Canadian
Cancer Clinical
Trials Network

EDGE: Clinical Trials Management System

Frequently Asked Questions & Answers

1. **How are usernames and passwords created, stored and managed?**
   The usernames and passwords are created, stored and managed by the administrative users of the organizations at the users' site, or designated EDGE support staff. The system requirement for passwords for EDGE includes:

   - At least eight characters long
   - Uppercase characters (A-Z)
   - Lowercase characters (a-z)
   - Numbers (1 -9) or symbols

   The password expiration policy (# of days before the password expires) is set at 180 days.

2. **Is the application capable of integrating with our Active Directory?**
   EDGE has its own authentication system. EDGE does not use LDAP or AD (active directory for managing user names, passwords, permissions etc.). EDGE authorizes users using a local username and password database within the application.

3. **Who will be able to access data – and does information regularly traverse the internet?**

   The EDGE system provides administrative oversight through an audit function that tracks all activity and access. This will be monitored to ensure no unauthorized access. The physical EDGE database is hosted on its own dedicated server at OICR in a locked facility with restricted access. OICR's secure facility requires authorized card access and is monitored by motion sensing cameras. OICR personnel, on a need to have access basis, have access to the OICR datacentre via authorized card access.

4. **Are passwords/credentials "hashed"?**
   Passwords are one-way hashed so they cannot be retrieved; they can only be reset.

5. **Are passwords/credentials encrypted?**
   Yes.

6. **Does the system use Role Based Access Controls (e.g., different levels of authorization based on someone's role)?**
   Yes, the system uses role-based access controls.

7. **Does the system keep track of all errors, login successes/failures, viewing, changes or deletions of data?**
   All changes to data can be tracked. A technical error log is recorded for EDGE developers. Login successes and failures are recorded by EDGE, and three incorrect login attempts will lock an account.

8. **Please describe the hosting facility of EDGE in OICR.**
   EDGE resides in a secure virtual machine, within OICR's virtualized infrastructure that is hosted in a locked facility on the OICR premises.

9. **Can we import all of our patient appointments to EDGE?**

The importing function is not intended for importing patient appointments and is intended mainly for trials and patient accrual.

10. How much IT support is needed? Will the administrative user need to have some IT background?

Users will access the 3CTN EDGE server over the Internet from computers or workstations at their individual site; no additional hardware or software is required to access the system.

The browser requires Internet Explorer (IE) 8 and higher, or Google Chrome, Firefox, or Safari. The system is user friendly and is built from a Research Administration perspective, so anyone who has knowledge of clinical trials will be able to use the system. There will also be 'super users' responsible for providing assistance in each region.

[**Note**: The regional Super User will assist sites with adoption of EDGE within the region by (1) coordinate EDGE implementation; (2) identifying, formalizing and implementing associated best practices; (3) providing high-quality training and education to Lead Local Admin Users; (4) facilitating communication, collaboration and exchange of knowledge associated with EDGE; and (5) assisting users in troubleshooting issues.]

11. How much is the cost of using EDGE? How many users can you have per hospital? Is cost based on the number of users?

For large 3CTN sites such as PMCC, C17, BCCA and QCROC, the total fee of a regional node (NCC and its affiliated NACCs) is $12,000 per year. The fee cannot be covered by 3CTN funds. EDGE may be used for academic and industry cancer trials. It is up to the NCC and its affiliated NACCs to decide if they want to share the subscription fee. The fee does not cover use of EDGE for non-cancer trials. There is no limit to the number of users.

After discussions with EDGE, the fee structure has been revised based on the size of the site (as below) with exception for PMCC, C17, BCCA and QCROC:

Size of site	Definition	Annual Subscription Fee
small	< 10 staff; <25 active trials	$1000
medium	between 10-15 staff; between 25-50 active trials	$2000
large	more than 15 staff; >50 active trials	$4000

12. Who inputs the information for the global studies? In Canada, there is a similar site - canadianclinicaltrials.ca that lists all Canadian studies. Is it your goal that EDGE will replace this?

EDGE is not a clinical trial listing. It is a project management system that houses a lot more information. The portfolio list we will host and make available just allows people to see what is on the 3CTN portfolio. It draws from many listings, including www.canadiancancetrials.ca and www.clinicaltrials.gov. It does not replace it.

13. Is the software bilingual? Do you have the opportunity as a user to select your language of preference?

EDGE is only available in English. There will however be a French speaking support person.

14. Could you please clarify what would be the structure of the system within 3CTN if an institution wants to implement EDGE outside of cancer?

3CTN will assist 3CTN sites to implement EDGE for all cancer studies if they are interested. If an institution wants to use it for purposes beyond cancer studies, a different structure applies.

15. If we participate in 3CTN, is EDGE mandatory?

The use of EDGE is not mandatory as it is ultimately your decision; however we do hope that many sites will adopt EDGE, as use of the same system will make working across Canada easier. We do recommend people adopt a formal system beyond Excel or paper-based systems. If you choose not to, you will need to provide 3CTN with any required information which will subsequently be uploaded to the 3CTN EDGE system.

16. What are the benefits of having EDGE at network institution and sites

At Network Institution/Province Level:

- Facilitate and promote a collaborative research environment
- Support and promote best practices within the clinical research process
- Streamline regulatory processes
- Reduce the burden of reporting recruitment data on sites
- Convenient and efficient: Every centre in the province or network institution will go into the same system, which will allow centres to view available trials across all centres. A decision can then be made to cross-refer patients or to open a desired trial at a second site.
- Capabilities of tracking metrics on individual trials to create tailored reports for our different stakeholders such as the funders, investigators, foundations and the public
- An essential resource to support member sites and ultimately increase trial efficiency at the site level and patient recruitment across the entire Network.
- Canadian patients and researchers having increased access to academic trials

At recruiting site level:

- Streamline the screening and recruitment process
    - Easy to find bottleneck of trial activation and recruitment process
    - Facilitate team coverage: all files in one place
    - Less time needed to answer the questions: Less phone calls and emails
    - Efficient data handling
- Convenient and centralized document storage
    - No working binders needed to the clinic or home.
    - Latest documents available: Paper less/light/more email space released
    - Store as many as files for daily usages: source documents, work sheets, flow sheets, SAE tracking
- Recruit more patients
    - More time with the patients: Patient care and paper balance
- Work load balance:
    - Easy to quantify your workload/help inform the capacity by having the volume and complexity information
- Financial benefits: All of the efforts will help bring income to the department while advancing clinical research for patients

17. What kind of support of 3CTN Coordinating Centre will provide to the sites who adopt EDGE?

- 'Super user' training and networking
- Monthly demo to interested sites and answering of inquiries

- First line EDGE support, and UK contact
- Work closely with the pilot sites
- Project plan and site training package to assist sites in their implementation:
    - General EDGE implementation document (intro, background, inventory of available documents)
    - Implementation timelines
    - Readiness checklist
    - PIA
    - Training Guide
    - Data dictionary
    - Communication plan
    - Support/contact information (online support menu)
    - Set up global templates

18.Where is the data stored? How is it backed up? What is the privacy impact?
Most of the questions are addressed in the Privacy Impact Assessment Report (PIA). The report is available upon request. The reason it is stored at OICR, (the legal entity behind 3CTN and its data storage in compliance with all regulations) is to avoid data storage outside of Canada, and to save sites from incurring costs to set up local storage.

Selected files and folders in the EDGE production application server are backed up daily incrementally at 11 pm and fully every Saturday at 11 pm.

The contents for backup are from these locations, selected according to EDGE Support:
C:\inetpub
E:\Edge
E:\Files
E:\Portfolio

EDGE databases are backed up fully using SQL backup utilities. The backup files are then backed up to tape daily at 12 am.

The OICR System Administrator conducts monthly maintenance to ensure the operating system is fully patched.

19.Is it in compliance with 21CFR11?

EDGE is compliant with the FDA 21 part 11, as there is an audit log that provides a time date stamp for actions within the system and the user who has committed the action.

However, formal requirements for FDA compliance is normally not relevant to EDGE; instead pertains to concepts related to a CDMS / eCRF which requires full compliance. 21CFR part 11 is not applicable as EDGE is not a CRF or source document system/EMR. It is a project management tool, just like other quality systems hospitals have. Some of the components will be in the PIA.

20.Do we need to indicate EDGE in the consent template to our patients?

There is agreement that the requirement to inform patients about the use of a CTMS database probably needs to be outside the parameters of consent forms for individual studies and be an institutional responsibility.

The primary reason is that the CTMS database is a Quality Management/Quality Improvement initiative, at the institutional level (with further use of aggregate statistics by 3CTN) and information in the database is not relevant to a particular research study, (i.e., is not study-specific data for purposes of data analysis, etc.), but is being collected for administrative/planning/evaluative purposes by the institution, and subsequently for use by 3CTN.