

Supporting Clinical Trials During the COVID-19 Pandemic

Position Statement 23rd March 2020

COVID-19¹ has been designated by the WHO as a global pandemic². World-wide, countries have declared a national emergency with services closed and unprecedented pressure on health services. In Australia, the Commonwealth Department of Health has declared COVID-19 infection as a health emergency³. Biopharmaceutical, Medical device companies and Clinical Research Organisations (CROs) (Clinical Trial Sponsors) conducting clinical trials in Australia have prepared this statement in recognition of the challenges the health system faces. We acknowledge the physicians, nurses, allied healthcare workers and scientists for their efforts during the course of this pandemic.

Clinical trials remain critical in the path to bringing innovative drugs, vaccines and therapies to consumers and patients in Australia in a safe and regulated manner. Given the anticipated growing impact of COVID-19 on the health system and a range of services, Clinical Trial Sponsors are working with their doctors and nurses to prepare for disruption to normal research activities due to this pandemic. At all times, the safety and continuity of care of clinical trial participants is the key concern of Clinical Trial Sponsors and clinical trial centre staff.

Clinical Trial Sponsors are committed to the delivery of clinical research and will work to ensure that the clinical trials already underway are managed as well as can be during the pandemic. Clinical Trial Sponsors are working closely with clinical trial centre staff to understand what additional support can be provided to overcome the challenges that are presenting due to COVID-19 disruptions.

Clinical Trial Sponsors acknowledge and will comply with all federal and state health directives and will maintain a watch and act position in relation to these directives⁴.

Importantly a risk-based assessment of all clinical trial activities will ensure that the safety of patients and clinical staff involved in trials is considered and the integrity of the clinical trial data is maintained⁵.

A flexible and supportive clinical trials environment should ensure that Australian patients are best placed to get early access to experimental vaccines and treatments for COVID-19.

¹ <https://www.who.int/health-topics/coronavirus>

² <http://www.euro.who.int/en/health-topics/health-emergencies/coronavirus-covid-19/news/news/2020/3/who-announces-covid-19-outbreak-a-pandemic>

³ <https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/coronavirus-covid-19-current-situation-and-case-numbers>

⁴ <https://www.health.gov.au/>

⁵ <https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods#block-views-block-file-attachments-content-block-1>

But this will rely on Australia's ability to ensure that Clinical Trials can continue to be set up and patients can be accessed. In fact, this is an opportunity to identify measures that will deliver rapid responses to critical health issues and harmonisation of ethics, governance and regulatory processes.

Support for the Clinical Trials Sector – *The R&D Taskforce COVID-19 Working Group*

The Research & Development Taskforce has formed a COVID-19 Working Group to support the clinical trials sector as the effects of the COVID -19 pandemic are felt around the nation.

It is acknowledged that a strong collaborative sector-wide effort will be required, as there are many stakeholders involved in the delivery of clinical trials. The Working Group will seek to engage with representatives from all sectors including, Pharmaceutical, CRO, Medical Device and Biotechnology companies, Phase I units, Governments and Health Depts, Ethics committees and Governance, and Academic groups.

The Working Group will look at all aspects of clinical trial delivery with the intent of ensuring that trial participants and trial sites are supported and where possible, that patients continue to receive treatment and all safety activities are completed.

The goal will be to identify practical solutions to support clinical trial sites as all parties work together to mitigate the effects on clinical trial patients until the COVID-19 situation eases.

Clinical Trial Participants

Protecting the safety and well-being of participants is at the forefront of all activities associated with clinical trials. As the COVID-19 pandemic unfolds in Australia additional strategies will need to be implemented to ensure that the safety, well-being and ongoing conduct of clinical trials are maintained, with as little interruption and inconvenience to the participant as possible.

Good communication with clinical trial participants will be essential in the coming weeks and months to alleviate any concerns they may experience. Continued communication regarding their trial experience together with clear information about access to hospitals will be critical. If participants are required to change their visit schedule, location of clinic visit, or trial procedures then providing as much notice and information as possible is essential. Where required or possible, trial participants may be encouraged to conduct trial 'visits' by the use of telemedicine.

Clinical Trial Centre staff – Doctors, Nurses and Pharmacists

Investigators, Study Coordinators and Clinical Trial Pharmacists will likely require additional support during the coming months. Study Site staff and Clinical Trial Sponsors will need to collaborate even more closely than normal to minimise disruption to ongoing clinical trials and ensure minimal inconvenience to participants. This will include:

- Ensuring the ongoing safety and welfare of the trial participants is not compromised;
- Working together to examine alternate ways that clinical trials proceed with minimal interruption;
- Exploring options for virtual meetings and remote monitoring with state health departments and hospitals;
- Identifying possible protocol amendments that reflect the changing environment whilst ensuring compliance;
- Managing ongoing recruitment of new participants.

Role of Clinical Trial Sponsors

Clinical Trials Sponsors have an obligation to ensure that clinical trial participants continue to receive access to treatments as part of their clinical trial participation, as well as protecting participant safety in relation to the trial.

Clinical Trial Sponsors recognise and understand that the clinical trial site staff may be under increasing pressure as their own work environment is necessarily changed by patients affected by COVID-19. Clinical Trial Sponsors also acknowledge the necessary redeployment in some cases of research staff to COVID-19 activity.

Clinical Trial Sponsors will work with clinical trial centre staff to examine innovative solutions to maintain the welfare of clinical trial participants and allow their participation to continue in an as uninterrupted manner as possible. Strategies may include:

- Reduced frequency of onsite monitoring activities;
- Examine the possibility of conducting certain site 'visits' by teleconference or webinar;
- Utilise remote monitoring where possible;
- Facilitate Direct-to-Patient supply of study treatment, where appropriate and approved by HREC;
- Proactively work with trial sites to minimise protocol deviations;
- Assist and educate site staff on how to document variations to usual procedures and processes.

Ethics Committees

Ethics Committees have a vital role to play during the COVID-19 pandemic.

It is recommended that Clinical Trial Sponsors are in regular contact with the relevant Ethics Committees to minimise the impact on clinical trial participants. This may involve seeking review and approval for matters such as:

- Protocol Amendments;
- Protocol Deviations;
- Variation to the methods of supply of Investigational Product or supporting treatments;
- Modifications to pathology collections, as some collection facilities may be overwhelmed;
- The conduct of remote Participant ‘visits’ and/or assessments;
- Modified communications to patients, such as revised Participant Information Sheets and Consent forms;
- Review of individual patient participation in a clinical trial if they become affected by COVID-19;
- Any specific clinical trial related safety concerns.

Clinical Trials for COVID-19 Treatment and Prevention

It is recognised that clinical trials will be required to develop new vaccines and treatments to combat the COVID-19 virus. Australia has well developed and highly-regarded early phase clinical trial facilities and other trial centres and expertise to conduct these clinical trials. These facilities are well prepared and immediately ready to assist in the development of these treatments, should they be required.

This Position Statement was developed by the Research & Development Taskforce (RDTF), representing the innovative development of new medicines and medical devices. The RDTF is represented by Medicines Australia, AusBiotech and the Medical Technology Association of Australia.