Research Study Central Coordinating Team (CCT)

The research study CCT responsibilities are to provide the Ottawa Methods Centre (OMC) – Data Management Services (DMS) team with the ***final*** Case Report Forms (CRFs), make all required changes and modifications in a timely manner, and carry-out EDCS ***final validation*** checks and perform acceptance testing before the research study web-EDCS release into 'live' mode.

The research study CCT roles are to coordinate the selection of study users, activate sites, maintain the master user list (keep it up to date) and to provide study site users with proper training and all necessary information regarding the usage of the web based EDCS. In addition, the research study CCT must regularly check the data in the EDCS and perform data quality control. Their responsibilities are to ensure that all users of the system are adequately trained, entered correct data, and assigned with the proper user role, either blinded or un-blinded. Any form changes, form flow and/or special requests must be reviewed and approved by the research study CCT before sending them to the OMC-DMS to work on it. The research study CCT must always maintain the latest copy of the research study case report forms and the forms must be properly dated and with updated versioning.

In summary, the research study CCT must:

- Keep the case report forms up to date
- Track all requested changes that are sent to the OMC-DMS
- Test and confirm all changes before it goes into live mode
- Provide timely feedback after mock-up version and changes
- Keep the latest copy of the Master User Access List

CLINICAL SITES

The site user roles are to collect study data, verify and enter site participant data into the web based EDCS properly, correctly, and timely. The site coordinators are responsible for verifying data after entering data into the EDCS and to respond to any queries from the research study CCT. The site coordinators are responsible for notifying the research study CCT if there are any staff changes, any new site user, and any issue with the EDCS. The research study CCT will review and relay the messages to the OMC-DMS team. Clinical sites do not contact OMC-DMS directly for any staffing changes or CRFs change request. It must be done via the research study CCT.

Data Management Services (DMS)

The OMC–DMS is responsible for the design, coding, testing, implementing, and maintaining of the web-based EDCS. DMS will only work on the development of the study web-EDCS when the case report forms are final (or very close to final, >95%). Changes after it's designed, developed, and tested are time-consuming and costly. However, changes are inevitable (and it may alter estimated cost) and the OMC-DMS responsibilities are to make changes upon request from the research study CCT. The OMC-DMS must test the web-EDCS properly after any form, code and/or database modifications before submitting it to the research study CCT for final acceptance tests and validation checks. The OMC-DMS responsibilities are to provide adequate support when needed during support hours (08:00 – 16:00 ET). Below is the list of items that OMC-DMS does not provide to the research study CCT:

- Final data collection forms, list of changes
- Web-EDCS training guide, manual
- Study SOPs, DMPs
- Master User Access List

The cost estimate that the OMC-DMS provides is to use our web-EDC platform without making changes to the web platform core design. However, it is fully customizable, if you wish to change our platform design to suit your study needs, it will result in extra charges. Further, any changes after the mock-up version of the web-EDCS may result in extra charges as it will requires more work.