20 March 2020

COVID-19 Guidance on Clinical Trials

Guidance for clinical trial Sponsors, sites and researchers

COVID-19: Guidance for clinical trial Sponsors, sites and researchers

NSW Health is responding to an outbreak of a novel coronavirus (COVID-19), first diagnosed in China in December 2019.

This guidance has been provided to minimise the adverse health impacts on NSW clinical trial participants and reduce the burden and disruption to health-related services in NSW.

Safety of clinical trials participants and risk reduction remains a priority for NSW Health. Sponsors, sites and researchers are advised to consider the wider impact of COVID-19 on their clinical trials portfolio and participants, as related to health system reprioritisation, restrictions on movement, and supply chain challenges.

Where possible all new clinical trial arrangements should be managed prospectively as a Protocol Amendment. However changes may need to be implemented as Urgent Safety Measures (NHMRC Safety Monitoring and Reporting in Clinical Trials 2016) and reported immediately.

Sponsors are reminded to consider the need to obtain Participant Informed Consent for changes to trial conduct. NSW Health also requests that any changes are designed to have minimal impact on the NSW Health system including HREC, Research Governance and clinical trial unit staff.

Active clinical trials

Sponsors, sites and researchers should consider:

- The risks to participant safety in either (i) continuing a clinical trial or (ii) discontinuing a clinical trial where there are no other treatment options. Where there is an unacceptable risk to participant safety in continuing a clinical trial, sponsors and sites should decide whether to temporarily halt recruitment or discontinue the trial altogether.
- Availability of Principal Investigator and delegation of responsibility– consider healthcare reprioritisation and the PIs primary responsibility of the trial under ICH-GCP. Availability of clinician investigators and research nurses will be impacted as resources are diverted to essential services.
- Trial visits – changes to participant visits including reduction in visits, establishment of satellite sites, conduct of out-of-hospital visits, remote consultations, telephone calls, emails and postal questionnaires.
- Continuity of IP to participants – safety of participants and discontinuation of investigational product should be carefully considered, including the safety of abruptly interrupting study drug. Dispensing, shipping and storage arrangements should be reviewed.

  This may include;

  - dispensing to a third party where a trial participant is in self-isolation or practicing social distancing
  - dispensing an extended supply of study drug beyond protocol-mandated dispensing
  - couriering study drug to participants' homes,
  - chain of custody and temperature monitoring requirements.
- Protocol amendments and deviations – contact the reviewing HREC and Research Governance Office in accordance with the attached advice for protocol amendments, deviations and safety reports. Requested changes should be prioritised and managed to reduce the administrative burden on NSW Health staff. Quality of documentation practices at site and by Sponsors must be maintained. New trials of potential COVID-19 therapeutics must follow established TGA and NHMRC processes including HREC approval.
- Changes to monitoring arrangements including reduction in frequency and/or increased remote monitoring.

Clinical trials currently in start-up phase or planned for 2020

Consider your planned clinical trial portfolio for 2020 and allocate according to capacity. Trials currently in start-up phase through Q2 2020 may require review and postponement depending on the developing COVID situation.

For further queries please contact: clinicaltrialsNSW@health.nsw.gov.au

For the most recent information on COVID-19, please refer to the NSW Health Website.