

International Clinical Trials Day

May 24, 2021

- COVID-safe measures such as telehealth consults for trials, and local deliveries of trial medicines are now serving to improve clinical trial processes beyond the pandemic
- Australia's contribution to global clinical trials continues to grow, telehealth and other digital measures offer potential to increase access via 'teletrials'
- In 2020 Novartis contributed to 141 Australian studies, with an investment of AUD20m1

Australian research community's 'teletrial' innovations from the pandemic keeping clinical trials going strong

International Clinical Trials Day, May 20, recognises contribution of all those involved in clinical trials

Australia has been swift to permanently adopt telehealth and other technology measures brought in during 2020 to ensure increased access to clinical trials for Australians.

Chief Scientific Officer at Novartis Australia and New Zealand, Dr Simon Fisher said the adoption of technology in healthcare during the pandemic had hugely accelerated in clinical trials just as it had for doctor/patient consultations.

Technology and tele-monitoring are enabling clinical trials to be more accessible for people in remote and regional areas of Australia, who previously wouldn't have been able to participate in trials usually based at metropolitan based centres.

These measures are playing an increasingly important role in accelerating patient assessment and recruitment for genetic conditions, according to Professor Robyn Jamieson,

Head, Eye Genetics Research Unit, Children's Medical Research Institute & Save Sight Institute.

Professor Jamieson who is also Head of Specialty, Genomic Medicine, Faculty of Medicine and Health, University of Sydney said there is an enormous amount of scope for technology and telehealth to improve genomic disease diagnosis and assessment of patients for suitability for clinical trials:

"Given the highly complex nature of reviewing genomic diagnostic data and staging of disease, the ability to have video conferencing with specialists able to easily connect and review the information can greatly speed up this analysis, decision making and recruitment into trials.

"In addition, it can make clinical trials more accessible to a greater number of patients and centres around Australia," said Professor Jamieson.

Dr Simon Fisher said one of the biggest learnings from last year was that clinical trials can still be overseen effectively, even with far less frequent travel. "Much of the monitoring can be done remotely, meaning more Australians can participate in the clinical trials, and the trials can be done more efficiently," he said.

"This is something Novartis has embraced in our clinical trials and the concept of remote monitoring not only makes the trial more efficient, it greatly benefits the patients taking part in the trials. We haven't yet moved to

fully virtual clinical trials but that is potentially something for the future," Dr Fisher concluded.

Teletrials have been defined as when a clinician at a larger centre (primary site) enrolls and treats patients in clinical trials in partnership with smaller regional and rural centres, allowing patients to participate closer to home.²

With technology, it means the search for and enrollment of patients in clinical trials can be accelerated with patients more aware of when and where trials are happening.

Australian research centres have been in a much stronger position to continue with clinical trials than many counterparts in other parts of the world where trial involvement had to be put on hold due to the pandemic. Dr Fisher said there was a global slow down in clinical trials but this year it is starting to pick up again.

In 2020, Novartis managed 141 studies, ranging from start-up activities to being in the process of closing out. In 2020, our investment was around AUD\$20m million. The company supports clinical trials in areas of innovation across a large range of disease areas including in oncology, haematology, ophthalmology, cardiovascular disease and multiple sclerosis.

The Novartis Trial Monitoring Organisation is one of the largest units of all the pharmaceutical companies in Australia devoted to clinical trial support – with 50 dedicated associates – and is a big contributor in Australia to local clinical trials, with more than 600 patients at more than 300 Australian centres.

Some of the measures Novartis has adopted on an ongoing basis include:

- Using tele-health (phone calls, video calls) so the trial doctors can check on a patient's progress remotely
- Hospital in the home allows some trial treatments, care and tests to be done at home
- Local pathology laboratory tests allow patients to get tests done outside hospital for safety monitoring
- The trial medicine can be delivered to home or the local pharmacy, avoiding the patient having to go to hospital to collect the study medicine.

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For further information and media enquiries:

Camilla Jury, Camilla.jury@novartis.com / +61 439 949 776

+61 439 949 776

+61 439 949 776

1. Investment via both Novartis AG and Novartis Pharmaceuticals Australia Pty in Australian local and local sites of global trials, includes study and staffing costs, excludes travel
2. Victorian Comprehensive Cancer Centre, Teletrials. Available from: viccompcancerctr.org/what-we-do/clinical-trials-expansion/teletrials/

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