

VALUE-ADDED FEATURES **INCLUDE** _____

SECURITY

- Data is transferred from hospitals and institutions to the QIPCM centralized repository via HTTPS (Secure Socket Layer (SSL)).
- Data always resides within the secure environment and cannot be downloaded or copied by the users ensuring data is never shared with inappropriate parties.
- 2-factor authentication services for access to the QIPCM virtual environment for users outside of the firewall perimeter.
- The gateway server provides secure, encrypted access from the user's access device to the virtual environment.
- All servers are scanned for viruses and malware/spyware regularly, the signatures of antivirus software are updated daily. Upgrades and patching are applied and tested regularly. Data is scanned for viruses/malware prior to committing to the file storage.
- Server room access control systems are in place to verify authorization at every physical access point to the QIPCM servers. Only privileged users with access permissions and additional security training are granted access. All employees receive general security training.
- Access audit logs are collected for all virtual machines accessing the QIPCM environment.
- All queries and retrievals from the PACS are logged and auditable.
- AE title access permission audit logs are collected.
- Data Backup- High level of fault tolerance and redundancy. Triple mirrored disk providing robust storage for both software and data.

PRIVACY

- De-identification tools provide fully customizable de-identification schema.
- All PHI is removed at the remote site BEFORE data is transferred securely to QIPCM unlike web-based anonymizers.
- Quality Assurance is performed on a subset of all datasets to ensure compliance.



REGULATORY

QIPCM complies with the following:

- Applicable requirements of US Code of Federal Regulations, Title 21, Chapter 1, Part 11 (CFR21Part11)
- International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice E6
- Health Canada Food and Drug Regulations Part C, Division 5. Drugs for Clinical Trials Involving Human Subjects
- QIPCM maintains an extensive and comprehensive quality management system (QMS)
- QIPCMs regulatory team ensures all requirements put forth by the agencies are adhered to.

DATA ACCESS CONTROL

- Access to the QIPCM virtual environment is granted only to individuals named by the study PI or Sponsor.
- The study PI or Sponsor can give or retract data access to collaborators as needed.
- Study data access is permissioned only to those individuals nominated by the PI or sponsor.

IMAGING SCIENCE EXPERTISE

- The QIPCM team consists of researchers, physicists, clinical trial experts and regulatory experts with many years of experience.
- Support starts with imaging protocol development to get the best out of trial imaging and acquire high quality data and continues throughout a study lifetime.

GRANT WRITING SUPPORT

• We are keenly aware of the challenges in funding research and we are always looking at ways to help. Grant writing support is available to study investigators.



ACADEMIC AND INDUSTRY RELATIONSHIP FACILITATION

- The QIPCM platform was built with collaboration in mind. Sharing data with your academic colleagues, or development with your industry partners can all be done through the secure QIPCM environment. The data will always remain under your control.
- QIPCM is constantly on the lookout for ways to maximize the potential of your data. We are happy to facilitate conversations with our extensive network of Key Opinion Leaders (KOL) and industry partners.

CONTACT _____

JULIA PUBLICOVER
DIRECTOR, TRANSLATIONAL RESEARCH AND INNOVATION
julia.publicover@uhn.ca