Canadian Cancer Trials Group | Groupe canadien des essais sur le cancer

Academic Cooperative Group Implementation of the Initiative to Streamline Clinical Trials

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Outline

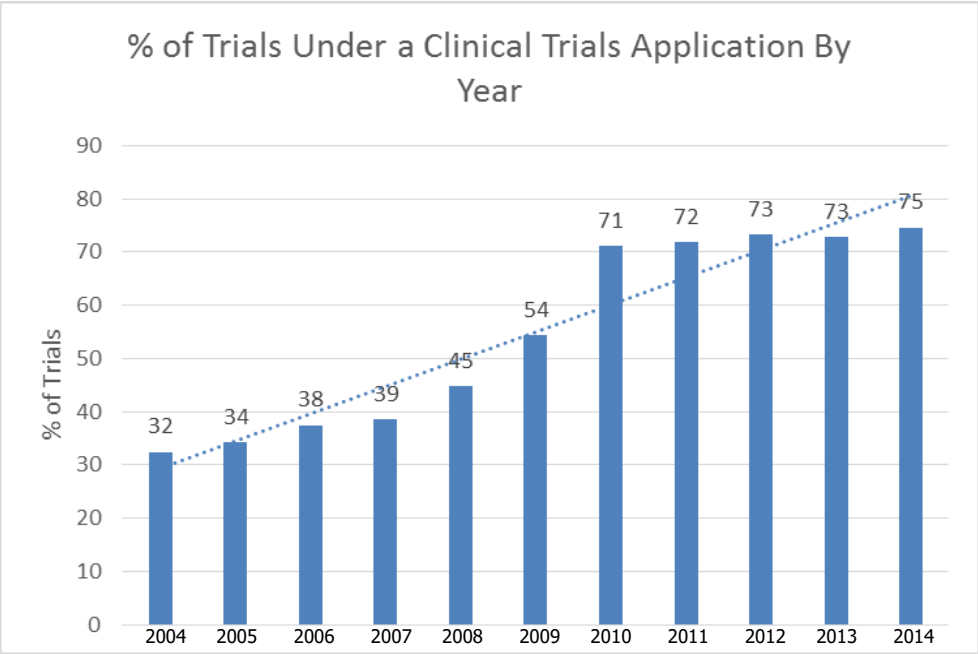
- Background
- Implementation of recommendations by CCTG
  - Investigational medicinal product and CTA filing
  - Delegation of duties
  - Risk-based approach to monitoring
- Conclusions/future directions

Background

- Threats to the conduct of Canadian oncology clinical trials identified (Report on the State of Clinical Trials in Canada, October 2011)
- Initiative to Streamline Clinical Trials (ISCT) Working Group formed in 2012 http://n2canada.ca/isct/
  Expand on and facilitate recommendations
- Develop practical interpretations of current regulations to facilitate Canadian clinical trials

Investigational Product

- CTA requirements not currently risk-based, have significant cost and resource implications, barriers steadily increasing



- **<u>ISCT Recommendation</u>**: Appropriately justified standard-of-care (SOC) drugs do not require a CTA

Investigational Product: Implementation

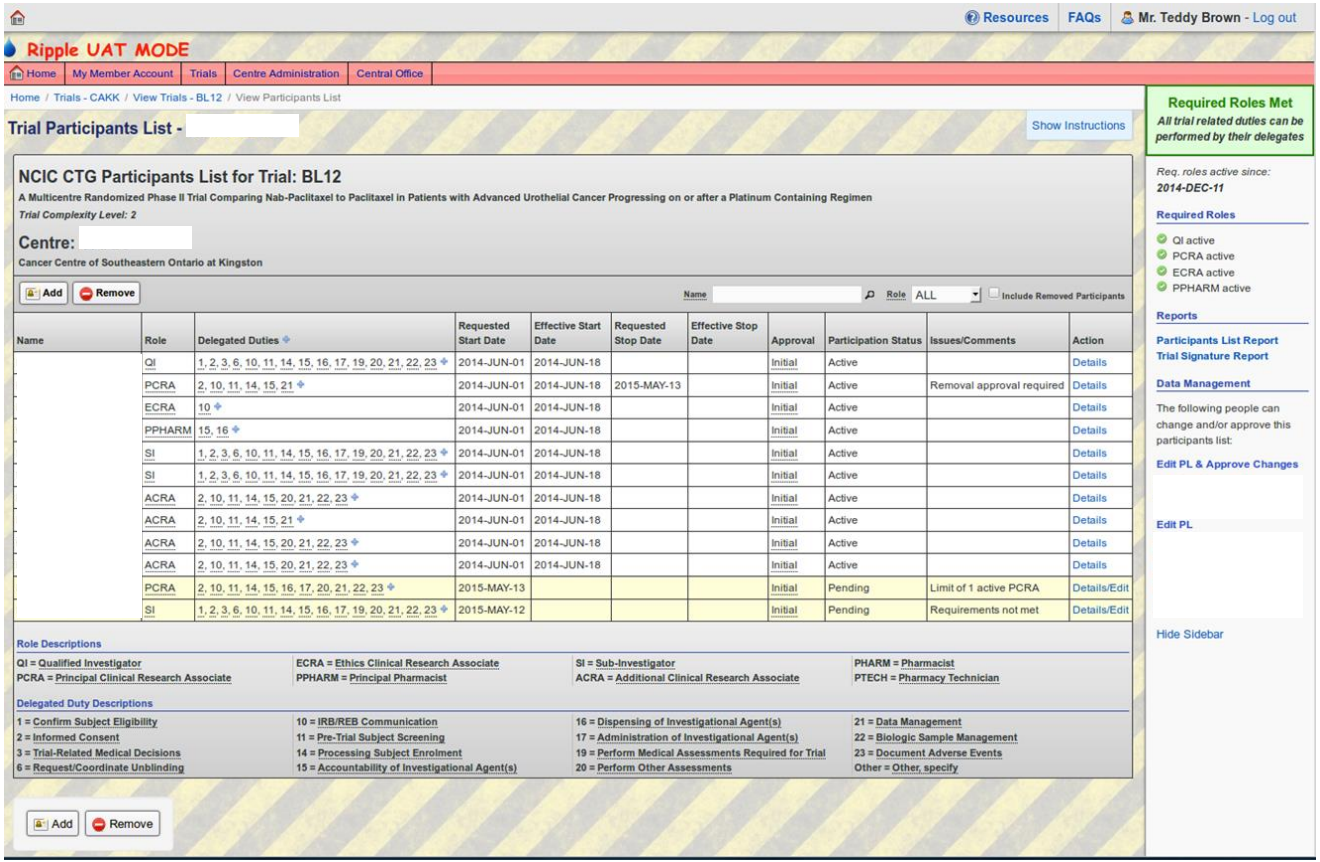
Pemetrexed/platinum chemotherapy +/- selumetinib in NSCLC

- Carboplatin with pemetrexed is a recommended regimen within Cancer Care Ontario guidelines, standard-of-care, and funded provincially
- Fits within ISCT guidelines
- Health Canada acknowledged no CTA required for Carboplatin

Delegation of Duties

- Guidelines on training and education required for perform tasks related to trial conduct are not specific
- Lack of documentation surrounding trial-specific training
- **ISCT Recommendation**: Roles required as part of standard-of-care or on an ad hoc basis are not required to be documented as part of the trial delegation log

Delegation of Duties: Implementation



Resources | FAQs | Mr. Teddy Brown - Log out

Ripple UAT MODE

Home | My Member Account | Trials | Centre Administration | Central Office

Home / Trials - CAKK / View Trials - BL12 / View Participants List

Trial Participants List -

Show Instructions

NCIC CTG Participants List for Trial: BL12

A Multicentre Randomized Phase II Trial Comparing Nab-Paclitaxel to Paclitaxel in Patients with Advanced Urothelial Cancer Progressing on or after a Platinum Containing Regimen

Trial Complexity Level: 2

Centre:

Cancer Centre of Southeastern Ontario at Kingston

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
	QI	1, 2, 3, 6, 10, 11, 14, 15, 16, 17, 19, 20, 21, 22, 23	2014-JUN-01	2014-JUN-18			Initial	Active		Details
	PCRA	2, 10, 11, 14, 15, 21	2014-JUN-01	2014-JUN-18	2015-MAY-13		Initial	Active	Removal approval required	Details
	ECRA	10	2014-JUN-01	2014-JUN-18			Initial	Active		Details
	PPHARM	15, 16	2014-JUN-01	2014-JUN-18			Initial	Active		Details
	SI	1, 2, 3, 6, 10, 11, 14, 15, 16, 17, 19, 20, 21, 22, 23	2014-JUN-01	2014-JUN-18			Initial	Active		Details
	SI	1, 2, 3, 6, 10, 11, 14, 15, 16, 17, 19, 20, 21, 22, 23	2014-JUN-01	2014-JUN-18			Initial	Active		Details
	ACRA	2, 10, 11, 14, 15, 20, 21, 22, 23	2014-JUN-01	2014-JUN-18			Initial	Active		Details
	ACRA	2, 10, 11, 14, 15, 21	2014-JUN-01	2014-JUN-18			Initial	Active		Details
	ACRA	2, 10, 11, 14, 15, 20, 21, 22, 23	2014-JUN-01	2014-JUN-18			Initial	Active		Details
	ACRA	2, 10, 11, 14, 15, 20, 21, 22, 23	2014-JUN-01	2014-JUN-18			Initial	Active		Details
	PCRA	2, 10, 11, 14, 15, 16, 17, 20, 21, 22, 23	2015-MAY-13				Initial	Pending	Limit of 1 active PCRA	Details/Edit
	SI	1, 2, 3, 6, 10, 11, 14, 15, 16, 17, 19, 20, 21, 22, 23	2015-MAY-12				Initial	Pending	Requirements not met	Details/Edit

Role Descriptions

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

Delegated Duty Descriptions

1 = Confirm Subject Eligibility | 10 = IRB/REB Communication | 16 = Dispensing of Investigational Agent(s) | 21 = Data Management
2 = Informed Consent | 11 = Pre-Trial Subject Screening | 17 = Administration of Investigational Agent(s) | 22 = Biologic Sample Management
3 = Trial-Related Medical Decisions | 14 = Processing Subject Enrolment | 19 = Perform Medical Assessments Required for Trial | 23 = Document Adverse Events
6 = Request/Coordinate Unblinding | 15 = Accountability of Investigational Agent(s) | 20 = Perform Other Assessments | Other = Other, specify

Add | Remove

Required Roles Met

All trial related duties can be performed by their delegates

Req. roles active since:
2014-DEC-11

Required Roles

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

Reports

Participants List Report
Trial Signature Report

Data Management

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

Edit PL & Approve Changes

Edit PL

Hide Sidebar

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Risk-based Monitoring

- On-site monitoring costly, complex
- **ISCT Recommendation**: Implement a risk-based approach to monitoring. Central monitoring of selected critical study parameters
- Centralized monitoring can fulfil the role of on-site monitoring including source data verification, site performance, and evaluation
- Systemic approach allows detection of trends in the data
- Electronic data capture can improve data submission rates

Risk-based Monitoring: Central

	Radiation Trial	Novel Agent Trial
Risk Category	Low risk	High risk
CTA Required?	No	Yes
Remote Monitoring	N/A	Within 1 week of first patient enrolment; Q 2-3 months as more enrolled
Data Collection		
Consent Form	✓	✓
Pathology Reports		✓
Relapse/Progression Documentation		✓
Operative Reports		✓

Risk-based Monitoring: On Site

	Radiation Trial	Novel Agent Trial
Source Data Verification	Min. 10% at 100% of sites	100% of defined critical data, 55% overall
Essential Documentation	Sample	100%
Frequency	Annual visits	Known site/no issues: 12 weeks New site/prior issues: 6 weeks
Triggered monitoring	N/A	• Monitor concerns • Drug related SAE • Major violations • Analysis/inspection/audit

Conclusions/Future Directions

- CCTG experience implementing these specific recommendations has led to efficiencies and streamlining of systems
- Consistency and flexibility in interpretation of regulations continue to pose a challenge
- CCTG will continue to explore opportunities for efficiency as part of ongoing ISCT activities
- ISCT working group continues to address areas of concern, and track the success of the recommendations
- http://n2canada.ca/isct/

Questions?