Clinical Trials and Q&A for Health Consumer Organisations and patients

The innovative pharmaceutical manufacturing industry is doing all we can to respond to the COVID-19 pandemic.

The safety and wellbeing of patients, research participants and healthcare workers are our absolute priority. With the growing impact of COVID-19, many pharmaceutical companies have taken the decision to temporarily pause recruitment of new participants in interventional studies and starting new studies, with the exception of certain studies where life-threatening conditions have few or no other therapeutic options.

The most important responsibility we have is to protect and care for the patients currently in our clinical trials. The industry is taking this step proactively, to help clinicians and healthcare institutions focus on the participants currently in our clinical trials and patients who need support during the pandemic.
In addition, it is also critical that public health systems remain able to respond to the needs of the community and those impacted by COVID-19.

Clinical trials remain a critical path to bringing innovative drugs, vaccines and therapies to patients in Australia in a safe and regulated manner. Pharmaceutical manufacturers and Clinical Trial Sponsors are working in conjunction with study site doctors and nurses to address changes to normal research activities.

At all times, the safety and continuity of care of clinical trial participants is the key concern. Each Clinical Trial Sponsor will work directly with their clinical trial centres to manage key challenges and disruptions to ensure continuity of care.

Please contact your clinical trial staff member to discuss your personal situation as each circumstance will be different.

Q&A

Why has the pharmaceutical industry temporarily paused recruitment of new participants in clinical trials?
The industry is doing this in the interests of public health. The safety and wellbeing of patients, research participants and healthcare workers are paramount. It is also critical that public health systems remain able to respond to the needs of the community and those impacted by COVID-19.

How long will this temporary pause last for?
Each Clinical Trial Sponsor manages their clinical trials differently so please check with your study doctor or study nurse to see how you might be impacted.

Wherever possible, patients already enrolled in ongoing trials will not be impacted. Clinical Trial Sponsors will continue research and development activities for future trials and regulatory submissions and we expect over time to resume study recruitment and start new studies.

As the situation evolves, the pharmaceutical industry will continue to evaluate and take all necessary steps to support patients and our healthcare colleagues and keep them informed of any developments.

Who do I contact for more information about my clinical trial?
Please contact you study site doctor or nurse directly. The study clinic or hospital location will have measures in place in response to COVID-19, and patients should follow their study staff guidance.

How are Clinical Trial Sponsors managing existing patients during this time?
Clinical Trial Sponsors will continue to monitor and evaluate the COVID-19 pandemic situation. Patients will be contacted directly by the study doctor or study nurse to ensure they receive support throughout this time.

Will new sites for ongoing studies be approved during this time?
This will vary by Clinical Trials Sponsors; however, most are pausing new site additions over the short-term. The situation will continue to be reassessed and any changes will be communicated directly to the study site.

What if patients who are enrolled in a current clinical trial are unable or unwilling to attend site visits?
Patients who are unable or unwilling to attend protocol-specified trial visits and procedures, will remain in the trial for as long as deemed appropriate and with consent from the participating patient. Clinical Trial Sponsors are deploying alternative ways to connect clinical trial staff and participants for continuity of care. These efforts may include remote monitoring, changes to how medicines are delivered to patients and local laboratory use.

What about new clinical trials?
With the COVID19 back drop a decision has been made by most Clinical Trial Sponsors not to start new sites or studies over the short-term. This will be reviewed on a regular basis and they will commence again when deemed safe to restart. The study sites will be directly contacted with any updates.

What happens if a patient is showing symptoms of COVID-19 or has tested positive to COVID-19?
If you develop symptoms of COVID-19 infection or have a confirmed diagnosis of COVID-19 infection you should:

- Follow the standard self-isolation advice immediately.
- Contact their GP

It is important that participants inform clinical trial site staff if they are showing symptoms or test positive to COVID-19 in advance of attending any trial visits.
For all clinical study participants - please contact your clinical trial site staff member immediately.

What about Investigator-Sponsored Research (ISR) / Investigator-Initiated Trials (IIT) - will they continue?
Each institution/hospital/clinic will provide guidance on their particular study.

Clinical trial sponsors during this time will continue to review newly proposed study concepts through their normal procedures.

How is the industry working together on clinical trials during the evolving COVID-19 pandemic?

The Research & Development Taskforce (RTDF) has formed a COVID-19 Working Group to support the clinical trials sector as the pandemic continues.

The Working Group will seek to engage with representatives from all sectors including, Pharmaceutical, Contract Research Organisations (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 patients and trial sites are supported and where possible, that patients continue to receive treatment and all safety activities are completed.

Click here to view the RTDF position statement on Supporting Clinical Trials During the COVID-19 Pandemic

Clinical trial sponsors will review and act in accordance with the following guiding principles:

- Ensure safety for patients and clinical trial staff
- Ensure adequate study treatment supply is maintained
- Compliance to all regulatory requirements
- Monitor emerging Health Authority guidance and HREC recommendations
- Ensure the scientific integrity of clinical research
- Will comply with all federal and state health directives