encoded by synthetic genes, which can then re-programme the body's immune system to produce antibodies against coronavirus.

14 September 2020

UK Government announcement

The Government announced that it had secured the supply of 60 million doses of a Covid-19 vaccine candidate being developed in France. Valneva SE, a specialist vaccine company, announced a "major partnership" with the UK worth around £433million. The doses will be provided in the second half of 2021. There is an option for the Government to access a further 130 million doses between 2022 and 2025, the company said. Britain had already signed deals for more than 340 million doses of a coronavirus vaccine. The total stockpile means that [if the vaccines all work] there will be enough for every person in Britain to have five doses. Most of the vaccines require two to be effective.

14 September

University of Oxford vaccine trial

Brazilian trial of Oxford vaccine resumes.

12 September 2020

University of Oxford vaccine trial

University of Oxford resumes vaccine trial across all UK clinical trial sites. The independent review process has concluded and following the recommendations of both the independent safety review committee and the UK regulator, the MHRA, the trials will recommence in the UK. Information about the illness of the volunteer has not been disclosed for reasons of participant confidentiality.

9 September 2020

University of Oxford vaccine trial

Data under review for Phase 2 and 3 study. Pause to vaccination to allow review of safety data due to unexplained illness in one volunteer. AstraZeneca and Oxford University suspended their phase three vaccine trials after a British female participant fell ill with a rare neurological condition.

20 July 2020

University of Oxford vaccine trial

The results of the Phase 1 and 2 trial published today in the scientific journal, The Lancet, indicate no early safety concerns and induces strong immune responses in both parts of the immune system.

27 June 2020

University of Oxford vaccine trial

Trial of Oxford vaccine starts in Brazil.

23 June 2020

University of Oxford vaccine trial

Participants in South Africa's first clinical trial for a vaccine against Covid-19 are to be vaccinated this week.

The vaccine being used in the South African trial is the same as that being used in the UK and Brazil.

3 June 2020

University of Oxford vaccine trial

Brazilian Health Regulatory Agency approves trial of Oxford vaccine, considering 2,000 volunteers to be tested in the country.

22 May 2020

University of Oxford vaccine trial

The Oxford Vaccine Phase 2 and 3 clinical trial explained in press release as summarised below.

What is the purpose of this research study?

The purpose of this study is to test a new vaccine against COVID-19 in healthy volunteers. This study aims to assess how well people across a broad range of ages could be protected from COVID-19 with this new vaccine called ChAdOx1 nCoV-19. It will also provide valuable information on safety aspects of the vaccine and its ability to generate good immune responses against the virus.

What is the vaccine being tested?

ChAdOx1 nCoV-19 is made from a virus (ChAdOx1), which is a weakened version of a common cold virus (adenovirus) that causes infections in chimpanzees, that has been genetically changed so that it is impossible for it to grow in humans. Genetic material has been added to the ChAdOx1 construct, that is used to make proteins from the COVID-19 virus (SARS-CoV-2) called Spike glycoprotein (S). This protein is usually found on the surface of SARS-CoV-2 and plays an essential role in the infection pathway of the SARS-CoV-2 virus. The SARS-CoV-2 coronavirus uses its spike protein to bind to ACE2 receptors on human cells to gain entry to the cells and cause an infection.

Has the vaccine been tested on animals?

Our collaborators at Rocky Mountain Laboratories (NIAID/NIH) have conducted a rapid yet thorough investigation and demonstrated good safety and efficacy of a single dose of ChAdOx1 nCoV-19 in the rhesus macaque model that they had previously established. We were able to review the data before vaccinations in the clinical trial were initiated. There are also animal studies underway in Australia and the UK, and the results will be published once those studies are complete.

What does the study involve?

In total this study will enrol up to 10,260 adults and children across the UK. The phase 2 part of the study involves expanding the age range of people the vaccine is assessed in, to include a small number of adults and children: aged 56-69, aged over 70, and aged between 5-12 years. For these groups, researchers are assessing the immune response to the vaccine in people of different ages, to find out if there is variation in how well the immune system responds in older people or children. The group of children will be recruited later in the trial, once extensive safety data is available from the adult studies. The phase 3 part of the study involves assessing how the vaccine works in a large number of people over the age of 18. This group will allow assessment of how well the vaccine works to prevent people from becoming infected with COVID-19. Adult participants in both the Phase 2 and

Phase 3 groups will be randomised to receive one or two doses of either the ChAdOx1 nCoV-19 vaccine or a licensed vaccine (MenACWY) that will be used as a 'control' for comparison.

30 April 2020

University of Oxford vaccine trial

An agreement with the UK-based global biopharmaceutical company AstraZeneca for the further development, large-scale manufacture and potential distribution of the vaccine candidate currently being trialled by the University.

23 April 2020

University of Oxford vaccine trial

The Oxford Vaccine Phase 1 clinical trial explained in press release.

21 April 2020

University of Oxford vaccine trial

Announcement by the Secretary of State for Health of funding for the evaluation of the new vaccine.

2 April 2020

University of Oxford vaccine trial

Experts have estimated that it will take 12-18 months to develop a new vaccine at high speed. Under normal circumstances, most vaccine development programmes take more than five years, so this is still a considerably accelerated timescale. This 12-18-month prediction includes the time taken to develop manufacturing processes to produce the vaccine on a larger scale, as well as preclinical testing in animals and evaluation of the vaccine in human participants in a clinical trial. Scientists need to assess the safety and efficacy of the vaccine over a number of weeks and months through phase 1, 2 and 3 clinical trials. If the vaccine is safe and efficacious, regulatory approval is needed before the vaccine can be deployed. Many of these stages can be undertaken more quickly if there are no unexpected roadblocks. Firstly, the use of a platform technology approach, i.e. a vaccine delivery system that has been used before and can be adapted for a new pathogen, can shorten the initial vaccine development time. Also, in an emergency situation, large scale manufacturing could be carried out concurrently while the clinical trial is ongoing, which can shorten the overall timescale for vaccine development. This would mean that if the clinical trial is successful, the vaccine would be ready in larger quantities, to be deployed immediately. Finally, regulatory review of promising candidates is also undertaken faster in an epidemic, because more staff and resources are dedicated to the review process. Oxford University is using all these strategies in order to try to make a vaccine available as rapidly as possible once it is proven safe and effective. The ChAdOx1 nCoV-19 vaccine timeline

Phase 1

Vaccinate 510 volunteers aged between 18-55, half with the new vaccine and half with a control vaccine.

Phase 2

Extend the maximum age of trial participants to 55-70 years, then over 70.

Phase 3

Vaccinate 5000 volunteers aged over 18 years, half to receive the new vaccine. Clear efficacy endpoints will be used to assess the effectiveness of the vaccine, and volunteers from phase 1 and 2 will be included in the follow-up.

27 March 2020

University of Oxford vaccine trial

Oxford vaccine programme opens for clinical trial recruitment. Screening of healthy volunteers (aged 18-55) for their upcoming ChAdOx1 nCoV-19 vaccine trial in the Thames Valley Region. The vaccine based on an adenovirus vaccine vector and the SARS-CoV-2 spike protein is already in production but won't be ready for some weeks. The trial, a collaboration between the University's Jenner Institute and Oxford Vaccine Group clinical teams, will recruit up to 510 volunteers, who will receive either the ChAdOx1 nCoV-19 vaccine or a control injection for comparison. The trial has been approved by UK regulators and ethical reviewers.

15 March 2020

University of Oxford vaccine trial

The current status is that they have identified a vaccine candidate and are working towards the first clinical testing phase. A chimpanzee adenovirus vaccine vector (ChAdOx1), developed at Oxford's Jenner Institute, was chosen as the most suitable vaccine technology for a SARS-CoV-2 vaccine as it can generate a strong immune response from one dose and it is not a replicating virus, so it cannot cause an ongoing infection in the vaccinated individual. At the same time as preparing for and conducting the first clinical trial, production of the vaccine is being scaled up ready for larger trials, and potentially, future deployment.

11 March 2020

World Health Organisation [WHO]

The WHO declared Covid-19 a pandemic. This means that the disease has spread worldwide, and it is the first time that a coronavirus has led to a pandemic.

11 February 2020

World Health Organisation [WHO]

The disease caused by SARS-CoV-2 was officially named "Covid-19".

30 January 2020

World Health Organisation [WHO]

The outbreak was declared a public health emergency of international concern.

11 January 2020

University of Oxford vaccine trial

A team in Oxford led by Prof. Sarah Gilbert, Prof. Andrew Pollard, Prof. Teresa Lambe, Dr Sandy Douglas and Prof. Adrian Hill started work designing a vaccine. The clinical trial is being conducted in collaboration with multiple study sites across the UK.

11 January 2020

General comment

Before the first case of coronavirus had been reported outside China, scientists had already sequenced the virus. On January 11, the genome of the coronavirus was posted to GenBank, an

open-source database of nucleotide sequences maintained by the US federal government. On the same day, the Chinese government submitted the sequence to the World Health Organisation.