ACT Webinar

“Preparing for Regulatory Interactions: How Much is Enough?”

Speaker:
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Webinar Abstract:
Productive industry interactions with regulatory authorities are critical for clinical development. However, it can be challenging to determine how much preparatory time and effort will be needed to accomplish the desired goals. How many studies need to be conducted and how much information provided, without wasting resources or overwhelming regulators? Several key questions should be considered in preparing for a regulatory interactions or meetings. These include: What key issue(s) need to be discussed/agreed to with a regulatory authority? What is the optimal timing to inform clinical development? What information should be provided to a regulatory agency to enable a decision? Is a face-to-face meeting needed, or will written responses or a teleconference suffice? Finally, each regulatory authority is different, and the current requirements of the specific regulatory agency are important. This presentation will address each of these topics using examples to give attendees a foundation for ensuring productive and effective regulatory interactions.