Enhancing Adoption of Innovative Clinical Trial Approaches
Hybrid Public Meeting • Kellogg Conference Hotel • Washington, D.C.
March 19, 2024 | 10:00 am – 5:00 pm ET
March 20, 2024 | 12:30 pm – 5:00 pm ET

Agenda: Day 1

10:00 am  Welcome

10:10 am  Fireside Chat
U.S. Food and Drug Administration leadership will introduce the meeting’s objectives, while highlighting ongoing activities and initiatives in the clinical trial innovation space within the Center for Drug Evaluation and Research (CDER).

10:30 am  Session 1: Evolution of Clinical Trial Research and the Current State of Trial Innovation
Panelists will discuss current healthcare trends and how the landscape of clinical trial innovations have been evolving to meet the pressing health care challenges of tomorrow.

11:30 am  Break

11:40 am  Session 2: Regulatory and Compliance Considerations
Panelists will examine implementation of innovative clinical trials from a regulatory standpoint. Discussion will cover the exploration of practical opportunities to adopt innovative approaches from compliance of Good Clinical Practice and other guidelines.

12:55 pm  Lunch Break

02:10 pm  Session 3: Patient-Centric and Recruitment Considerations
Panelists will highlight factors related to patient-centric design and execution in innovative clinical trials. Discussion will encompass opportunities to incorporate patient perspectives in trial design, facilitate recruitment and retention, ensure informed consent, and optimize other processes for enhancing clinical trial participation.
03:25 pm Break

03:35 pm Session 4: Infrastructure and Organizational Considerations
Panelists will evaluate innovative approaches to clinical trials within existing infrastructure and health care delivery systems. Discussion will focus on opportunities to bolster technical and analytical capabilities, organizational culture for participation in research, site readiness to conduct research, and access to research.

04:50 pm Closing Remarks

05:00 pm Adjournment
Agenda: Day 2

12:30 pm Welcome and Day 1 Recap

12:45 pm Session 5: Global Regulatory Collaboration on Clinical Trial Innovation
Regulatory agencies representing several jurisdictions will share internal collaborations, future outlook, and anticipated goals to further cultivate clinical trial innovation globally. Organizations representing prospective clinical trial sponsors will also share their perspectives on opportunities to enhance harmonization worldwide.

01:55 pm Break

02:05 pm Session 6: Collaborations Across Industries to Leverage Innovation
Clinical research stakeholders will share their experiences and insights from collaborating to implement innovative clinical trials and explore adoption strategies across the clinical research ecosystem. Panelists will explore enacted innovative approaches to clinical trials including point-of-care, platform, decentralized and pragmatic. Use of tools for trial design and use of real-world data and real-world evidence will also be discussed.

03:20 pm Break

03:30 pm Session 7: Future Directions on Clinical Trial Innovation
Panelists will summarize key insights and takeaways from the workshop discussions and reflect on potential next steps for CDER and its partners to consider in support of innovative clinical trials. Discussion will also think through continued engagement and connection with CDER's innovation efforts by industry, academic, patient, and other stakeholders. Panelists will highlight the impact of clinical trial innovation and how success for implementation can be measured.

04:45 pm Closing Remarks

05:00 pm Adjournment

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