N2 NETWORK OF NETWORKS
RÉSEAU DES RÉSEAUX

2020 N2 Annual Conference Overview

Day 1 Presentation Overview

Health Canada: Guide 100 Update and Inspections

Shila Rastegar (Health Canada)

Health Canada provided an update to Guide 100 and inspections in Canada.

- Information about Clinical Trial Compliance Program and the Canadian regulatory framework
- Introduction to Health Canada's new Guidance document Part C, Division 5 of the Food and Drug Regulations

DOWNLOAD HEALTH CANADA GUIDANCE DOCUMENT

Initiative to Streamline Clinical Trials: Phase 2

Dr. Rachel Syme (N2) & **Karen Arts** (N2)

An update on the outcomes of the ISCT Phase 1 were provided and a discussion was held about building on Phase 1 to establish Phase 2 of the ISCT.

- Came out of Canadian Cancer research Alliance Recommendation to streamline the clinical trials Regulatory Environment
- Phase 1 began in 2012
- Developed guidelines for trials requiring a CTA in consultation with Health Canada in nine key areas (monitoring, CTA, drug accountability, equipment and facilities, delegation of duties, validation of electronic systems, source data documents, trial costs and Inspections and the Health Canada website) which were published in 2014 and then applied by sites
- These guidelines are now reflected in 2019 Health Canada Guide 100
- Now planning for ISCT phase 2 to identify additional regulatory burdens and develop recommendations as in Phase I to address them, including an inventory of issues sites receive push back from Health Canada on.
- Additional volunteers and a Lead are being sought for this initiative

Big Data, Technology, and Privacy in Changing Times (moderated by Tammy Mah-Fraser)

Panel review of experiences and perspectives related to technology in clinical research.

eConsent to Streamline Mobile Health Research: A Case Study in Pediatric Arthritis

Dr. Chitra Lalloo (The Hospital for Sick Children)

- Review of mHealth and the iCanCope with Pain app
- Insight into the potential of the ResearchKit for eConsent
- Case study of ResearchKit in pediatric arthritis

Opportunities for Research: Impact of Information (It's Everywhere)

Dr. Frank Naus (AllPhase)

- The CRO Perspective on big data, technology a privacy
- Discussed linking big data to real world evidence (RWE) because RWE is the bridge between research and practice
- Patient support programs can be a key element to generating RWE

Big Data and mHealth from an REB Perspective

Martin Letendre (Veritas IRB)

- Review of big data and mHealth from an REB perspective
- Big data and mHealth research is varied
- REB faces various epistemological challenges, so they should adopt a systemic approach

Realizing Big Data through Responsible, International Data Sharing

Dr. Adrian Thorogood (McGill University)

- Review of big data from lobbyist perspective
- Big data is an excellent opportunity through collective action, if handled responsibly, and governance to improve lives

What People Were Saying

This was a great conference and thank you as always for bringing us all together to try and find ways that we can do clinical research better. You guys are doing a great job!!!

Keep up the great work! I love getting the face time with those involved in N2 and Health Canada. The space felt a little small because the attendance was great. The food was great. Thank you for organizing this.

This was a really great conference. I learned a lot, got to meet up with some old friends, and network with some new ones. Will definitely recommend sending representatives again next year.

n2@n2canada.ca
n2.canada.ca
itstartswithme.ca / cacommenceavecmoi.ca