Initiative to Streamline Clinical Trials: Have The Guidelines Helped Cut Through the Red Tape?

ISCT Guidelines

In 2011, the Canadian Cancer Research Alliance (CCRA) report on the State of Cancer Clinical Trials In Canada identified the magnitude of the threat to the conduct of oncology clinical trials. The report noted that with falling performance metrics, increasing complexity and workload, and an increasingly onerous regulatory environment, clinical trials were at risk, and observed that “Without clinical trials, the outcomes of cancer patients will not continue to improve”. One of the recommendations in the report recommended engaging with Health Canada and other key stakeholders to foster agreement in appropriate interpretations of the Health Canada Food and Drug Regulations and ICH Good Clinical Practice (GCP) guidelines.

In response, the Initiative to Streamline Clinical Trials (ISCT) Working Group was organized in 2012, and included members who are experts in clinical trial conduct across many therapeutic areas. The primary objective of the ISCT was to develop specific, pragmatic, and practical interpretations of current regulations, laws and guidelines, in order to facilitate, rather than limit, Canadian clinical trials, by expanding on recommendations such as those of the CCRA and OECD. The guidelines were finalized in February 2014 and are available at http://n2canada.ca/isct/.

Since the 2011 CCRA report, the ISCT Guidelines has been one of many initiatives underway nationally to address threats to the clinical trial enterprise. While results are promising, understanding of the current environment as well as the implementation and impact of the ISCT Guidelines by academic Investigators, Institutions, and Sponsors is needed to determine future actions required.

Completing this survey will inform future directions of the ISCT Working Group, and provide information to be presented in discussions with Health Canada. We appreciate your support in taking the time to complete the survey. The survey is anonymous and results will be aggregated.

1. Please indicate your role

- ◯ Sponsor
- ◯ Investigator
- ◯ Research Manager
- ◯ Quality Assurance Manager
- ◯ Clinical Research Associate
- ◯ Pharmacist or Pharmacy Technician
- ◯ Ethics Coordinator
- ◯ Prefer not to answer
- ◯ Other (please specify)

2. What therapeutic area(s) does your research activity include?

- [ ] Oncology
- [ ] Pediatrics
- [ ] Cardiovascular
- [ ] Respiratory
- [ ] Mental Health
- [ ] HIV
- [ ] Neurology
- [ ] Diabetes
- [ ] Rheumatology
- [ ] Gastroenterology
- [ ] Orthopedics
- [ ] Other (please specify)

3. What region(s) is your organization in?

- [ ] BC
- [ ] Alberta
- [ ] Saskatchewan
- [ ] Manitoba
- [ ] Ontario
- [ ] Quebec
- [ ] Nova Scotia
- [ ] New Brunswick
- [ ] PEI
- [ ] Newfoundland
- [ ] Yukon
- [ ] Nunavut
- [ ] NWT
- [ ] Other (please specify)

4. How many Health Canada inspections have you been involved in, in the past 3 years?

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5. Prior to this survey, had you heard about the ISCT Guidelines?

- Yes
- No

Comments

6. Have you reviewed or downloaded the ISCT Guidelines (http://n2canada.ca/isct/)?

- Yes
- No

7. How often do you review the ISCT Guidelines?

- Have never accessed the ISCT Guidelines
- Weekly
- Monthly
- Annually

Comments

8. Have you applied the ISCT recommendations in the following areas within the last three years?

	Recommendation implemented?	Post implementation, has this been cited as an observation on an inspection?
CTA and Safety Reporting		
Drug Accountability and Labelling		
Monitoring		
Equipment & Facilities		
Delegation of Trial Related Drugs		
Validation of Electronic Systems		
Source Documents and Record Retention		
Trial Costs		

Are there additional areas you would like to see recommendations for, where regulations would benefit from streamlining? Any comments or additional findings?

9. What was the impact of implementing the guidelines? (eg. reduced cost, reduced time, increased quality?)

CTA and Safety Reporting	
Drug Accountability and Labelling	
Monitoring	
Equipment & Facilities	
Delegation of Trial Related Duties	
Validation of Electronic Systems	
Source Documents and Record Retention	
Trial Costs	

10. What have been the barriers to implementing the guidelines?

11. Any additional comments?