

2015-2016 Research Education Across Atlantic Canada Hospitals (REACH)

Time:

noon to 1 p.m.

Registration Required***Location:**

Royal Bank Theatre

Halifax Infirmary, 1796 Summer Street, Halifax, NS B3H 3A7

September 29, 2015: *Investigator Responsibilities—An auditor's perspective*

Speaker: Marianne Vanderwel, M.Eng., M.Sc., Quality Management Consultant

This presentation will review some of the investigator's responsibilities when conducting clinical trials, from an auditor's perspective. Common audit findings as well as some specific examples from regulatory authority inspections will be reviewed.

October 20, 2015: *Qualifications and Training: More than Pieces of Paper*

Speaker: Janet Gallant, RN, BScN, CCRP, Program Manager, Research Education, NSHA

In the past few years there has been an increased focus on documentation of qualifications and training of researchers and other team members. In addition, it is critical that researchers and team members plan for development and maintenance of competency in conducting research. Expectations for qualifications, training and documentation will be reviewed along with resources and tips to support competency. This topic, although not new, is reflective of recent inspection findings.

November 10, 2015: *It Finally Happened! An Inspection of Investigator Sponsored Research*

Speakers: Janet Gallant, RN BScN CCRP, Program Manager, Research Education, NSHA

Julia Enikeeva RN BScN MPH, Program Manager, Research Quality, Research Services, NSHA

Health Canada recently conducted an inspection of a clinical trial at NSHA that was initiated and sponsored by a physician investigator. The results of the inspection indicate that the standards that are expected from a sponsor-investigator are the same expectations as for a trial sponsored by industry. This session will discuss findings, impact and outcomes. This session is essential for anyone engaged or planning to conduct this type of research to ensure Health Canada's expectations are met.

January 12, 2016: Topic: TBA

Speakers: Research Support Colleagues from Horizon Health Network in New Brunswick

March 8, 2016: *Are you Ready to be the Sponsor of a Clinical Trial?*

Speakers: Jennifer Thurlow, MSc, Contract Grant Facilitation and Support, NSHA

Janet Gallant, RN, BScN, CCRP, Program Manager, Research Education, NSHA

Proper planning prevents poor performance! It is imperative that teams and researchers understand their responsibilities when acting as a sponsor of a clinical trial. This session will outline and describe the considerations to ensure regulatory compliance and the importance of early planning to ensure success. This topic is a result of Health Canada inspection results as well as local audit findings.

May 10, 2016: *Recipes for Success: Investigator- Sponsored Research*

Speaker: Janet Gallant, RN, BScN, CCRP, Program Manager, Research Education, NSHA

Audit and inspection findings for investigator-sponsored research are frequently related to systems and procedures for quality assurance. Such systems and procedures are essential for participant safety, data integrity and regulatory compliance. Well conceived and written documents including the protocol, monitoring plan, standard operating procedures and system validation are critical to the success of every trial. Tips, tools and resources will be discussed.

***Registration: elaine.strohm@nshealth.ca**

Joining Sessions Remotely from NSHA

If you would like to join remotely from NSHA, contact: elaine.strohm@nshealth.ca at least one week in advance of the session.

If this is your first time joining remotely, please contact Elaine at least two weeks in advance to ensure you have the capabilities required to join the session.