

## **EDGE: Clinical Trials Management System Data Hosting**

### **Frequently Asked Questions & Answers**

#### **1. 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 Equinix (formally Q9) in a locked facility with restricted access (See Equinix fact Sheet). Equinix personnel, on a need to have access basis, have access to the Equinix datacentre via authorized card access.

#### **2. Are there any change in vendor after data moving out of OICR?**

Equinix will not be the vendor for the EDGE application. The only change that is occurring is the location of the data housing - everything else remains the same.

Equinix will be referenced in the site agreement as the approved Canadian Hosting Environment. All responsibility for hosting resides with University of Southampton, so, if the application is not running because of an issue - that is the responsibility of the University of Southampton to resolve. Subscribers will not need to have contact with Equinix.

#### **3. How much is the cost of using EDGE in the new agreement? How many users can you have per hospital? Is cost based on the number of users?**

After discussions with EDGE, the fee structure is based on the size of the site. For the new agreement, you can include cancer and non-cancer trials. The size is based on your active trials (cancer and non-cancer) running per year. For more details please contact the Coordinating Centre at [info@3ctn.ca](mailto:info@3ctn.ca).

#### **4. 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 may however be a French speaking support person.

#### **5. 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. Using 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.

#### **6. What are the benefits of having EDGE hosted in Equinix instead of OICR?**

OICR can only support cancer research projects. In Equinix, there is no such limitation. It can also allow the merging of the three hosting versions of EDGE into one and facilitate better data standardization and collaboration.



## **7. What kind of support from the 3CTN Coordinating Centre will be provided to the sites who adopt EDGE?**

For 3CTN member sites, it remains the same; for non-3CTN member sites, please refer to your site agreement.

- 'Super user' training and networking;
- Monthly demos to interested sites and answering of inquiries;
- First line EDGE support and UK contact and;
- Project plan and site training packages to assist sites in their implementation including:
  - General EDGE implementation documents (intro, background, inventory of available documents);
  - Implementation timelines;
  - Readiness checklist;
  - Training Guide;
  - Data dictionary;
  - Communication plan;
  - Support/contact information (online support menu); and
  - Setting up global templates.

## **8. Where is the data stored? How is it backed up? What is the privacy impact?**

Most of these questions are addressed in the Equinix Fact Sheet. The reason it is stored at a centralized location in Equinix (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. Each centre needs to conduct its own privacy impact assessment. OICR/3CTN has completed one for its own institution and can be available upon request.

Back up procedures for EDGE data base are as follows:

- A transactional back up is taken every 30 minutes;
- A differential back up is taken every 4 hours; and
- A full back up is taken every night at 2am (EST).

In an event of failure the most recent full back up is restored, the differential back up is restored onto this and the transaction logs are restored.

All backups are stored on a 2 week rolling cycle with the oldest files being deleted and replaced with the most recent backups.

The backup and restore procedures are tested by the Clinical Informatics Research Unit regularly.

## **9. 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; it 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. EDGE is a project management tool, just like other quality systems hospitals have. Some of the components will be in the PIA.



#### **10. Can you describe the system security?**

The system uses a 256 SSL certificate that is compliant to government requirements. The system is regularly tested against SSL/TLS best practice to check for known vulnerabilities. The system scores "A" against the testing methodology scoring over  $\geq 80$  against SSLLABS.

<https://www.ssllabs.com/projects/best-practices/index.html>

#### **11. Does EDGE has an official electronic signature? For example DocuSign?**

The use of an Electronic signature in EDGE is not the same as DocuSign. DocuSign provides management services for digital transactions. EDGE Signature is used by individual users to store a digital signature.

#### **12. Was EDGE built with SharePoint (<https://products.office.com/en-CA/sharepoint/collaboration?ms.officeurl=sharepoint>)?**

EDGE was not built using SharePoint. The application is developed using Microsoft's ASP.NET MVC architecture with C# and Javascript. The database is served from Microsoft SQL Server 2008. It is hosted on a Microsoft Windows Server machine using Microsoft Internet Information Server. The source code is unavailable for modification.

#### **13. Do you have SOPs about EDGE?**

As EDGE is used in different ways by different organizations, it is the responsibility of each organization to outline in local SOP's how the system should and should not be used. No usage guidelines are mandated by EDGE. 3CTN provides EDGE Implementation Manual and Project Plan templates, and Project plan samples from other sites as references to the adopted sites.

#### **14. 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.