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Information Technology at CCTG

New Investigators Course

August 9, 2019

Lam Pho

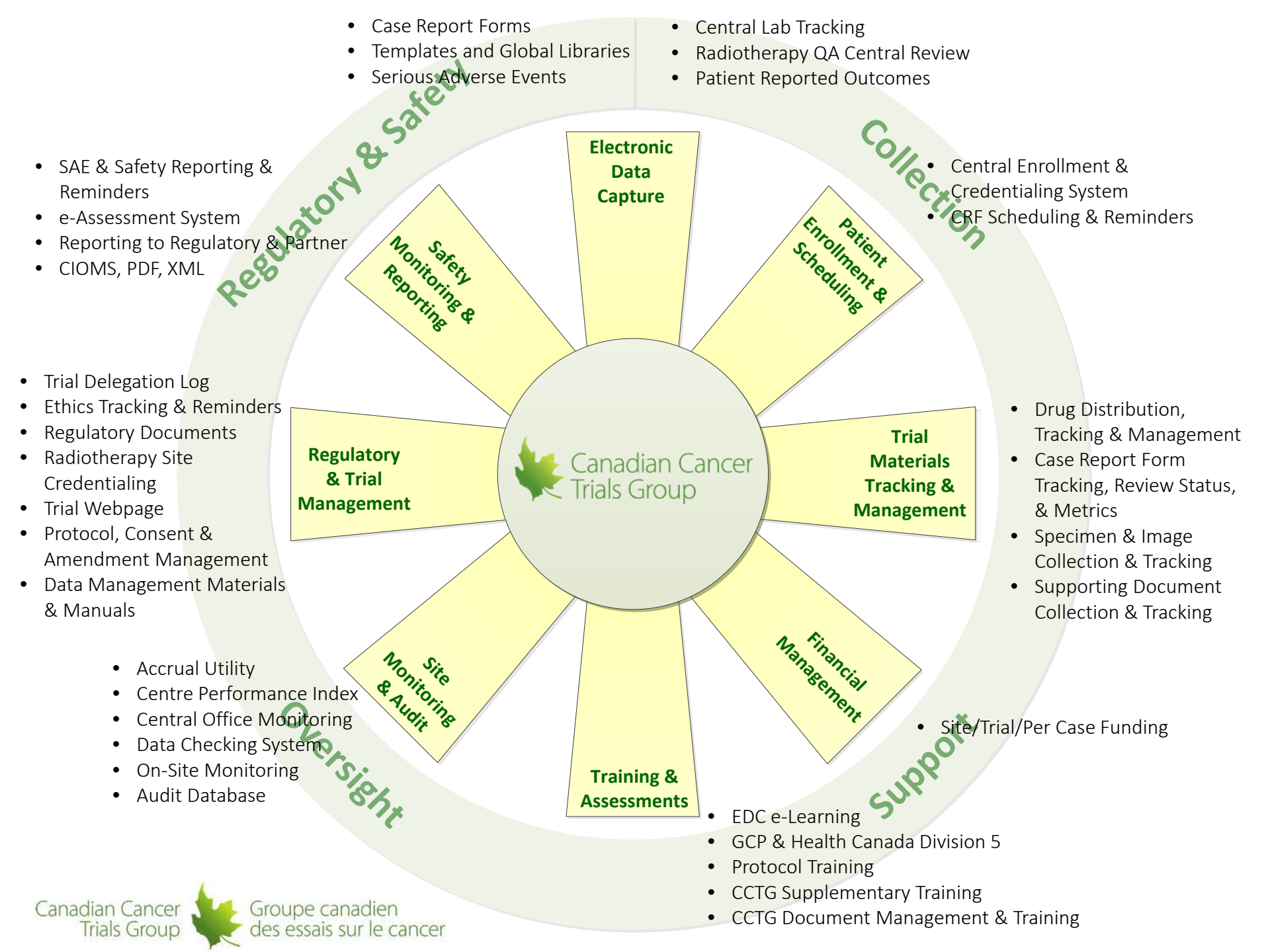
Chief Information Officer

Outline

- IT at CCTG
- Systems & Applications
  - Electronic Data Capture (EDC) at CCTG
  - Roster Interface Program & Participants List Environnements (RIPPLE)
  - Site Training Utility (STU)
- Current Projects that might be interested to you
  - Clinical Data Acquisition Standards Harmonization (CDISC)
  - CCTG Data Sharing Portal
  - Symptom IQ App

IT Team at CCTG

- 20+ IT Staff
- Develop and support systems and applications for capturing, storing and reporting on, clinical trials research and data including:
  - Patient enrollment & Electronic Data Capture
  - Member & Site administration
  - Training utilities
  - Trial-related materials, communication and more
- Provide programming support for Statistical Analysis



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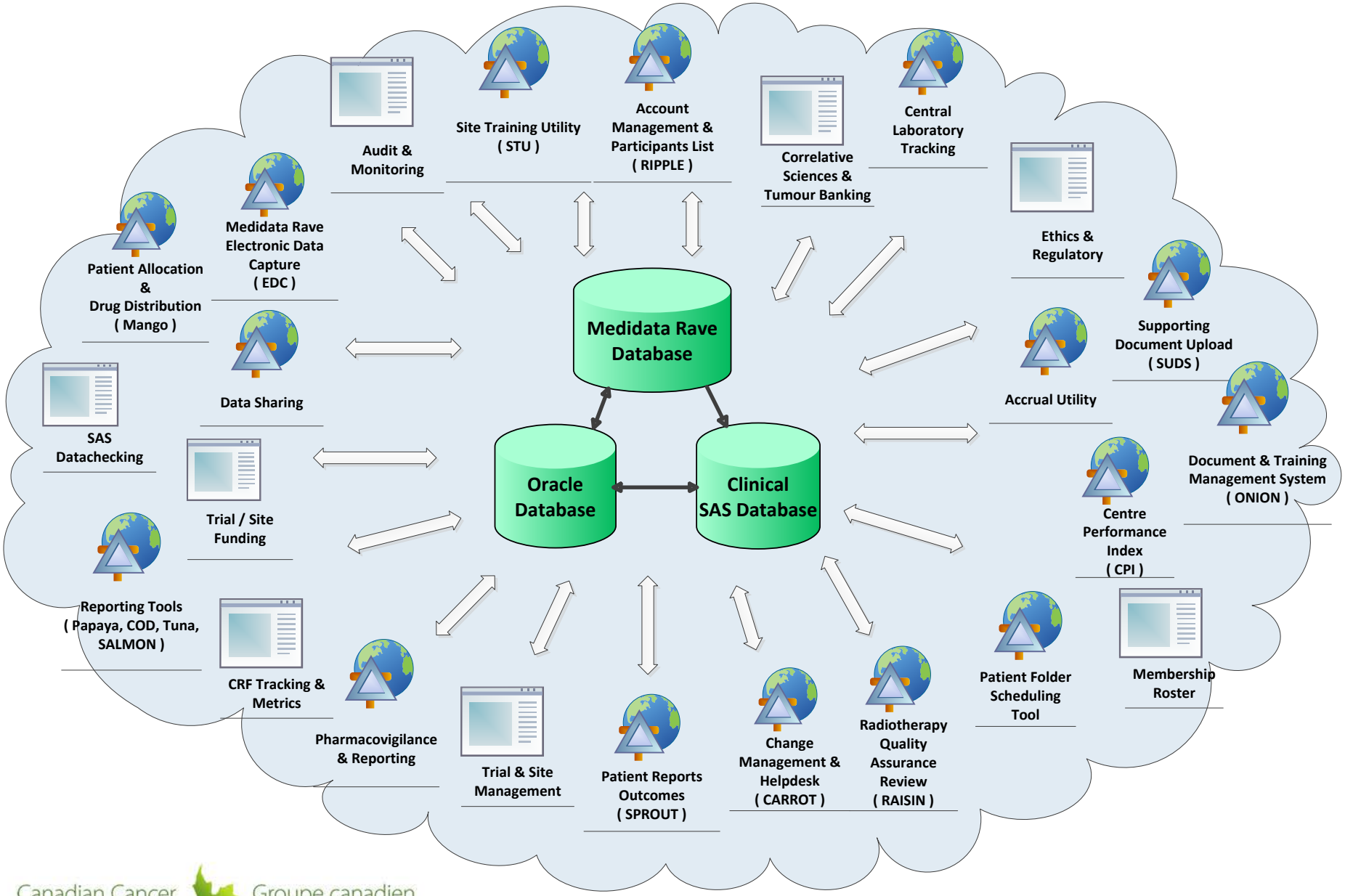
Systems & Applications



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What is Electronic Data Capture (EDC) System

- Is a computerized system designed for the collection and management of clinical data in electronic format
- Can help increase efficiency, ensure data quality, reduce the time and cost of clinical trials, and help meet regulatory compliance
- Many many EDC systems on the market e.g. Medidata Rave, OpenClinica, REDCap, etc.

Overview of EDC at CCTG

- Selected Medidata Worldwide Solution Inc. as EDC provider in late 2006; Medidata Rave EDC
- Rolled out first EDC trial in 2007
- 83 trials are currently in EDC (simple to very complex design)
- Some phase III trials are international trials including a 3,583 patients breast trial led by CCTG through NCI US/CTEP
- As of today
  - Over 4,300 users and 1,145 sites from Canada, USA, South America, Europe, Australia and Asia
  - Over 15,000 patients

EDC Features

- Global library to support standardization, consistency and accuracy across studies
- Upload support documents
- Audit Trail
- Comments
- Real-time data checking (auto-firing system queries) and manual queries
- Data verification
- Data review by various roles within the system
- Assignment of protocol violations / deviations
- Task summary (“to do” list)
- Data Freeze/Lock
- Lab Administration
- Patient Scheduler/Reminder
- Various environments: Development, UAT, Training, Production, etc.
- Integration with in-house system via web services/APIs i.e. CCTG registration/Randomization system

CCTG EDC Details (cont'd)

- SAE reporting within Rave EDC (module built by CCTG)
  - Enter SAEs into the same system as all other patient data
  - Reduce the collection of redundant data
  - Use CTCAE dictionary (mapping to MedDRA codes)
  - Email notifications of new/updated SAEs to all relevant partners
  - Ability to generate CIOMS reports as well as PDFs and XML transfer
  - Integrates with CCTG built SAE Assessment System

- Modern features of EDC now include features like cloud data storage, clinical trials analytics, monitoring modules, interactive dashboards, and electronic medical record integration

Benefits of EDC at CCTG

- **Security**: Defined user groups and roles within the system
- **Consistency**: Standardized CRFs, global libraries, central labs for data collection
- **Accuracy**: Dictionaries, real-time edit checks and queries increase data quality
- **Traceability**: Audit trail tracks who-what-when for all data changes
- **Efficiency**: Electronic submission into a single-source eliminates reporting on paper and then entering electronically
- **Accessibility**: Data is available in real-time for both the site and CCTG

Benefits of Medidata Rave EDC (cont'd)

- Compliant to standards such as:
  - FDA 21 CFR Part 11
  - ICH GCP
  - EU GMP Annex 11
  - Japan MHLW

  https://learn.mdsol.com/regulatory-compliance/regulatory-compliance-at-medidata-122360742.html
- Certified for CDISC ODM (Operational Data Model)
  - Platform-independent format for exchanging and archiving clinical and translational research data, along with their associated:
    - Metadata
    - Administrative data
    - Reference data
    - Audit information

  https://www.cdisc.org/resources/odm

EDC Training

- Delivered through various mechanisms:
  - Web based e-Learning modules
    - Mandatory for all users
    - Must pass before gain access to specific trial e-CRFs
    - Role-specific content and duration
  - Learning material
    - CCTG Generic EDC Guidebooks and presentations (including SAE reporting)
    - trial-specific training presentations if needed
  - Live webcast
  - Face to Face training
  - Recorded webcast
- CCTG certified trainers author training materials and conduct live training

Standard user groups (e.g. Site Users, Trial Team) and roles (see table) access control for security and integrity

-Based on CCTG Membership Roster which includes Trial PL (site users) and Trial Team (CCTG staff)

-This includes adding/granting access and removing/revoking access

	Clinical Research Associate	Investigator	Read Only	Monitor	Auditor	Study Coordinator	Project Coordinator	Research Associate
Role-Permissions								
Create Subject	X	X						
Modify Primary Record	X	X	X	X	X	X	X	X
See Audits	X	X	X	X	X	X	X	X
Can Batch Sign		X						
Use Primary Subject Name	X	X	X	X	X	X	X	X
Use Secondary Subject Name								
Set Clinical Significance								
View Subjects With Any Status	X	X	X	X	X	X	X	X
View All Sites In Site Group			X	X	X	X	X	X
Subject Admin					X	X		X
Can View Study Grid	X	X	X	X	X	X	X	X
Share Subjects						X		
Use Lab Maintenance								
Can Inactivate Form						X		X
Can Reactivate Form						X		X
Role-Actions								
Entry	X	X		X		X	X	X
See Entry			X	X	X	X	X	X
Sign		X						
REVIEW								
QUERY								
STICKY NOTES								
PROTOCOL DEVIATIONS								
FREEZE/LOCK								

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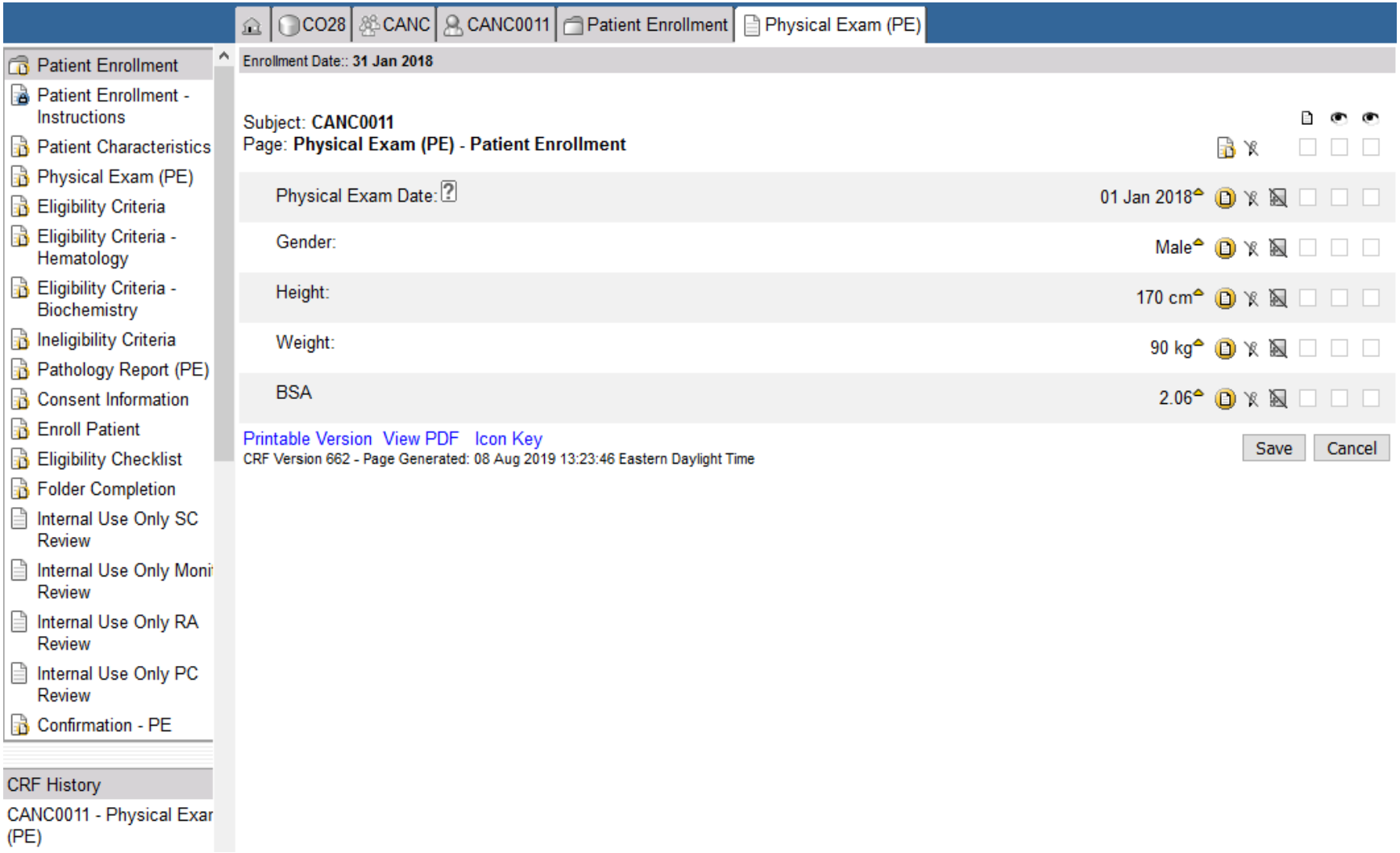
EDC – Medidata Rave



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Roster Interface Program & Participants List Environment

Guidelines
Regulations
Polices

Guidelines & Regulations

- **GCP Guidelines**
  - **2. Principles of ICH GCP:** 2.8 Each individual involved in conducting a trial should be **qualified** by **education**, **training**, and **experience** to perform his or her respective task(s).
  - **4. Investigator:** 4.1.1 The investigator(s) should be **qualified** by **education**, **training**, and **experience** to assume responsibility for the proper conduct of the trial, should meet all the **qualifications** specified by the applicable regulatory requirement(s), and should provide evidence of such **qualifications** through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB/IEC, and/or the regulatory authority(ies).
  - **4. Investigator:** 4.1.5 The investigator should maintain a list of appropriately **qualified** persons to whom the investigator has delegated significant trial-related duties.
  - **5. Sponsor:** 5.6.1 The sponsor is responsible for selecting the investigator(s)/institution(s). Each investigator should be **qualified** by **training** and **experience** and should have adequate resources (see 4.1, 4.2) to properly conduct the trial for which the investigator is selected.

http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php

Guidelines & Regulations (cont'd)

- **Canadian Food and Drug Regulations**
  - C.05.010. Every sponsor shall ensure that a clinical trial is conducted in accordance with good clinical practices and, without limiting the generality of the foregoing, shall ensure that (e) at each clinical trial site, there is no more than one **qualified** investigator; (f) at each clinical trial site, medical care and medical decisions, in respect of the clinical trial, are under the supervision of the **qualified** investigator; (g) each individual involved in the conduct of the clinical trial is **qualified** by **education**, **training** and **experience** to perform his or her respective tasks;

http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/compli-conform/1024-eng.pdf

Guidelines & Regulations (cont'd)

- **FDA Guidance**
  - Sponsors are required to select only investigators **qualified** by **training** and **experience** as appropriate experts to investigate the drug (21 CFR 312.53(a)).
  - The investigator should ensure that any individual to whom a task is delegated is **qualified** by **education**, **training**, and **experience** (and state licensure where relevant) to perform the delegated task.

http://www.fda.gov/downloads/Drugs/.../Guidances/UCM187772.pdf

http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm214282.pdf

Guidelines & Regulations (cont'd)

- Initiative to Streamline Clinical Trials (ISCT): Guidance for Investigators/Sponsors
  - Canadian Cancer Research Alliance initiative to develop specific, pragmatic and practical interpretations of current regulations, laws and guidelines, in order to facilitate, rather than limit, Canadian clinical trials
  - 7. **Delegation of Significant Trial Related Duties**
    - The Qualified Investigator (QI) is a **qualified** health care professional who is responsible for ensuring there is an adequate number of staff, and that staff are **qualified** and **trained** to perform the duties they are delegated, as required by the study protocol.
    - **Recommendation**: The delegation list, either the initial list or any modified version, will be created and maintained by the QI, or **delegate**, in a timely manner.

http://n2canada.ca/isct_downloads/ISCT_version.pdf

Policies

- **Sponsor Policies**
  - As sponsor, CCTG will ensure trials are conducted at sites by **qualified** personnel.
  - Investigators must meet the applicable credentialing requirements defined by CCTG according to requirements of the trial being conducted.

Guidelines, Regulations, Policies

- Both the investigator & sponsor are responsible for qualified, educated, trained, experienced personnel
- Require policies, procedures and systems to ensure compliance
  - CCTG Investigator Credentialing Policy, Standard Operating Procedures, training systems
  - Sites must also have their own applicable SOPs

Requirements
Delegation
Compliance

Training & Credentialing Requirements: Investigator

Requirement	Trial Participation
Member Site with active CCTG Participating Agreement	Required
Sponsor Investigator Registration (e.g. CCTG, CTEP)	Required
Generic Training: ICH-GCP, Canadian Food and Drug Regulations (Part C, Division 5)	Required
Protocol-Specific Training	Required
Protocol-Specific Essential Documents (i.e. Financial Disclosure)	Required

Investigator Registration

- Investigators must submit an initial CV to CCTG for review and approval prior to participation
- Determines the qualification and scope of participation
- CV update is required every 2 years
- CTEP sponsored trials require annual CTEP Investigator Registration
  - CTEP Investigator # and current status integrated with CCTG systems via automatic data transfer

https://www.ctg.queensu.ca/public/roster/investigator_requirements.html

Training Requirements: Clinical Trial Personnel

Requirement	Trial Participation
Member Site with active CCTG Participating Agreement	Required
Generic Training: ICH-GCP, Canadian Food and Drug Regulations (Part C, Division 5)	Required
Protocol-Specific Training and Medidata Rave	As required by role

Trial Delegation Log

- Indicates the Trial Qualified Investigator (QI) for the cancer sites as per regulations
- Used by the QI to provide documentation of Trial Delegation to qualified clinical trial personnel (CTP)
- Required prior to a site joining a trial, and for all additions and removals of CTP
- Essential Trial Delegation Log elements include:
  - Trial and site clearly identified
  - Full name of CTP
  - Clinical trial role and trial-related tasks delegated by QI
  - Start (and stop) dates for participation

Overview of RIPPLE

- Member account registration and administration
- Collection of credentialing and other required documents
  - Investigator CV, Health Canada Qualified Investigator Undertaking Form, etc.
- Inventory of training and credentialing requirements for all Clinical Trial Personnel
- Trial Delegation Log administration and Trial PI review
  - Standard training and credentialing requirement checks as well as easy configuration of trial-specific requirements
- Real-time integration with the CTEP/NCTN Delegation of Tasks Log for applicable NCTN trials
- Reports available for sponsor and regulatory visits as evidence of **qualification**, **training**, **delegation** and **approval**
- **Built by CCTG** and launched in April 2014 on 93 trials across 85 sites with over 26,000 role assignments

Benefits of RIPPLE

- Single-source Trial Delegation Log for both site and sponsor
  - Clearly identifies Trial QI and other personnel with trial-related duties as well as dates of participation and approval
  - No filing and reconciling of paper forms
- Real-time enforcement of training and credentialing requirements prior to trial participation
  - Increased compliance with trial requirements, CCTG policies, GCP guidelines & Health Canada regulations

Benefits of RIPPLE (cont'd)

- Notification system for outstanding actions; sites can add additional recipients based on the recipient's role
  - Supports Trial PI oversight of Trial Delegation Log
- Electronic Trial Delegation Log data can be leveraged for practical uses into other CCTG systems
  - Grant system access, e.g. trial website, EDC, supporting applications (safety reporting, credentialing systems)
  - Validation of investigator and CRA for patient enrollment

User Access & Management

Application Name	Trial PL Role Access	CCTG Central Office Staff Access
Mango	☑	☑
Accrual Utility	☑	☑
Ethics Utility	☑	☑
GCP/Division 5 Training	☑	☑
RIPPLE	☑	☑
Safety Utility	☑	☑
Site Training Utility	☑	☑
Website	☑	☑
ONION	☒	☑
Safety Reports e-Assessment	☒	☑

Refer to application documentation for specific user access controls

Trial Participants List - CAZZ SCL32

Show Instructions

Participants List for Trial: SCL32

A Randomized Phase II Trial of Maintenance Therapy With Treatment or Placebo in Patients with Small Cell Lung Cancer

Trial Complexity Level: 1

Centre: CAZZ

The Ripple Institute of Eastern Ontario Queen's University

Add | Remove | Name | Role: ALL | Include Removed Participants

Name	Role	Delegated Duties	Requested Start Date	Effective Start Date	Requested Stop Date	Effective Stop Date	Approval	Participation Status	Issues/Comments	Action
Dr. Qualli Investigator	QI	1, 2, 3, 6, 10, 11, 14, 15, 16, 17, 19, 20, 21, 22, 23	2015-SEP-18	2015-SEP-18			Initial	Active		Details
Mr. Prince Cra	PCRA	2, 10, 11, 14, 15, 16, 17, 20, 21, 22, 23	2015-SEP-18	2015-SEP-18			Initial	Active		Details
Ms. Ethil Cra	ECRA	10	2015-SEP-18	2015-SEP-18			Initial	Active		Details
Dr. Genny Practitioner	SI	2, 6, 10, 11, 14, 15, 16, 17, 19, 20, 21, 22, 23	2015-SEP-18	2015-SEP-18			Initial	Active		Details
Mrs. Jane Doe	ACRA	2, 10, 11, 14, 15, 16, 17, 20, 21, 22, 23	2015-SEP-18	2015-SEP-18			Initial	Active		Details
Mr. Helpy McHelperson	ACRA	2, 10, 11, 14, 15, 16, 17, 20, 21, 22, 23, Other	2015-NOV-19	2015-NOV-19			Initial	Active		Details
Mr. Demo Pharma	PPHARM	15, 16	2015-SEP-18				Initial	Pending	Requirements not met	Details/Edit
Dr. Iam Noncompliant	SI	1, 2, 3, 6, 10, 11, 14, 15, 16, 17, 19, 20, 21, 22, 23	2015-SEP-30				Initial	Pending	Requirements not met	Details/Edit
Ms. C.R.A. Noncompliant	ACRA	2, 10, 11, 14, 15, 16, 17, 20, 21, 22, 23	2015-OCT-02				Initial	Pending	Requirements not met	Details/Edit
Mrs. Addy Cra	ACRA	2, 10, 11, 14, 15, 16, 17, 20, 21, 22, 23	2015-SEP-18	2015-SEP-18	2015-OCT-05	2015-NOV-06	Initial, Stop	Removed		Details

Role Descriptions

QI = Qualified Investigator
PCRA = Principal Clinical Research Associate
ECRA = Ethics Clinical Research Associate
PPHARM = Principal Pharmacist
SI = Sub-Investigator
ACRA = Additional Clinical Research Associate
PHARM = Pharmacist
PTECH = Pharmacy Technician

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Required Roles Pending

Performing trial related duties at this time may cause violations to be recorded for your centre

Req. roles pending since:
2015-SEP-18

Required Roles

- PPHARM pending
- QI active
- PCRA active
- ECRA active

Reports

Participants List (Summary)
Participants List (Detailed)
Training & Credentialing
Trial Signature Report

Data Management

The following people can change and/or approve this participants list:

Edit PL & Approve Changes

Dr. Qualli Investigator (QI)
Mr. Remo Ross Admin (PLD)

Edit PL

Mr. Helpy McHelperson (RRA)
Mr. Remo Ross Admin (RRA)
Mrs. P.L. Admin (PLA)
Mr. Testy McTesterson (PLA)

Hide Sidebar

Trial Participant Summary - Dr. Iam Noncompliant, SI

Show Instructions

Trial Role					Start Date				Stop Date			Status	
Trial	Centre	Name	Role	Delegated Duties	Requested Start Date	Date Requirements Met	QI Approval Date	Effective Start Date	Requested Stop Date	QI Approval Date	Effective Stop Date	Participation Status	Issues / Comments
SCL32	CAZZ	Dr. Iam Noncompliant	SI	1, 2, 3, 6, 10, 11, 14, 15, 16, 17, 19, 20, 21, 22, 23	2015-SEP-30	**	2015-SEP-18	**				Pending	Requirements not met

Options

Edit Record | Remove Record

Role Requirements (0/5)

GCP Training: Not Met

Required GCP training has NOT been completed. GCP Training is required for all participants added to a trial Participants List. To resolve, the participant must complete the required GCP training modules. If an alternate GCP training program/certificate has been completed and you wish to inquire about equivalency please contact: training@ctg.queensu.ca.

To resolve, please visit: GCP Utility

NIH Training: Not Met

NIH Protection of Human Research Participants Training has not been completed as required. This is a requirement for all investigators on a trial Participants List. To resolve, the investigator must complete the NIH Protection of Human Research Participants. Once completed, please upload the certificate of completion to this investigator's membership record in RIPPLE.

To resolve, please visit: Required NIH Training

Curriculum Vitae: Not Met

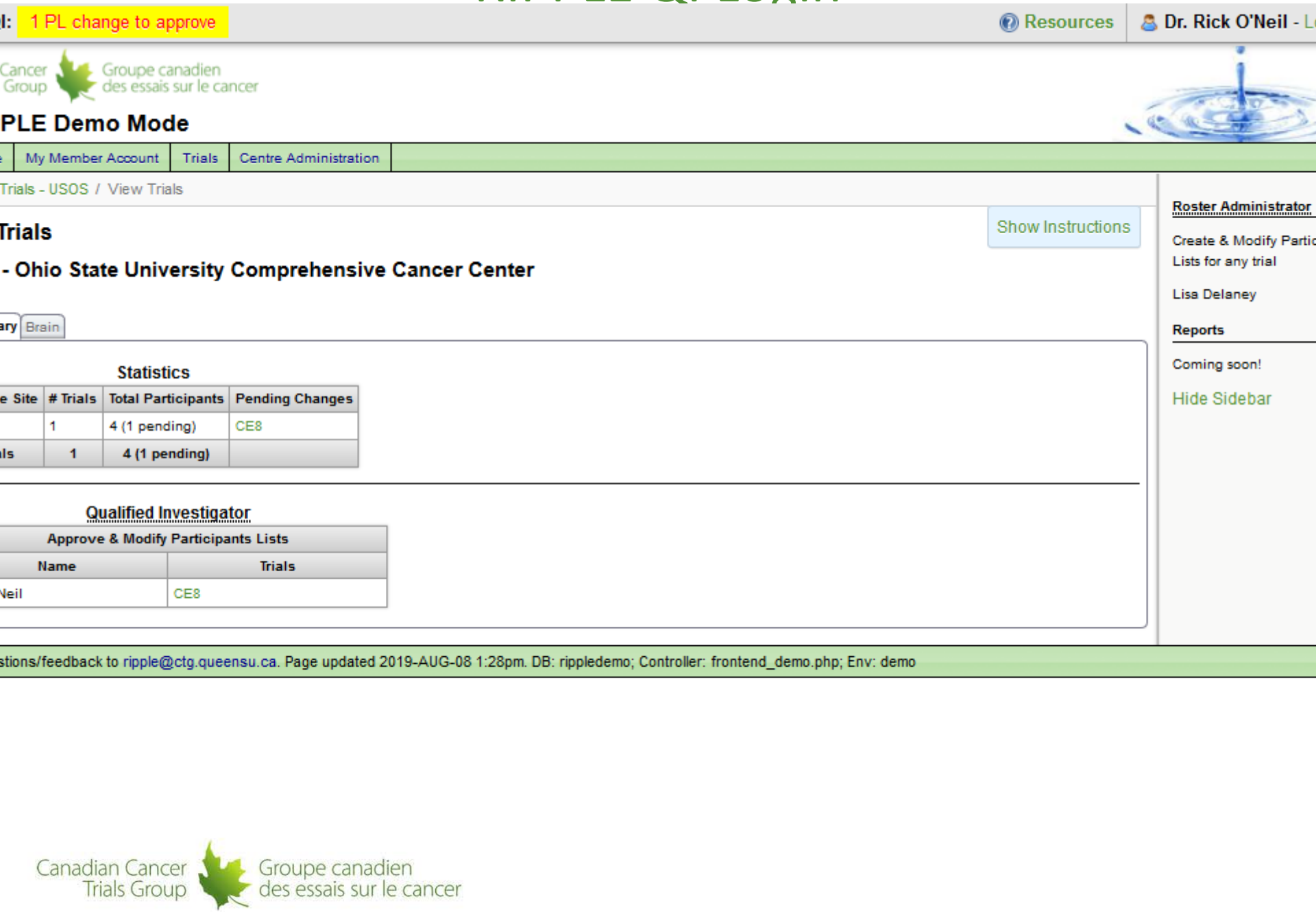
A CV has not been received and approved for this investigator . If a CV has never been submitted for this investigator the CV should be uploaded by the member or the site Remote Roster Administrator to the investigator's membership account in RIPPLE. If a CV has been previously submitted, please contact roster@ctg.queensu.ca to review any outstanding issues.

To resolve, please visit: Submit CV

Investigator Type Requirement: Not Met

This investigator is not credentialed as a Type 1 Investigator and therefor they to not meet the requirements to be active on this trial (Trial Complexity Level 1).

RIPPLE QI Login



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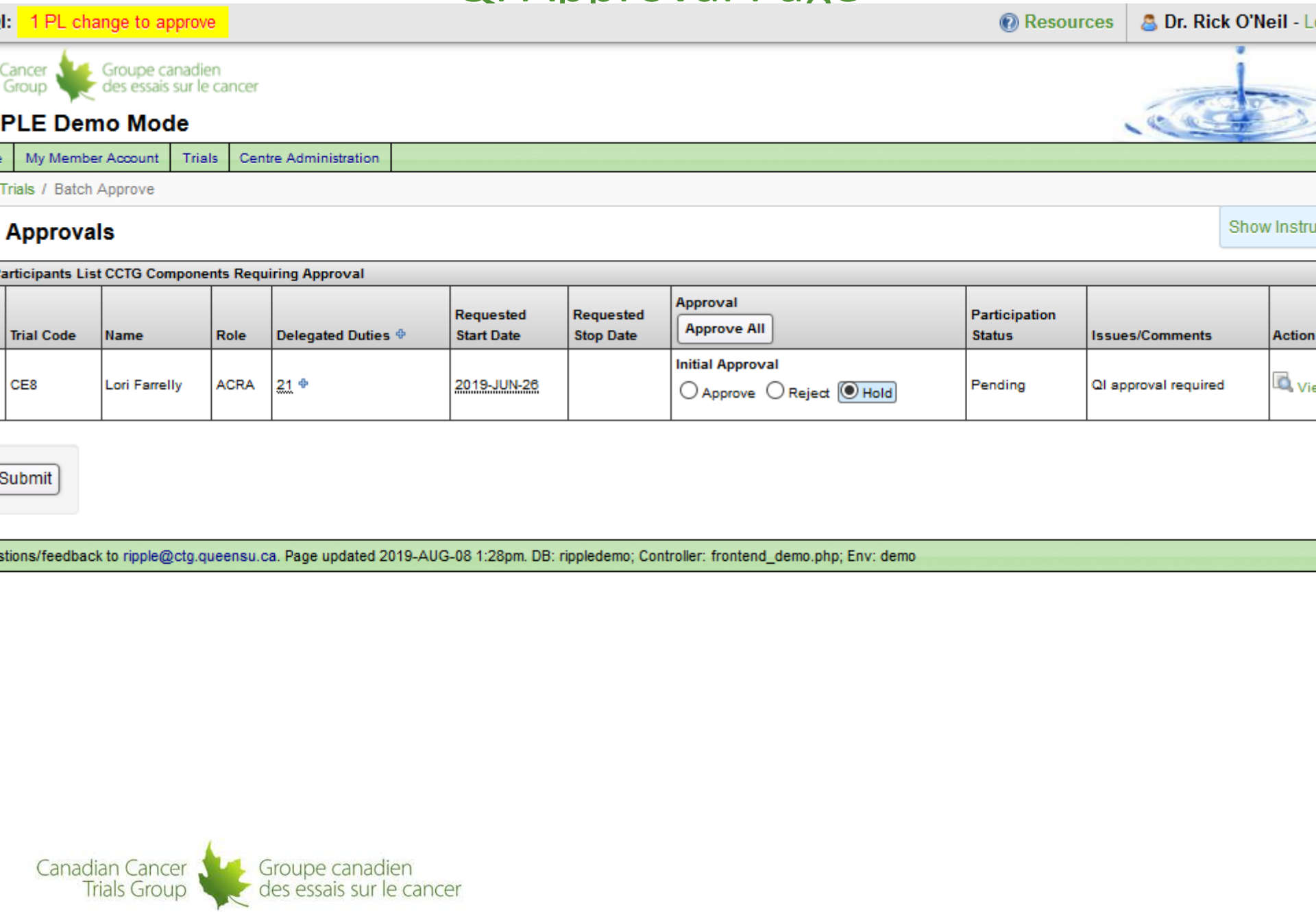
QI Approval Page



Site Training Utility (STU)

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STU

- Site Training Utility (STU) is an online utility which delivers training slides for both generic aspects of trial conduct and protocol-specific training

- Documentation of training is required for internal staff with significant trial-related duties as well as external clinical trial personnel at our member sites participating on our studies

STU

- The development of our Site Training SOP laid the groundwork for Site Training Utility (STU) to house all training needs

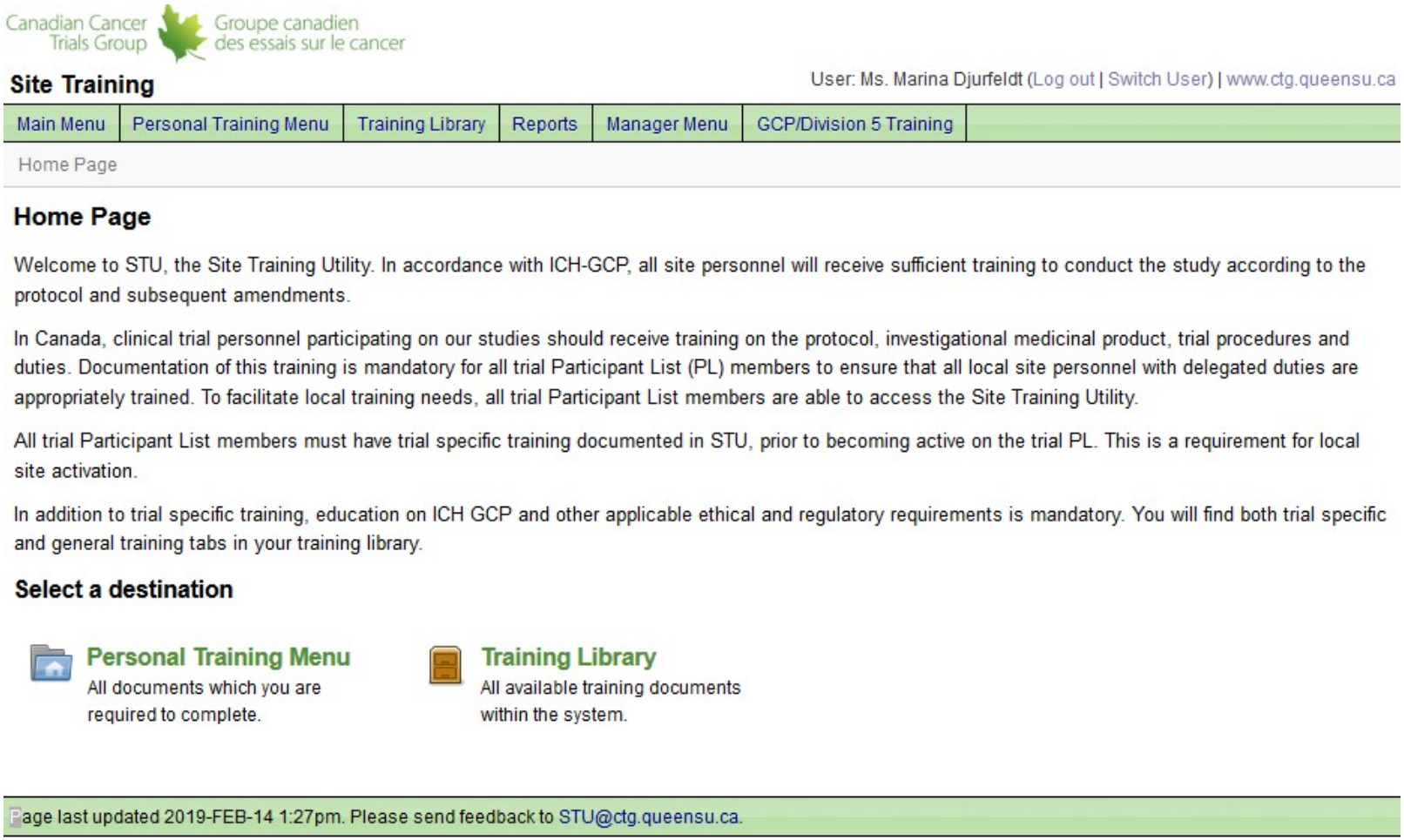
- STU was launched in Spring 2012 and protocol training was required for all new trials activated after April 2013

- Protocol-specific training including information regarding conduct of study, IMP, trial procedures and duties is also required by role

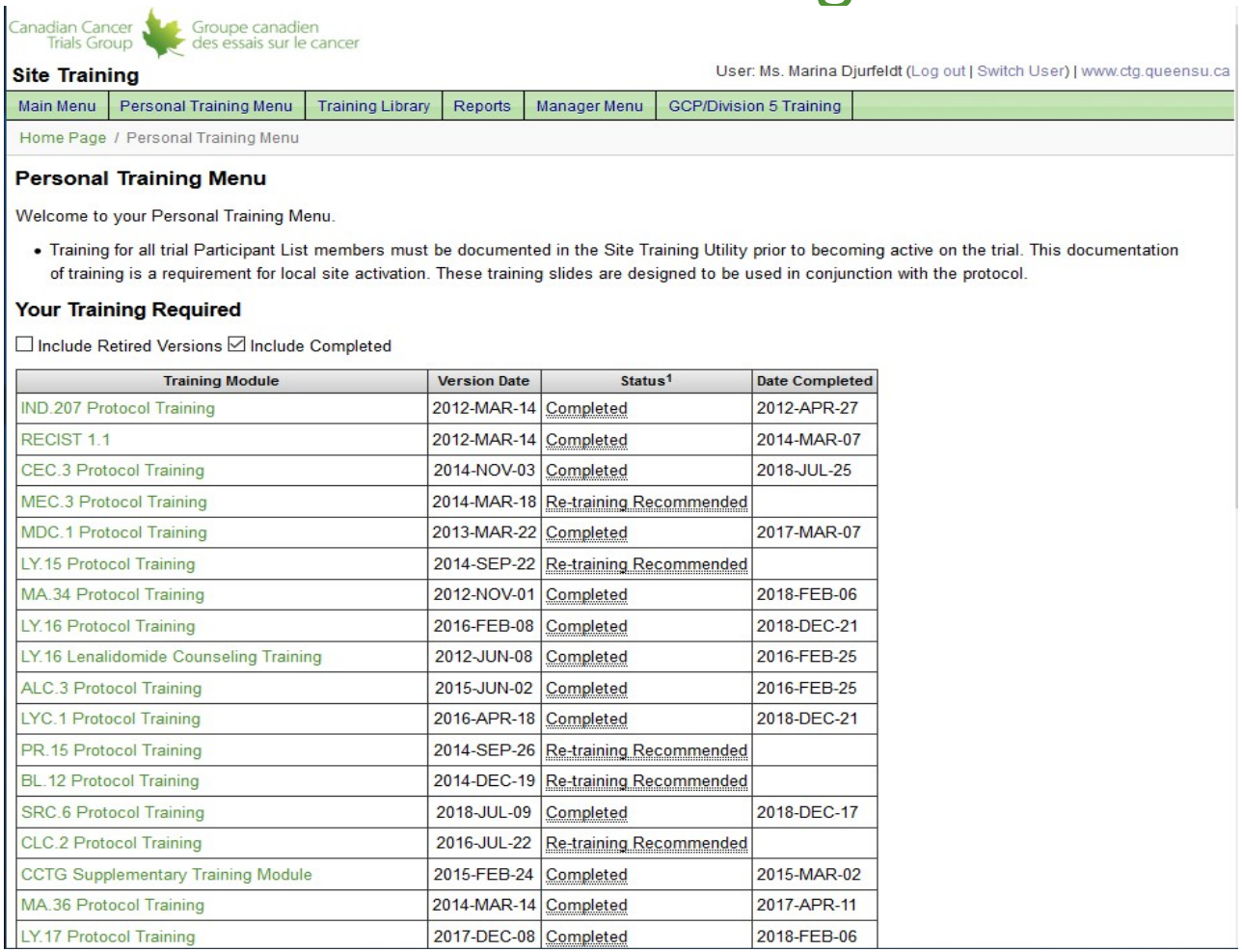
Training Requirements

- International Conference on Harmonization - Good Clinical Practices (ICH-GCP)
- Canadian Food and Drug Regulations, Part C, Division 5
- CCTG Supplementary Training, as required
- Protocol-Specific Training as required by role
- Medidata Rave Training, as required

CCTG SITE TRAINING UTILITY (STU)



Personal Training Menu



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Site Training

User: Ms. Marina Djurfeldt (Log out | Switch User) | www.ctg.queensu.ca

Main Menu | Personal Training Menu | Training Library | Reports | Manager Menu | GCP/Division 5 Training

Home Page / Personal Training Menu

Personal Training Menu

Welcome to your Personal Training Menu.

- Training for all trial Participant List members must be documented in the Site Training Utility prior to becoming active on the trial. This documentation of training is a requirement for local site activation. These training slides are designed to be used in conjunction with the protocol.

Your Training Required

☐ Include Retired Versions ☑ Include Completed

Training Module	Version Date	Status[1]	Date Completed
IND.207 Protocol Training	2012-MAR-14	Completed	2012-APR-27
RECIST 1.1	2012-MAR-14	Completed	2014-MAR-07
CEC.3 Protocol Training	2014-NOV-03	Completed	2018-JUL-25
MEC.3 Protocol Training	2014-MAR-18	Re-training Recommended	
MDC.1 Protocol Training	2013-MAR-22	Completed	2017-MAR-07
LY.15 Protocol Training	2014-SEP-22	Re-training Recommended	
MA.34 Protocol Training	2012-NOV-01	Completed	2018-FEB-06
LY.16 Protocol Training	2016-FEB-08	Completed	2018-DEC-21
LY.16 Lenalidomide Counseling Training	2012-JUN-08	Completed	2016-FEB-25
ALC.3 Protocol Training	2015-JUN-02	Completed	2016-FEB-25
LYC.1 Protocol Training	2016-APR-18	Completed	2018-DEC-21
PR.15 Protocol Training	2014-SEP-26	Re-training Recommended	
BL.12 Protocol Training	2014-DEC-19	Re-training Recommended	
SRC.6 Protocol Training	2018-JUL-09	Completed	2018-DEC-17
CLC.2 Protocol Training	2016-JUL-22	Re-training Recommended	
CCTG Supplementary Training Module	2015-FEB-24	Completed	2015-MAR-02
MA.36 Protocol Training	2014-MAR-14	Completed	2017-APR-11
LY.17 Protocol Training	2017-DEC-08	Completed	2018-FEB-06

Site Training

Main Menu | Personal Training Menu | Training Library | Reports | Manager Menu | GCP/Division 5 Training

Home Page / Reports

Reports

Centre Training Report

View required & completed training for a centre.

Trial Training Report

View required & completed training for a trial.

Training M	Document Ve	Centre	Title	First Nam	Last Name	Required/Reco	Training	Date Complete
CE.7 Protc	2018-APR-23	CAMP	Ms.	Jessy	Abed	recommended	N	
CE.7 Protc	2018-APR-23	CAGQ	Ms.	Josee	Allard	status pending	N	
CE.7 Protc	2018-APR-23	CAHN	Dr.	Jean-Paul	Bahary	recommended	Y	2018-JUL-19
CE.7 Protc	2018-APR-23	CATC	Ms.	Maria	Balachova	recommended	N	
CE.7 Protc	2018-APR-23	CALM	Ms.	Christine	Ballantyne	recommended	N	
CE.7 Protc	2018-APR-23	CANL	Dr.	Glenn	Bauman	status pending	N	
CE.7 Protc	2018-APR-23	CAHN	Miss	Silvine	Benth	recommended	N	
CE.7 Protc	2018-APR-23	CABN	Dr.	Lara	Best	recommended	N	
CE.7 Protc	2018-APR-23	CAGH	Dr.	Jocelyn	Blanchard	recommended	N	
CE.7 Protc	2018-APR-23	CAHA	Dr.	Christian	Boukaram	status pending	N	
CE.7 Protc	2018-APR-23	CABN	Dr.	David	Bowes	recommended	N	
CE.7 Protc	2018-APR-23	CAMP	Ms.	Maria	Braganza	recommended	N	
CE.7 Protc	2018-APR-23	CALM	Ms.	Catherine	Bucci	recommended	Y	2018-DEC-20
CE.7 Protc	2018-APR-23	CABN	Ms.	Susan	Burbridge	recommended	N	
CE.7 Protc	2018-APR-23	CABN	Ms.	Kara	Bursey	recommended	N	
CE.7 Protc	2018-APR-23	CAHN	Miss	Adriana	Carbonaro	recommended	N	
CE.7 Protc	2018-APR-23	CANC	Ms.	Sue	Casey	required	Y	2018-MAY-30
CE.7 Protc	2018-APR-23	CAMP	Dr.	Tatiana	Conrad	recommended	N	
CE.7 Protc	2018-APR-23	CAGH	Ms.	Sophie	Couture	recommended	N	
CE.7 Protc	2018-APR-23	CABN	Dr.	Wladyslav	Cwajna	recommended	N	
CE.7 Protc	2018-APR-23	CANC	Mr.	Conor	Dellar	required	Y	2018-MAY-28
CE.7 Protc	2018-APR-23	CATC	Ms.	Sonali	Deshpande	recommended	Y	2018-SEP-21
CE.7 Protc	2018-APR-23	CABN	Ms.	Kendra	Dill	recommended	N	
CE.7 Protc	2018-APR-23	CANC	Ms.	Marina	Djurfeldt	not required	Y	2018-MAY-29
CE.7 Protc	2018-APR-23	CABN	Miss	Stevie	Dugas	not required	Y	2018-NOV-19
CE.7 Protc	2018-APR-23	CAGH	Dr.	Annie	Ebacher	required	Y	2018-NOV-12

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Clinical Data Acquisition Standards Harmonization (CDISC) Overview

FDA Requirements and CDISC

- CDISC – Clinical Data Interchange Standards Consortium
- FDA Requirement:
  - Sponsors whose studies started after Dec. 17, 2016, must submit data in the data formats supported by FDA and listed in the FDA Data Standards Catalog. This applies to -NDAs, BLAs, ANDAs, and subsequent submissions to these types of applications.
  - For INDs, the requirement starts after Dec. 17, 2017.
- Accepted FDA study data standards:
  - CDISC Standard for Exchange of Nonclinical Data (SEND) for nonclinical data
  - CDISC Study Data Tabulation Model (SDTM) for clinical data
  - CDISC Analysis Data Model (ADaM) for analysis of clinical data
  - CDISC Case Report Tabulation Data Definition Specification (Define-XML) for the metadata that accompany SEND, SDTM, and ADaM datasets

CDISC CDASH (Clinical Data Acquisition Standards Harmonization)

- Establishes a standard way to collect data in a similar way across studies
- Standardizes data collection formats and structures providing clear traceability of submission data into the SDTM
- Delivers more transparency to regulators and others who conduct data review
- ***Build and design CRFs in Rave EDC in CDASH format** i.e. CDISC domains → Rave global libraries*

CDISC SDTM (Study Data Tabulation Model)

- Provides a standard for organizing and formatting data to streamline processes in collection, management, analysis and reporting
- Supports data aggregation and warehousing
- Fosters mining and reuse
- Facilitates sharing
- Helps perform due diligence and other important data review activities
- Improves the regulatory review and approval process
- SDTM is also used in non-clinical data (SEND), medical devices and pharmacogenomics/genetics studies

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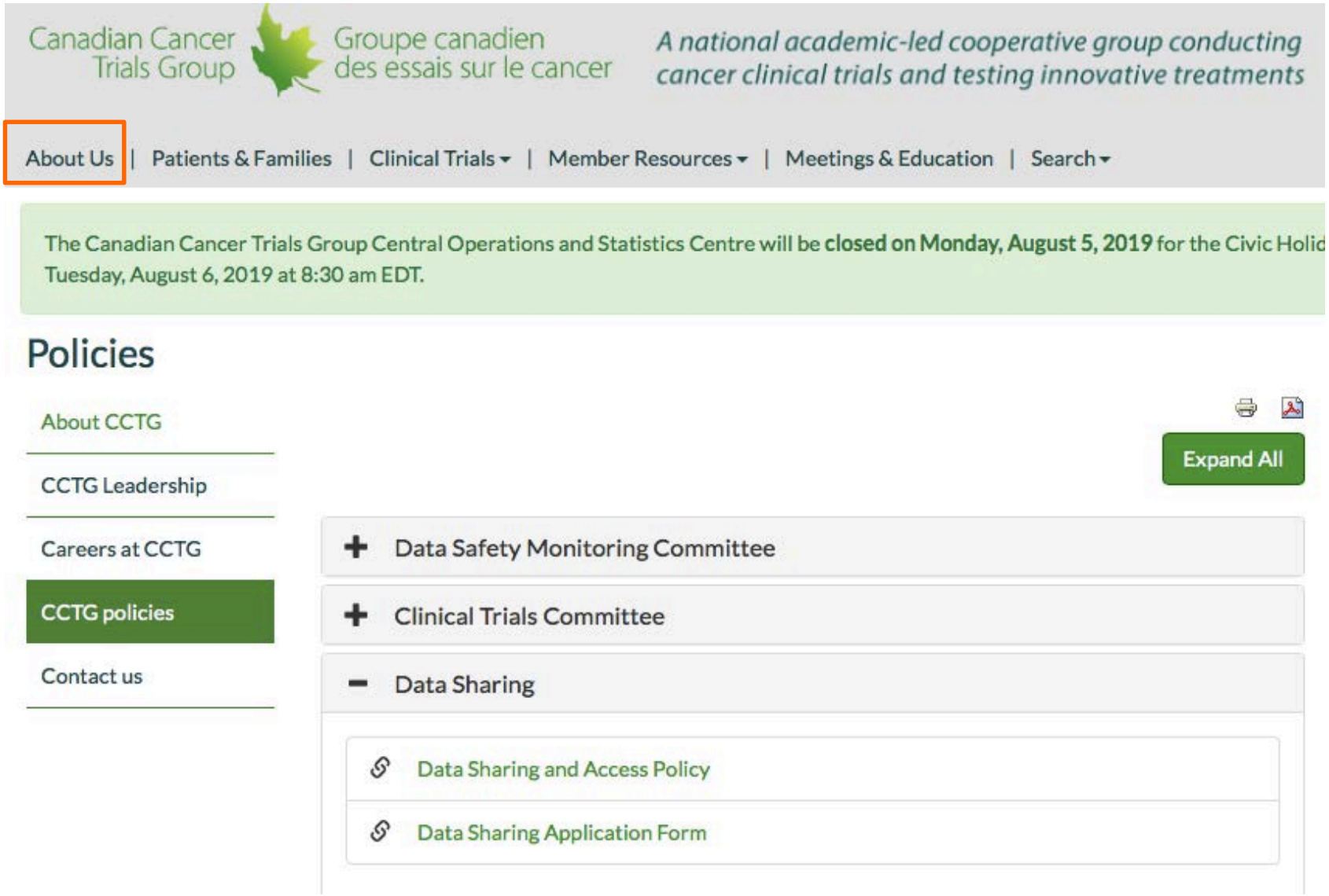
CCTG Data Access SHaring

(DASH System)

How to make a data sharing request



New dedicated data sharing portal with search engine in development

CCTG homepage

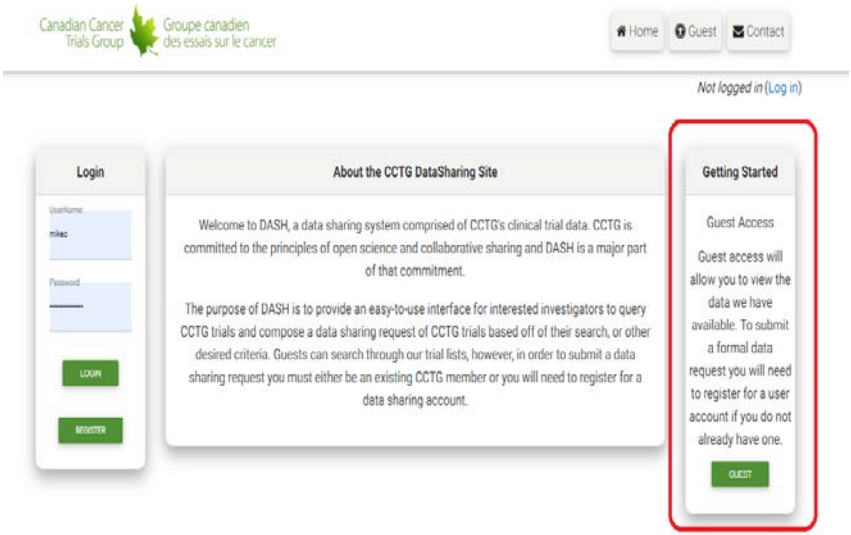
Objectives

- DASH is a web-based application that will allow interested investigators to query CCTG trials and compose a data access request based off of desired criteria.

- CCTG staff will then use DASH to review requests
  - and to provide access to CCTG trial result datasets for approved requests

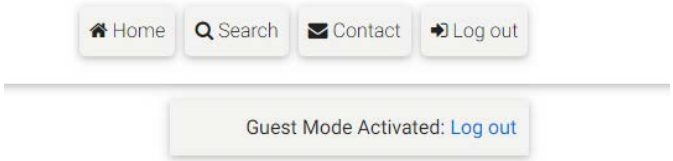
- The goal is to build a system that can effectively allow other researchers to request for data and perform their own data analysis, and bolster our commitment to open science initiatives.

- To the right, you can see the guest area highlighted.



- When guest access is accessed the user is able to search for trials, however they are limited to just this functionality. A CCTG (or Dash) account is needed to actually submit a request for Data.

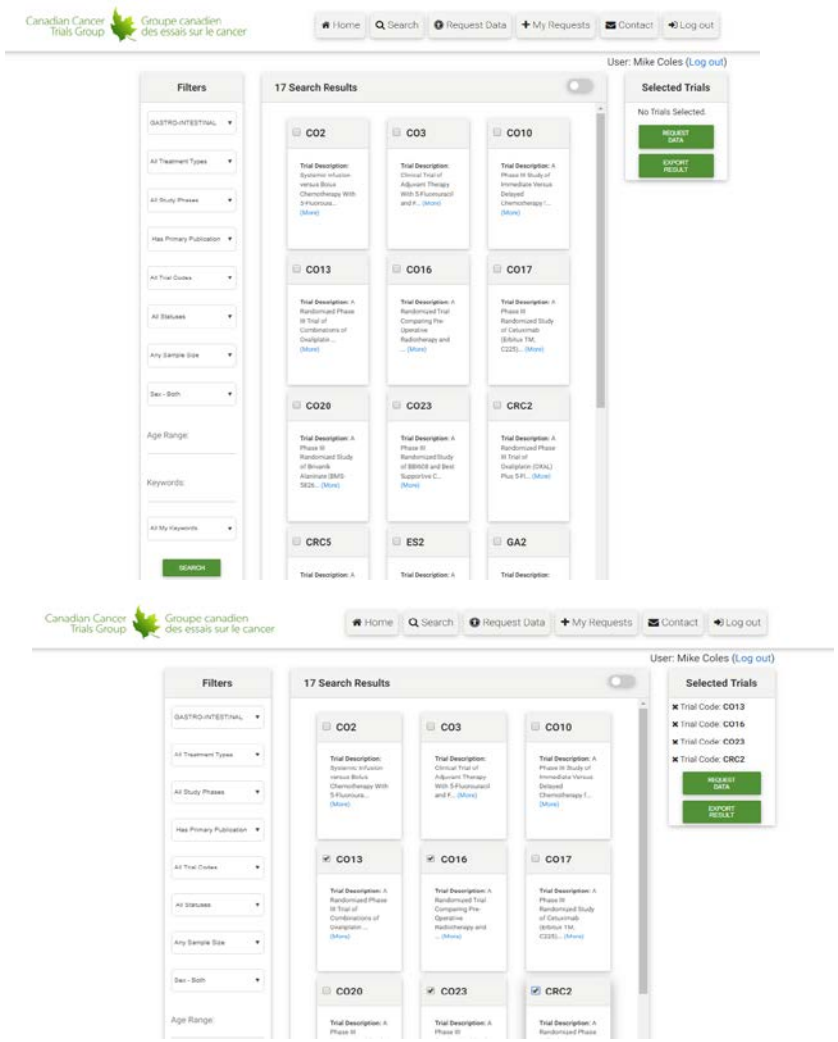
- The investigator clicks on the “Guest” button, and is logged in using Guest Access. You can tell guest mode is active by looking at the Guest mode activated banner – and by the appearance of the “Search” and “Contact” buttons in the navigation.



- The investigator has entered their search and clicked the search button. There are 9 results listed as trials that the investigator may be interested in (Greyed out results are trials that cannot be shared) .

- Notice to the right of the search results there is a selected trials section. This section will populate as the investigator selects trials using the checkboxes on each trial.

- At this point the user can use the Request Data Button to convert the search into a request for data.



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Symptom IQ App

What is the Symptom IQ App?

- Is a self reporting tool to help patients to track and manage symptoms, such as diarrhea, cough and fatigue
- Allow patients to review their symptoms daily in the application and note the presence of the symptom and if there is a change
- Patient's healthcare team be able to view the pattern of your symptoms in clinic visits and can advise patient on how to manage these symptoms.
- Based on your symptoms, patients may receive a notification on their phone to contact their designated nurse or the on-call physician as instructed by your cancer clinic team or follow their directions about when theyshould go to the emergency department.
- The app has been developed by the uMotif company in UK and is supported by Astra Zeneca. It is currently in discussion to pilot this app on one of our trials.

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Thank you!