FAST FACTS

University of Queensland scientists set to trial their COVID-19 vaccine

Overview

- The University of Queensland (UQ) COVID-19 Vaccine Team entered into a partnership with Australian early phase clinical trial specialist Nucleus Network.
- Nucleus Network is conducting Phase 1 clinical testing of the UQ vaccine at its Brisbane clinic at Herston.
- Nucleus Network in Brisbane (formerly Q-Pharm) has a long and successful track record of helping with the development of many vaccines, as well as drugs, through high quality clinical trials.
- As Australia's largest Phase 1 clinical trials specialist, Nucleus Network has partnered previously with UQ.
- A phase 1 clinical trial is predominantly to prove safety – following on from extensive animal and lab studies to ensure as much as possible the vaccine candidate is safe to administer in humans.
- The trial will also provide some preliminary information on how well the vaccine is likely to work.
- This is achieved by undertaking regular blood tests that look at antibody levels and other relevant markers of immunity at regular time points during the study.

Strategic investment paying off

- It is important to recognise the key role Queensland has played in facilitating the research capability the state now has - we are in a strong position to develop a COVID-19 vaccine.
- Over 20 years of strategic investment – via Smart State and Advance Queensland – has helped to provide the infrastructure to support the research and clinical trials as part of a truly global initiative.
- Renowned Queensland medical researcher Professor Ian Frazer says Queensland now has a critical mass of biomedical research capability, led by world leading scientists attracted to the state's universities and research institutes by quality research infrastructure and equipment.
- "There is no doubt that the development of Queensland as a 'Smart State' – initiated by Peter Beattie and continued through the current Advance Queensland initiative – has given us the capacity in 2020 to be world leading in biomedical research, and has positioned us well to play a significant part in the global efforts to prevent and to more effectively treat COVID-19," Professor Frazer says.
- "Queensland is also gradually expanding its ability to translate that research into clinical practice, which will be further enabled by increased investment into embedding clinical and translational research in health care, and by expanding the talent pool of clinicians and health care professionals trained in research and its translation."

UQ COVID-19 Vaccine – where they're up to

- The University of Queensland was tasked by the Coalition for Epidemic Preparedness Innovations (CEPI) to develop a vaccine against the novel coronavirus in January, supported by an initial investment of up to US$4.5 million.
- The UQ team has been working around the clock in developing their vaccine candidate.
- Their COVID-19 vaccine reached an important milestone in April, showing the ability to raise high levels of antibodies that can neutralise the virus in early pre-clinical testing.
- This is a result that came out of early pre-clinical testing of the vaccine candidate in small animal models. The neutralising antibody responses induced were measured at the Peter Doherty Institute for Infection and Immunity (Doherty Institute) in Melbourne.
- This bodes well for the vaccine – and is an important step in its development.
- In early April 2020, the team announced a partnership with Dutch company, Viroclinics Xplore, on further pre-clinical studies.
- Viroclinics Xplore has the specialist biosecurity facilities the team needed for working with a live virus.
- Viroclincs Xplore is investigating in more detail the vaccine's ability to protect from a direct challenge by the live virus in multiple animal models.
- The preliminary results from Viroclinics Xplore show the vaccine candidate is on track.
- In partnership with TetraQ[1] the team have recently completed GLP toxicology studies[2] which along with the preliminary data from Viroclinics have paved the way for the vaccine to receive ethical clearance under Australia's Therapeutic Goods legislation to proceed to human trial.
- The vaccine has been developed using UQ's molecular clamp technology that locks the 'spike' protein into a shape which allows the immune system to be able to recognise and then neutralise the virus.
- The team utilised the National Collaborative Research Institute's National Biologics facilities at both UQ and CSRIO in Melbourne to manufacture the material for the Phase 1 trial.
- They also worked with SyPharma to enable fill finish of the vaccine into vials for the Phase 1 study.
- Based in Victoria, SyPharm is a speciality contract manufacturing group specialising in manufacturing products for Phases 1, 2, and 3 clinical trials.
- UQ has also established a partnership with a major biotech, Cytiva.
- Formerly known as GE Healthcare Life Sciences, Cytivais using its custom chromatography resin capabilities in Sweden to enable efficient manufacturing of the vaccine. Another key component for this process was manufactured by Thermo Fisher here in Brisbane at their state-of-the art GMP facility.
- The UQ team has also been provided key adjuvant technologies from GSK, Dynavax and CSL/Seqirus and will be using MF59 from Seqirus for this clinical trial.
- Adjuvants help vaccines work better. An adjuvant is an ingredient used in vaccines that helps create a stronger immune response in people receiving the vaccine.

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[1] [1] Note from UQ research team: "glp tox – we have not spoken externally yet about the tetra Q data but is a key reason why we needed to wait until this point to start the trial. We understand some other programs have used platform data to run this in parallel." – TetraQ is a GLP recognised facility at the Herston Health Precinct.
[2] Toxicology studies are required to determine the adverse effects of the vaccine and the effect of dosage on toxicity

- In early June, CEPI and Australian pharma CSL Ltd announced they would fund the development and manufacture of UQ's "molecular clamp" enabled vaccine for COVID-19.
- The agreement would support subsequent late stage clinical trials, and industrial-scale manufacturing to allow the production of potentially millions of doses a year, should the vaccine be approved.
- The initial phase of large-scale production of the UQ COVID-19 vaccine is planned to take place at CSL's biotech manufacturing facilities in Melbourne.
- All going well – CSL anticipates that the production technology can be scaled to produce up to one hundred million doses towards the end of 2021.
- CSL will also subcontract other global manufacturers to increase the number of doses that can be produced and broaden the geographical distribution of vaccine production.
- Should clinical trials be successful, a vaccine could be available for distribution in 2021.

Phase 1 Clinical Trial

- Phase 1 Clinical Trials are predominantly to ensure the vaccine is safe in humans – and are based on the extensive data the research team has to date in the lab and in animals indicating that it is.
- They also check to see if it works by doing blood tests to check antibody levels against the vaccine – if these are high it will tell them the vaccine is more likely to be effective.
- The trial will be double blind and placebo controlled.
- But they still won't be sure until the larger studies are done to prove people who have received the vaccine are less likely to get infected than those who haven't received the vaccine.
- The Phase 1 study won't be completed until August 2021, but preliminary information will be available in around 2 to 3 months, which will inform the next steps.

The volunteers

- About 120 volunteers are involved in the trial.
- On 13 July, the first volunteers – 2 people called sentinels – will receive the vaccine candidate.
- The volunteers consist of people residing in Queensland.
- The volunteers are in the age range of 18 to 55.
- A thorough medical history is conducted by Nucleus Network doctors to ensure volunteers are fit, well and eligible to participate in the trial.
- Subjects return to the clinic for regular monitoring after the administration of the vaccine.
- A second dose will be given four weeks after the first dose and monitoring continues for 12 months.
- There are no additional isolation or social distancing requirements for volunteers as there is no live virus. There is absolutely no possibility participants can get COVID-19 from participating in the study.
- As with all clinical trials, there is also a proportion of volunteers who will receive a placebo, that is, they will not receive the active vaccine.
- Accordingly, all volunteers in the trial are still required to maintain social distancing and good hand hygiene practices to ensure they stay protected.

Safety

- Nucleus Network: "If we had any significant concerns regarding safety we would not be proceeding with the study. To be able to get to human trials any vaccine needs robust supporting information on both safety and efficacy from the lab as well as at least two animal studies. We mitigate these risks by:
    - only progressing vaccines that:
        - we are confident are safe
        - meet the requirement for an independent ethics committee review to ensure safety and efficacy are likely
    - only enrolling perfectly well people with no medical problems
    - having very experienced and well trained staff
    - carefully monitoring during and after the vaccine is administered."
- Nucleus Network principal investigator Associate Professor Paul Griffin has been the principal investigator on over 120 studies.
- His expertise is predominantly in early phase vaccine studies.
- Associate Professor Griffin also works clinically in infectious diseases and is a scientific advisory board member and director of the immunisation coalition. He has a great deal of experience with vaccines and vaccine clinical trials.
- All potential volunteers go through a detailed informed consent process with one of the trained study investigators (medical doctor) so all potential risks are clearly outlined prior to participating.
- All participants provide 'informed consent' when participating in a clinical trial.

Nucleus Network and Q-Pharm

- Q-Pharm was opened in 2002 by the then Queensland Premier, the Honourable Peter Beattie as a world-class, purpose-built clinical trial facility to take new drugs from scientific labs to patient tests to ensure they are safe for human use.
- Q-Pharm was formed by the Queensland Institute of Medical Research and The University of Queensland's technology commercialisation company UniQuest Pty Ltd.
- Since 2002 Q-Pharm has conducted 400 clinical trials.
- In February 2019, Q-Pharm was acquired by Nucleus Network, one of Australia's leading early-phase clinical research organisations.
- Nucleus Network owns 150 of the total 250 dedicated Phase 1 beds available in Australia over two sites in Melbourne and Brisbane.
- The network is supported by over 400 specialists.
- Nucleus Network is also trialling another COVID-19 vaccine candidate – for the United States of America biotech Novavax Inc., another Coalition for Epidemic Preparedness Innovations (CEPI) supported vaccine research project.
- In addition to the UQ vaccine trial in Brisbane, the Novavax vaccine is being trialled in Brisbane and Melbourne.

The search for a vaccine – global picture

- CEPI is supporting nine vaccine projects worldwide, including The University of Queensland project and the Novavax Inc. project.
- CEPI is also supporting the Chinese company Clover through its Australian subsidiary, with clinical trials just started in Perth.
- According to the World Health Organisation (as of 6 July 2020), there are 19 vaccine candidates out for human trial with a further 130 in pre-clinical evaluation.[3]
- According to the John Hopkins Coronavirus Resource Centre, there are now over 11 million confirmed cases of COVID-19 worldwide, with over 500,000 deaths.[4]
- In Australia (as of 7 July 2020) – there are 8586 confirmed cases of COVID-19 with 106 deaths.[5]

The economic impact

- According to the International Monetary Fund (IMF), world GDP has decreased by 4.9 percent this year.[6]
- The United States economy will shrink eight percent, Japan 5.8 percent, Brazil 9.1 percent, Mexico 10.5 percent and South Africa eight percent.
- International Labour Organization data estimates more than 300 million jobs were lost in the second quarter of the year.
- According to economic modelling compiled by former Reserve Bank board member Warwick McKibbin and fellow economist Roshen Fernando, the COVID-19 recession will cost the Australian economy at least $170 billion and weigh on the nation for years.
- If Australia suffers a second wave of the virus, the cost to the economy could reach almost $450 billion over the next five years.[7]
- According to the Australian Bureau of Statistics, 594,300 people lost their jobs in April, with a further 227,700 jobs lost in May.[8]
- Queensland has embarked on a massive economic recovery program.

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[3] https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines

[4] https://coronavirus.jhu.edu/map.html

[5] https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/coronavirus-covid-19-current-situation-and-case-numbers

[6] https://www.cnbc.com/2020/06/24/imf-global-economy-to-contract-with-coronavirus-recovery-slow.html

[7] https://www.smh.com.au/politics/federal/covid-19-to-cost-australia-170-billion-and-women-will-bear-the-brunt-20200625-p5561f.html

[8] https://www.abc.net.au/news/2020-06-30/job-losses-coronavirus-australia-covid-19/12401232

- To combat the pandemic, the Government committed more than $6 billion in support packages, and, last month, it released its Economic Recovery Strategy which has set out a plan to kick start the economy and get Queenslanders back to work[9].

[9] https://www.covid19.qld.gov.au/government-actions/our-economic-recovery-strategy#_stage-two