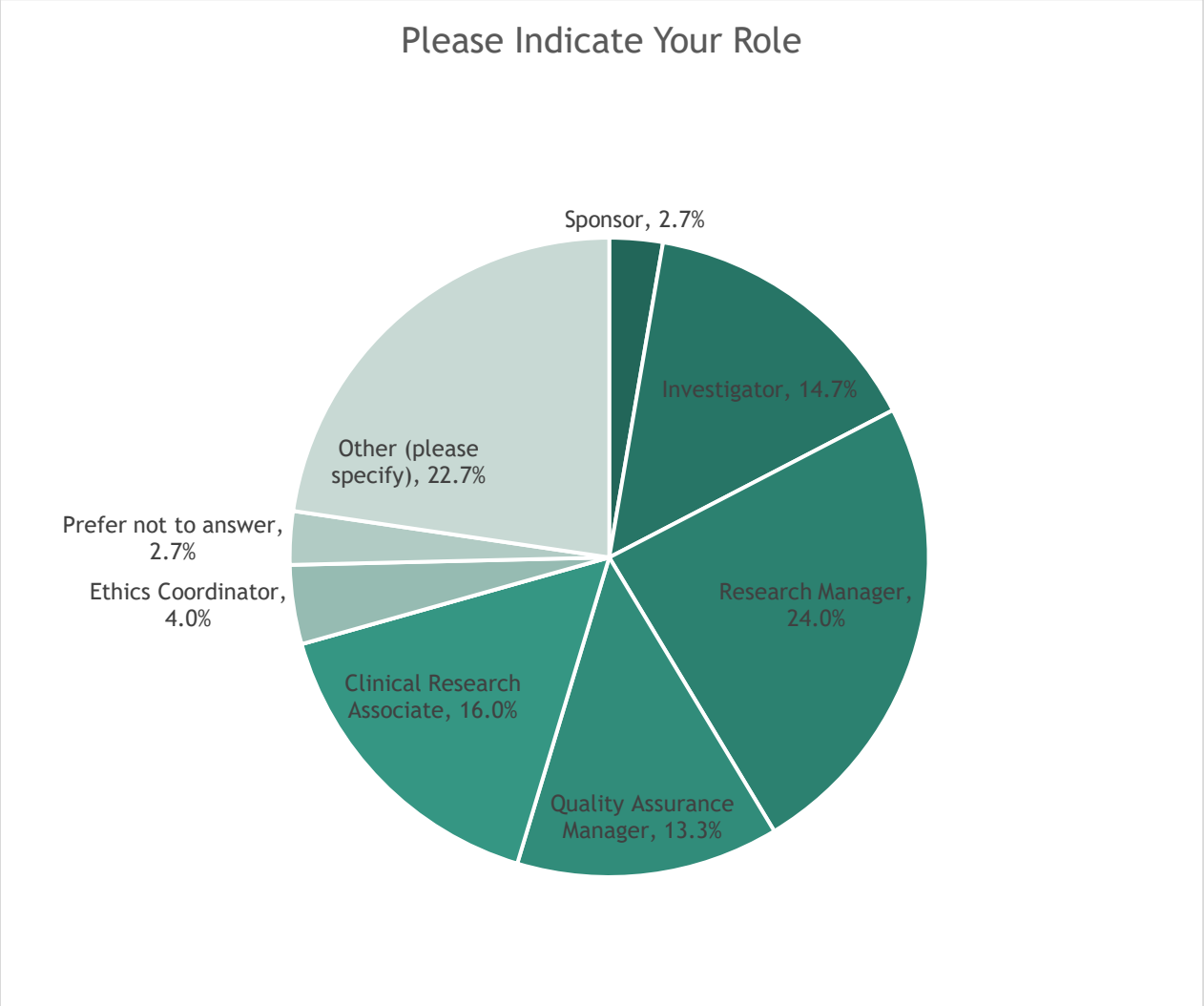
Initiative to Streamline Clinical Trials Survey Results

June 2017

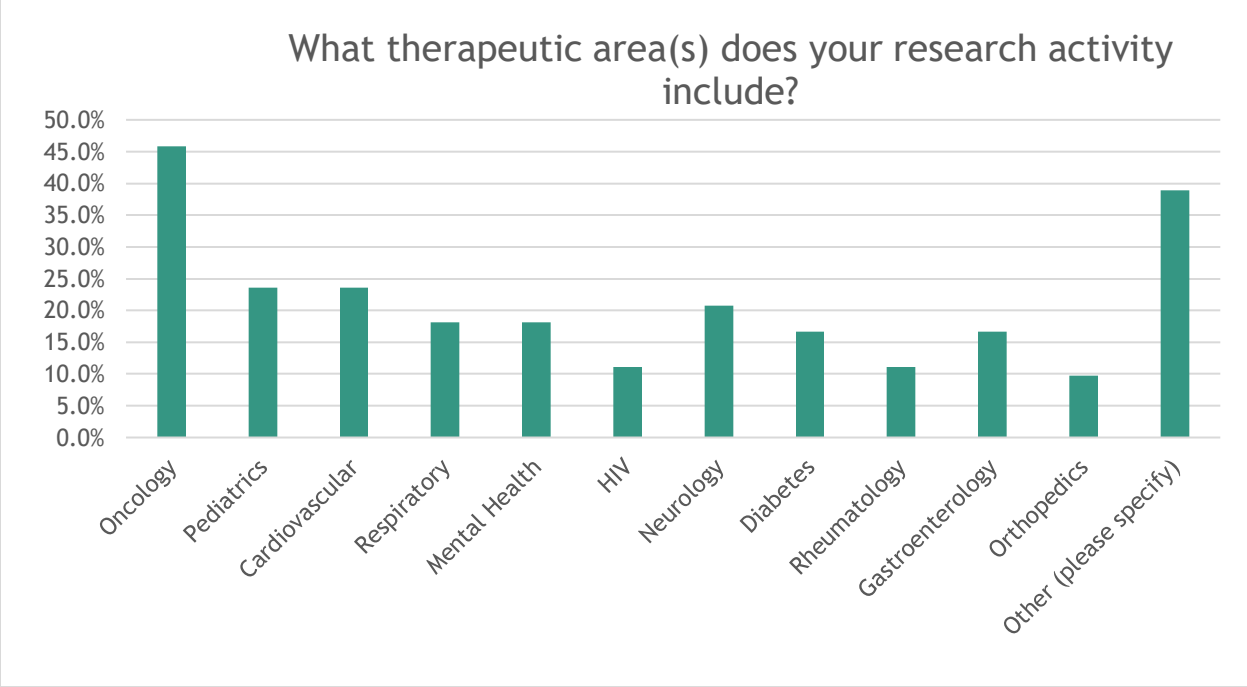
Abstract

The Initiative to Streamline Clinical Trials Working Group developed and distributed a national survey in Spring 2017 to assess the reach and impact of the guidelines. A total of 75 responses from clinical research professionals across 8 Canadian provinces, and 34 different therapeutic areas were collected.



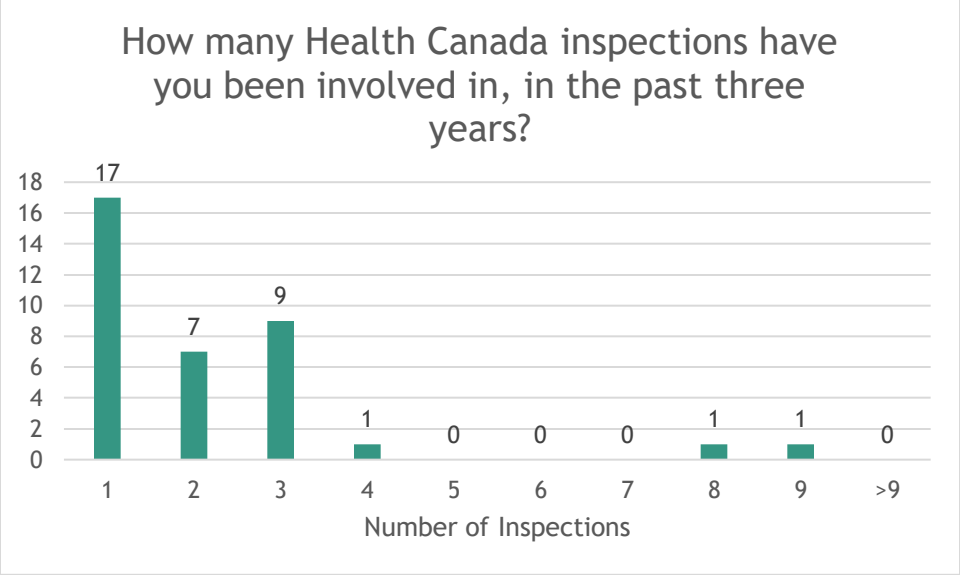
Responses for Other:

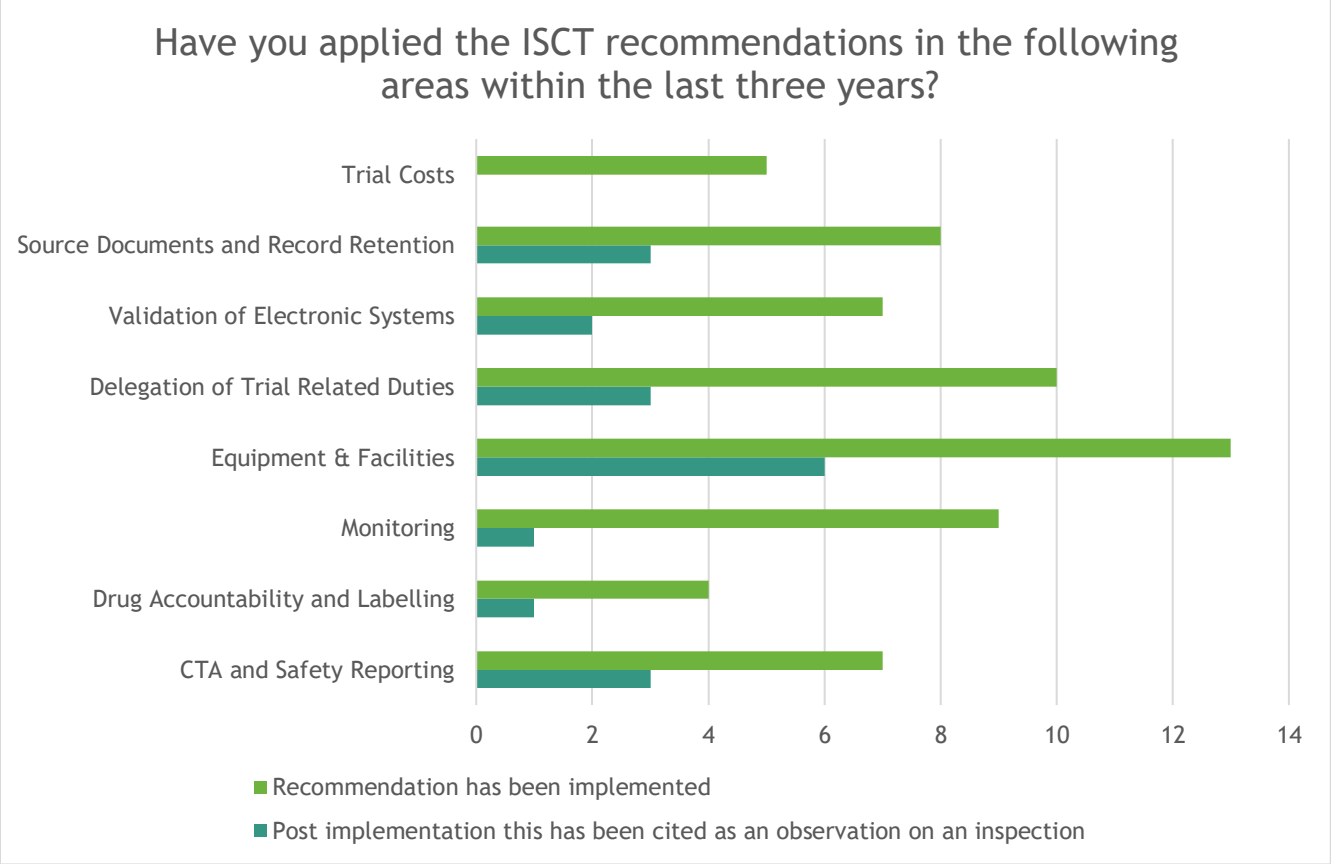
Clinical Research Administrator
Funder / Administrator
Quality Assurance Coordinator
Research Coordinator
Research Assistant
Start-Up Specialist
Quality Assurance Coordinator
Contracts Negotiation
Oncology Research Nurse
Research Coordinator
Research Ethics Board Chair
Regulatory Coordinator
Clinical Research Project Manager
Clinical Research Facilitator/Auditor
Research Coordinator (Site Level)
Clinical Research Coordinator RN
Non-Profit



Responses for Other:

All (4)
Emergency Department Research
General Surgery
REB
Sepsis, Critically Ill
Nephrology
Dermatology, Infectious Disease
QA Manager for The Institution
General Internal Medicine
Allergy
Acute Care (ICU)
All Therapeutic Areas in Pediatrics
Infectious Diseases, Communicable Diseases, Public Health
Contracts Negotiation
Hepatitis C, Vaccines
Hematology; Cellular Therapy
Thrombosis
Transplantation
Venous Thrombosis
Ophthalmology
Other Infectious Diseases (E.G., HepB, HepC)
Rehab, Obstetrics, Trauma, Burns
Allergy and Immunology
Genetics
Thrombosis
Quality Management for Institution


How many Health Canada inspections have you been involved in, in the past three years?
18
16
14
12
10
8
6
4
2
0
17
7
9
1
0
0
0
1
1
0
1
2
3
4
5
6
7
8
9
>9
Number of Inspections


Have you applied the ISCT recommendations in the following areas within the last three years?
Trial Costs
Source Documents and Record Retention
Validation of Electronic Systems
Delegation of Trial Related Duties
Equipment & Facilities
Monitoring
Drug Accountability and Labelling
CTA and Safety Reporting
0
2
4
6
8
10
12
14
Recommendation has been implemented
Post implementation this has been cited as an observation on an inspection

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

- Yes, evidence of CVs and training on a per study basis is unreasonable. Hospitals have credentialing offices that track licensing with relevant colleges (CPSO, CNO, etc). Same with lab licenses and normal ranges, filing on a per study basis is excessive. We work in accredited hospitals. If training and licensing is appropriate for clinical care of patients, why does research have to provide this evidence?
- We implemented the guidelines (although mostly already in place) + I'm not aware if an observation was noted since.
- Many of these recommendations were already in use at our site.
- Would like to work with HC to update the regulations in some areas to ensure that IITs can be feasibly done.
- Since the document has not been accepted as guidance from Health Canada we have not applied any of the recommendations….. want to be compliant with the regulations set out by Health Canada.
- ISCT has to be available for all investigators and researches
- For the source documents category, we have been implementing ISCT retrospectively after being cited by HC.
- Based on our inspection experience HC has not adopted ISCT
- No inspections since implemented. Inspector rejected the recommendation at the time of submission of the response to the report.

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

CTA and Safety Reporting

- Reduced Time
- increased quality
- Reduced time - protocol defined expected events collected as outcomes and not recorded, assessed or reported as AEs.
- Efficiency, no loss of quality
- reduced time for some tasks

Drug Accountability and Labelling

- increased time
- Increased Quality
- increased quality
- Efficiency, no loss of quality
- reduced time/workload for pharmacists

Monitoring

- reasonable approach appreciated by investigators and staff
- increased time and cost
- Reduced Time
- reduced time and cost
- no change
- Efficiency, no loss of quality
- reduced cost & workload
- Monitoring plan submitted and approved with CTA
- Remote monitoring creates more demand on the CRC and becomes repetitive

Equipment & Facilities

- inspector still sited observations on this
- increased time, and quality
- Reduced Cost
- increased quality
- Reduced time and cost for the research team and institutional biomedical engineering department as clinical equipment managed according to hospital policies and accreditation standards.
- Efficiency, no loss of quality
- reduced time
- reduced time

Delegation of Trial Related Duties

- hard to assess, perhaps reduced time
- increased time
- Increased Quality
- Reduced time - hospital clinical staff conducting study related tasks that are within their scope and unrelated to a drug listed on the NOL (dispensing, administering) do not have to complete general research (GCP, Div 5) or study specific training (protocol). Research team does not have to collect the licenses and CVs of those clinical staff. However, research staff do continue to inform department supervisors of impacted support services within the institution (labs) of changes to the study protocol/status and those individuals are listed as "supervisors" on the delegation log for the purposes of attesting that they are aware of the research taking place and that the staff they supervise are appropriately trained and qualified to do their clinical job.
- Efficiency, no loss of quality
- implementation is on-going, impact uncertain at this time

Validation of Electronic Systems

- hard to assess
- increased time
- Increased Quality
- reduced time and cost
- Efficiency, no loss of quality
- reduced time

Source Documents and Record Retention

- hard to assess
- Increased Quality
- reduced time and cost
- no change
- Efficiency, no loss of quality
- increased workload at the sites

Trial Costs

- granting agencies providing funds for monitoring when requested
- Reduced Cost
- More feasible:)

What have been the barriers to implementing the guidelines?

- Still subjective interpretation by inspectors and variability between inspectors; inconsistent interpretation of requirements by inspectors.
- Increases work on site
- Fear of lack of compliance to Health Canada regulations. Until they agree it seems risky to make changes.
- Man power
- Many hands involved
- 1 central contact
- We have been very wary about implementing the guidelines as our past experiences with Health Canada inspections is that they simply would not be considered acceptable. Once there is more buy-in from other institutions and Health Canada inspectors become familiar with the guidelines (and accept them), we may then be willing to implement the guidelines across the institution.
- Still the guidelines not 100% aligned with the regulation
- Time to address some of the complexities of implementing the recommendations within the pediatric environment. Currently working with a WG to address the CTA recommendations in pediatrics, effective March 2017. Will be reaching out to all pediatric centers in Canada to develop a strategy and precedence to reduce the number of drugs listed on individual NOLs, and perhaps the total number of NOLs altogether.
- Risk adverse institution.
- We have not been conducting investigator initiated clinical trials for which we could set policy and procedure. Either sponsor driven, CRO driven or academic SOP driven.
- Why would I implement another set of guidelines if there is no requirement for them. Once Health Canada is on board and it saves time vs a make work project- amazing bring them on.
- Adequate support staff in the trials unit to allow time to review and implement the guidelines.
- We are concerned with implementing the guidelines if they are not endorsed by the Health Canada inspectorate.
- Lack of awareness of the ISCT guidelines in the research community; would appreciate some educational opportunities on the guidelines. Unclear to what extent is Health Canada accepting the recommendations.
- Institutional resistance, including ethics boards, and internal institutional quality managers
- Health Canada inspectorate unwilling to accept interpretations of the regulations
- Health Canada needs to adopt and / or recognize these guidelines and accept them during inspections

- It is not clear that implementing the guidelines would keep our site from being cited for non-compliance in the event of an audit or inspection. More information about Health Canada's approval of the guidelines would give us support to push back to sponsors if cited in a monitoring or audit report.
- Don't agree with all of the recommendations.
- Insufficient human resources to follow through
- Acceptance by Health Canada
- HC does not acknowledge them. Tried to reference ISCT in response to inspection and told by inspector that these guidelines have not been accepted.