



Patient Engagement and Quality by Design: Co-Developing an Implementation Roadmap for Clinical Trials

WHEN

October 15th, starting at 3pm ending at ~ 4.30pm (9am – 10.30am US Eastern Time)

Description: Global regulatory frameworks increasingly emphasize the need for patient input into study design. Despite the wealth of patient engagement resources available, however, there is currently no harmonized roadmap for effective and efficient implementation to specifically support the key decisions in clinical trial design. As patient engagement has evolved, there are also new opportunities for engagement that may not be represented in existing models. This session will bring together sponsor representatives and investigators, patient advocates, and other experts to begin developing such a roadmap, overlaying existing patient engagement resources against the QbD approach to study planning developed by the Clinical Trials Transformation Initiative (CTTI).

Objectives:

- Discuss the role of patient engagement in a Quality by Design (QbD) approach to study planning, as highlighted in the current draft of ICH E8(R1), the International Council for Harmonisation's guideline on General Considerations for Clinical Studies
- Identify key decision points in clinical trial design, opportunities for patient input, and existing resources to support effective engagement.
- Support sponsor and patient group stakeholders in articulating the broader value proposition of Quality by Design and patient engagement for medical product development.

Discussion Leaders:

- Jaye Bea Smalley, Immunovant
- Karlin Schroeder, Parkinson's Foundation
- Kerstin Koenig, ICH E8 Expert Working Group Member
- Rick Bangs, Cancer Research Advocate

Pre-Session Survey (all attendees asked to complete by 6th October):

https://duke.qualtrics.com/jfe/form/SV_7Uyr5iSK3UFRUV

Optional Pre-read on Quality by Design:

<https://journals.sagepub.com/doi/full/10.1177/1740774516643491>

TO CONNECT

Please click this URL to join. <https://duke.zoom.us/j/91684163499?pwd=N2IYMXM2TUxVxkxkTHo3WEdzVHcvQT09>



Passcode: ctti

Or join by phone:

- US: +1 301 715 8592 or +1 312 626 6799 or +1 646 876 9923 or +1 346 248 7799 or +1 408 638 0968 or +1 669 900 6833 or +1 253 215 8782
- International numbers available: <https://duke.zoom.us/j/91684163499>

Webinar ID: 916 8416 3499

Passcode: 758454