



Australian Government
Department of Health
Therapeutic Goods Administration

Clinical trial processes

Information relating to COVID-19

31 March 2020

The Therapeutic Goods Administration (TGA) has received a number of enquiries about processes for clinical trials relating to COVID-19 (coronavirus).

The TGA is giving activities relating to the COVID-19 pandemic the highest priority.

Further guidance on the impact of COVID-19 on clinical trials for institutions, Human Research Ethics Committees (HRECs), researchers and sponsors is available on the [Department of Health website](https://www1.health.gov.au/internet/main/publishing.nsf/Content/Clinical-Trials) (<https://www1.health.gov.au/internet/main/publishing.nsf/Content/Clinical-Trials>).

CTN processes

The vast majority of clinical trials of unapproved therapeutic goods in Australia are conducted through the Clinical Trial Notification (CTN) scheme. This is also the case for clinical trials relating to treatment or prevention of COVID-19.

The CTN scheme is a notification scheme and, as such, we do not review or evaluate any data relating to the clinical trials at the time of submission. All material relating to the proposed trial, including the trial protocol, must be submitted directly to the relevant Human Research Ethics Committee (HREC).

Under the *Therapeutic Goods Regulations 1990*, once a CTN form is submitted and the relevant fee is paid, the trial is deemed to be 'notified' and the unapproved therapeutic good/s can be lawfully supplied for the purposes of the trial.

The TGA's acknowledgement of the trial is an administrative process and, for our purposes, is *not* required before the trial can begin. However, we appreciate that some HRECs and Approving Authorities do require TGA acknowledgement prior to commencement. We will accept CTN form submissions while the sponsor is obtaining any required approvals from the HREC and Approving Authority.

To submit a CTN, login to the [online TBS portal menu](https://business.tga.gov.au) (<https://business.tga.gov.au>). Refer to the [Clinical trial notification \(CTN\) form - user guide](https://www.tga.gov.au/publication/clinical-trial-notification-ctn-form-user-guide) (<https://www.tga.gov.au/publication/clinical-trial-notification-ctn-form-user-guide>) for guidance. If you do not have access to the online TBS portal menu, please contact TBS

Helpdesk at ebs@tga.gov.au (<mailto:ebs@tga.gov.au>) or 1800 010 624. The target time to process online CTNs is 5-7 working days.

For COVID-19 related trials, once you have submitted the online CTN form and paid the relevant fee, contact our Clinical Trials team on 02 6289 4614 or email clinical.trials@health.gov.au (<mailto:clinical.trials@health.gov.au>) and we will ensure the trial is processed as a priority.

See the TGA's [Clinical Trials web page](http://www.tga.gov.au/clinical-trials) ([//www.tga.gov.au/clinical-trials](http://www.tga.gov.au/clinical-trials)) for further information about clinical trials undertaken through the Clinical Trial Exemption (CTX) scheme. CTX requires an evaluation process by the TGA and timeframes and data requirements may vary. Trial sponsors should contact us about COVID-19 clinical trials proposed to be conducted under the CTX scheme as early as possible.

Variations due to COVID-19

For clinical trials notified under the CTN scheme, the TGA acknowledges that there may be deviations from trial protocols relating to the supply of the Investigational Medicinal Product (IMP) and resulting from potential quarantine and travel restrictions (for example, patients may need to be managed remotely). These deviations **do not** need to be notified to the TGA.

Other variations to the CTN in response to COVID-19 that **do not** need to be notified to the TGA include changes to:

- trial start/finish dates
- Product Information
- numbers of participants
- name of the trial approving authority.

Variations to the trial, such as changes to existing therapeutic goods, addition of therapeutic goods or addition of sites and those variations that are not in response to COVID-19 will continue to require notification to the TGA.

The TGA is handling enquiries relating to COVID-19 as a priority. For any questions regarding the clinical trial schemes please contact the clinical trials team at 02 6289 4614 or email clinical.trials@health.gov.au (<mailto:clinical.trials@health.gov.au>).

Category: Clinical trials

URL: <https://www.tga.gov.au/node/904199> (<https://www.tga.gov.au/node/904199>)