FAQs

National Clinical Trials Governance Framework – Clinical Trials Portal

Is the Clinical Trials Portal available only to those participating in the pilot, or can other organisations access it?

All health service organisations and interested stakeholders (for example university staff and students, industry representatives, consumer representatives or state or territory government representatives) can register with the Commission to access the Clinical Trials Portal. Users will be required to provide a professional email domain to register.

Are site contributors able to register new users if there is no site administrator for the health service organisation?

Site contributors do not have any administrative rights so they cannot register other users on behalf of their health service organisation. If a health service organisation does not have a site administrator, all site contributors (general users) will have to register and be verified by the Commission to access the Clinical Trials Portal.

User accounts have one of the following levels of access:

- **Basic access:** users with basic access are only able to view and edit their own submissions and generate basic reports
- **Clinical department access:** users with clinical department access are able to view and access submissions from other users within the same clinical departments and generate reports at the clinical department level
- **Health service organisation access:** users with health service organisation access are able to view and access submissions from all users within the same organisation and generate reports at the clinical department level and for the whole organisation.

You can request a specific level of access by contacting the Clinical Trials Team at **CTgovernance@safetyandquality.gov.au**.

How secure is the data hosted on the Clinical Trials Portal?

The Clinical Trials Portal is hosted on a secure HealthIT system. All users will be verified either by the Commission or by the designated site administrator for the health service organisation before they can access the Clinical Trials Portal. All users can be confident that their data is hosted in a secure environment and the Commission adheres to its **privacy policy** for holding and managing health information.

Which web-browsers can be used to access the Clinical Trials Portal?

To access the Clinical Trials Portal, users are recommended to use Chrome, Microsoft Edge or Firefox. Internet Explorer is no longer a supported system.

Is the information entered into the Clinical Trials Portal available to the accreditation assessment team at the time of assessment?

The self-assessment tool has been developed to assist health service organisations to undertake a gap analysis and assess their readiness to meet the actions in the

National Clinical Trials Governance Framework (Governance Framework). The operational metrics tool enables health service organisations to review their clinical trial operations through a series of automated reports. Entering and completing data can be undertaken as required by individual health service organisations as some may already have systems in place to report and review their clinical trial activities.

For the purpose of the pilot, the information entered in the Clinical Trials Portal will be accessed by the pilot consultants and accreditation assessors.

Will the Clinical Trials Portal be available after the pilot?

The Clinical Trials Portal will be available on an ongoing basis following the pilot. It is intended that the Clinical Trials Portal will be maintained and enhanced to allow for improved user experience by trial units and health service organisations more broadly.

Is there any option to import data from existing clinical trials management systems into the operational metrics tool?

The current system allows for manual data entry only. The Commission is developing the capacity to upload data as a CSV file. Following the pilot, the Commission will investigate the capacity to link the operational metrics tool to other system.

Is any commercial-in-confidence information required for the operational metrics tool?

The operation metrics tool does not collect any commercial-in-confidence information. Commercial-in-confidence information relates to the clinical trial protocol, the investigator's brochure, study materials, early study results and the investigational product.

The clinical trial information required for the operational metrics relates to the project title; the type of study; trial phase and sponsor type; time frame for human research ethics committee approval; local site authorisation and recruitment activity. The investment data section collects information on the expected income such as per patient payment. The financial information should be available in the clinical trial research agreement. Generally, this is the only information a trial coordinator has at hand to contribute to the organisation's financial and business planning.

Can the self-assessment be completed at a clinical trial unit level?

It is important that clinical trial units become familiar with the actions in the Governance Framework. This is because assessment to the Governance Framework includes clinical trial units and ensures all actions in the NSQHS Standards have been met by the health service organisation.

Health service organisations may wish to nominate someone to coordinate the completion of the self-assessment tool for the organisation. It is intended that this person would coordinate a whole of organisation approach inclusive of the clinical trials work force, clinical and non-clinical managers, human resources, finance and the executive to review the organisation's readiness to meet the actions in the Governance Framework.

Questions?

For more information, please visit:
safetyandquality.gov.au/clinical-trials

You can also contact the Clinical Trials team at:
CTgovernance@safetyandquality.gov.au