CENTER FOR DRUG EVALUATION AND RESEARCH

Center For Clinical Trial Innovation (C3TI)

We are excited to celebrate the six-month anniversary of the CDER Center for Clinical Trial Innovation (C3TI) with the inaugural issue of our newsletter. We have made tremendous progress since C3TI publicly launched in April. In May, we released our knowledge repository, known as C3TI Compass. C3TI Compass has almost 150 resources related to clinical trial innovation, and it continues to grow.

We are also strengthening our Demonstration Program, which will let selected drug developers test, implement, and scale certain innovations in clinical trials. It is a great opportunity for enhanced communication and interaction with CDER staff, and we encourage drug developers to apply to the program.

On an internal front, we have begun a multi-pronged effort to engage CDER staff on their experiences with innovative clinical trials. The programming includes symposia, innovation "Rounds," communications resources, and other knowledge-sharing endeavors.

Through our external outreach, we have been communicating C3TI's goals and initiatives to a broader audience. We have unveiled a public website, engaged the media, and developed a social media presence. Since our launch, we have spoken at approximately 30 external scientific meetings, conferences, and symposia. We have also responded to over 60 external inquiries from academia, industry, patient groups, and others.

Our newsletter is our latest communications effort, which will share news, events, and other important items about clinical trial innovation in the context of FDA. Thank you for exploring these innovations with us – we hope you find the insights valuable and inspiring!

Clinical Trial Innovation News

C3TI Features CDER Employee Who Participated in a Breast Cancer Clinical Trial

As we celebrate Breast Cancer Month in October, C3TI is honored to spotlight Strother D. Dixon, a CDER employee who participated in a breast cancer clinical trial. She shares her experiences in this editorial, including how she felt overwhelmed with the diagnosis, navigated the informed consent process, and recovered from the disease. She hopes her story inspires others to consider participating in a clinical trial.

FDA Issues Two Guidances to Advance Clinical Trial Innovation

FDA issued two guidances that align with C3TI's efforts to advance clinical trial innovation while minimizing research participation barriers, including through our Streamlined Trials Embedded in clinical Practice (STEP) Demonstration Project.

The Integrating Randomized Controlled Trials for Drug and Biological Products Into Routine Clinical Practice draft guidance is intended to support the conduct of randomized controlled drug trials with streamlined protocols and procedures that focus on essential data collection, allowing integration of research into routine clinical practice. FDA is accepting public comments on this guidance until Dec. 17. The Conducting Clinical Trials with Decentralized Elements final guidance provides recommendations regarding the implementation of decentralized elements in clinical trials.

CDER Releases Educational Video on Design of Rare Disease Clinical Trials

CDER has released the first video in the Learning and Education to Advance and Empower Rare Disease Drug Developers (LEADER 3D) educational video series titled, "Challenges, Strategies, and Regulatory Considerations for the Design of Rare Disease Clinical Trials." The video provides an overview of FDA's regulatory requirements and strategies for clinical trial design in rare disease drug development.

FDA Podcast Focuses on Real-World Data and Evidence Generation

In an FDA podcast, the agency's Chief Medical Officer Hilary Marston, MD, discusses the use of real-world data to generate real-world evidence to support the safety and effectiveness of medical products. She shares how the agency considers real-world evidence and clinical trial findings when making regulatory decisions.

FDA Publishes Article on Advancing Clinical Trial Participation in LGBTQIA+ Community

The agency published a Voices article describing FDA's participation in a community discussion on advancing clinical trial diversity for sexual and gender minority communications. The conversation focuses on the importance of inclusion and

representation in clinical trials, barriers to participation, and strategies that emphasize LGBTQIA+ community engagement.

CDER Issues 2024 Accelerating Rare disease Cures (ARC) Program Annual Report

CDER released the 2024 Accelerating Rare disease Cures (ARC) Program Annual Report, which describes ARC's accomplishments in 2024 and its outlook. Since its launch in 2022, CDER's ARC Program has become a key resource for the rare disease community and a driver of innovative approaches for rare disease drug development.

Upcoming Events

- 10/30: Finding Your Support Team While Participating in a Clinical Trial
- 11/6-11/7: FDA Clinical Trial Requirements, Regulations, Compliance, and the GCP Conference
- 11/8: Informed Consent – More than Just Another Document to Sign?
- 12/10-12/12: FDA Clinical Investigator Training Course (CITC) 2024

Spotlight: The C3TI Compass Glossary

The C3TI Compass Glossary can help navigate C3TI's Compass Knowledge Repository and the broader clinical trial literature. The glossary defines over 20 clinical trial terms, including area of research, drug development stage, and innovation type.

ICYMI: C3TI on the Road in September

Last month, C3TI staff spoke at many in-person and virtual conferences. See what information they presented. Interested in requesting a C3TI speaker? Submit a CDER Speaker Request here.

- 9/10: Biocom California Regulatory Affairs Committee Meeting
- 9/11: Critical Path Institute Global Impact Conference
- 9/11: Mansfield-PhRMA Research Scholars Program
- 9/17: Research!America National Health Research Forum
- 9/19: Virginia Community Health Care Association
- 9/19: Regulatory Affairs Professionals (RAPS) Convergence
- 9/26: The American Statistical Association (ASA) Biopharmaceutical Section Regulatory-Industry Statistics Workshop

- 9/26: DIA-Korea Regulatory Science Center (KRSC) Workshop
- 9/29: Society for Clinical Data Management (SCDM) Annual Meeting

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Questions or Comments? Contact C3TI at CDERClinicalTrialInnovation@fda.hhs.gov.
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