Medical Devices (includes In Vitro Diagnostics) Foundational

How to Review and Compile the Clinical Data in a Clinical Evaluation Report

Monday, September 23 4:00 PM - 5:30 PM Location: 204 B

Learning Level: Foundational

Session Leader(s)

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Speaker(s)

Christopher Brodrick, MSc
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Participants will be able to assess the clinical data available for a device and develop a CER regulatory strategy. They will understand the importance of properly scoping and defining the strategy and plan for the clinical evaluation. They will be able to define the scope of the CER and develop the plan for the clinical evaluation and CER.

Learning Objectives:

- Discuss how to assess the available clinical data, scope the CER, draft a Clinical Evaluation Plan, and understand the key sections of a Clinical Evaluation Report.
- Explain how to document the state of the art and searches (literature, vigilance, and clinical trials).
- Describe different methods to consider in appraising and analyzing the data.