

# Janssen to begin Covid-19 vaccine trials in the UK

- Phase three clinical trials for Janssen's Covid-19 vaccine to begin across the UK
- 6,000 volunteers from across the UK will take part in Janssen's trials to test its effectiveness
- Researchers urge the public to keep volunteering for vital studies to ensure people in the UK have access to different types of vaccines that work for them

Global pharmaceutical company Janssen will begin clinical trials of its potential vaccine in the UK from today (Monday 16 November), involving 6,000 volunteers across the country.

The Janssen Pharmaceutical Companies, part of Johnson & Johnson, is the latest study in the UK, jointly funded by the UK government's Vaccine Taskforce, to test the safety and effectiveness of a potential Covid-19 vaccine. It is the third potential vaccine to enter clinical trials in the UK, alongside US biotech company Novavax and University of Oxford / AstraZeneca whose studies are currently ongoing.

6,000 UK volunteers, some from the NHS Vaccines Registry, will take part in the Janssen studies at 17 National Institute for Health Research (NIHR) sites, including in Southampton, Bristol, Cardiff, London Leicester, Sheffield, Manchester, Dundee and Belfast. Recruitment into the study will complete in March 2021 and the trial will last for 12 months.

To date, over 300,000 people have signed up to the NHS Vaccines Registry to take part in vital coronavirus vaccine studies.

Experts have cautioned that no one vaccine is likely to be suited for everyone, and that a wide range of types are needed to ensure people across the UK have access to one that works for them, so they are urging more people to sign-up to ensure clinical trials that test the safety and effectiveness of potential vaccine candidates continue. The NHS vaccine registry particularly needs volunteers who are most vulnerable to the effects of coronavirus, including frontline health and social care workers and people from Black, Asian and ethnic minority backgrounds.

Business Secretary, Alok Sharma, said:

The start of further clinical trials in the UK is yet another step forward in the race to discover a safe and effective vaccine, and comes alongside recent news that we could be on the cusp of the first major breakthrough since the pandemic began.

While we are optimistic with the progress being made, there are no guarantees and it is possible there will be no one-size-fits-all

vaccine. That is why it is absolutely vital that while our scientists are cracking on with the job, we continue to follow the guidance to control the virus, protect the NHS and save lives.

The UK Government has developed a portfolio of six different vaccine candidates and secured access to 350 million doses to date, putting the UK in the best position for a vaccine. Of this, 30 million doses of the Janssen vaccine could be made available to the UK if it is safe and effective by mid-2021.

Professor Saul Faust, Director of the NIHR Southampton Clinical Research Facility and Chief Investigator for the Janssen Phase 3 trial, said:

Finding an effective vaccine with a good safety profile is a top priority in helping to protect us all more quickly against COVID-19. While the news of a potential vaccine is tremendously exciting, our ambition in the scientific community is to ensure we leave no stone unturned in the search for a solution to help end this pandemic.

All the vaccines that are being trialled work by generating immune responses to the same part of the coronavirus as the RNA vaccine that has announced some interim early results.

Chair of the Government's Vaccine Taskforce, Kate Bingham said:

The recent news about progress on the search for a vaccine is enormously exciting for the whole world, but we must not take our focus off continuing the important research to work out which vaccines work best for different people to provide long lasting, effective protection against Covid-19.

Many vaccines are needed both here in the UK, and globally, to ensure we can provide a safe and effective vaccine for the whole population. That is why the launch of this trial to establish the safety, effectiveness, and very importantly the durability, of the Janssen vaccine is so significant, and I would continue to encourage people to sign up and take part in vaccine trials.

By co-funding this study we are helping generate data for future regulatory submissions internationally as well as for the UK.

Black, Asian and minority ethnic Clinical Champion at NIHR Clinical Research Network North Thames, and consultant in Sexual Health and HIV at Barts Health NHS Trust, Dr Vanessa Apea, said:

COVID-19 still poses a significant threat to our health and our communities and many of us are still vulnerable to it. One of the ways we can reduce the threat and impact of this disease is a vaccine.

The topic of vaccines divides communities. For many, and in particular, Black, Asian and ethnic minority communities, the word vaccine generates a lot of anxiety, rooted in mistrust, which can understandably lead to reluctance in taking part in a trial.

We know that these communities are disproportionately affected by COVID-19 and this makes it even more important that any outcomes from research, including new treatments and ways to prevent the disease, work for all communities. Only by doing this can we truly take control of COVID-19, so we really need people from Black, Asian and ethnic minority communities to sign up to learn more and be part of research. Entering a clinical trial or receiving a vaccine is entirely a personal choice and should always be supported by accurate information.

Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer, Johnson & Johnson said:

We are delighted to be initiating our global Phase 3 trial in the UK to study the safety and efficacy of a two-dose regimen of our investigational COVID-19 vaccine candidate. This collaboration with UK researchers and the NIHR demonstrates our continued commitment to working together with partners around the world, and marks another positive step forward as we strive to find solutions to this global health crisis.

The UK public can support the national effort to speed up vaccine research and receive more information about volunteering for clinical studies by [visiting this page](#) to join the NHS Vaccine Research Registry.

The Registry was launched by the UK government in partnership with the NIHR, NHS Digital, the Scottish and Welsh governments and the Northern Ireland Executive in July. It aims to help create a database of people who consent to be contacted by the NHS to take part in clinical studies, to help speed up the development of a safe and effective vaccine.

#### **Notes to editors**

Janssen's phase three clinical trials will involve 30,000 people worldwide.

#### **Volunteering for COVID-19 vaccine clinical trials:**

People wishing to volunteer to support clinical trials can sign up for information on Covid-19 vaccine trials with the NHS Covid-19 vaccine research registry, developed in partnership with NHS Digital. It is helping large

numbers of people to be recruited into trials rapidly over the coming months – potentially meaning an effective vaccine for coronavirus can be found as soon as possible.

The service was commissioned as part of the UK Government's Vaccine Taskforce in conjunction with the National Institute for Health Research (NIHR) and the Northern Ireland, Scottish and Welsh Governments.

Anyone living in the UK can sign up online to take part in the trials through the NHS, giving permission for researchers to contact you if they think you're a good fit. Once you sign up, you can withdraw at any time and request that your details be removed from the COVID-19 vaccine research registry. The process takes about 5 minutes to complete. More information [can be found here](#).

### **About the Vaccine Taskforce**

The Vaccine Taskforce (VTF) was set up under the Department for Business, Energy and Industrial Strategy (BEIS) in May 2020, to ensure that the UK population has access to clinically effective and safe vaccines as soon as possible, while working with partners to support international access to successful vaccines. This is to place the UK at the forefront of global vaccine research, development, manufacture and distribution.

The Vaccine Taskforce comprises a dedicated team of private sector industry professionals and officials from across government who are working at speed to build a portfolio of promising vaccine candidates that can end the global pandemic. It is chaired by biotech and life sciences expert Kate Bingham, who was appointed by the Prime Minister Boris Johnson.

The Vaccine Taskforce's approach to securing access to vaccines is through:

- procuring the rights to a diverse range of promising vaccine candidates to spread risk and optimise chances for success;
- providing funding for clinical studies, diagnostic monitoring and regulatory support to rapidly evaluate vaccines for safety and efficacy; and
- providing funding and support for manufacturing scale-up and fill and finish at risk so that the UK has vaccines produced at scale and ready for administration should any of these prove successful.

The 4 different vaccine classes that the government has secured to date for the UK are:

- adenoviral vaccines (Oxford/AstraZeneca, Janssen)
- mRNA vaccines (BioNTech/Pfizer, Imperial)
- inactivated whole virus vaccines (Valneva)
- protein adjuvant vaccines (GSK/Sanofi, Novavax)

In addition the UK has secured rights to AstraZeneca's antibody treatment to neutralize the virus which can be used both as a short term prophylactic for those people who cannot receive vaccines (e.g. cancer and immunosuppressed patients) and front line workers exposed to the virus, as well as a treatment

for infected patients in hospitals.