



Overview of CDER's Small Business & Industry Assistance (SBIA)

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Captain, United States Public Health Service (USHPS)

Director, Small Business, and Industry Assistance (SBIA)

Division of Drug Information (DDI) Office of Communications (OCOMM)

Center for Drug Evaluation and Research (CDER)

Learning Objectives

- Locate the SBIA webpage and identify 3 resources SBIA offers that can help YOU
- Understand how to register for SBIA events and find recordings of past events

SBIA Mission



- Provide industry with immediate access to resources, education & training
- Allow for a more clearly informed and efficient developmental process
- Align with CDER's goal of approving safe and effective human drugs and biopharmaceuticals

SBIA Audience



Resources

- Direct Communication Services
- Training Resources
- Webpage
- News and Updates

Direct Communications Services



- **Phone:** 301-796-6707 | 866-405-5367
- **Email:** CDERSBIA@fda.hhs.gov
(Monday – Friday 8 AM – 4:30 PM ET)

Resources

- Direct Communication Services
- **Training Resources**
- Webpage
- News and Updates

Workshops and Conferences



Small Business and
Industry Assistance

2024 Regulatory Education for Industry



Hybrid
May 29-30



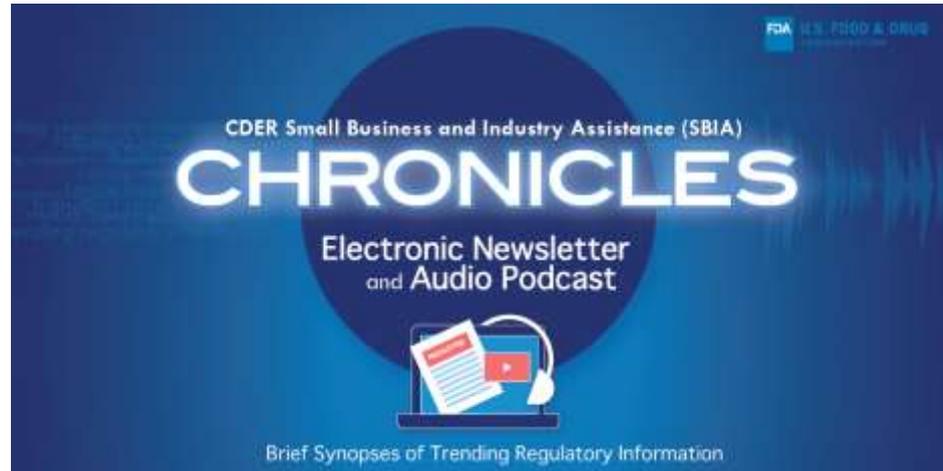
Small Business and
Industry Assistance

Clinical Investigator Training Course (CITC)



DECEMBER 6 – 7, 2023
Webcast

SBIA Chronicles



Short electronic newsletter and podcast, highlighting a specific regulatory issue in an easy-to-read format.

www.fda.gov/cdersbiachronicles

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CDER Small Business & Industry Assistance (SBIA)

A Comprehensive Resource for Information on Human Drug Development in Regulation

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Register for Upcoming Events

Date	Time	Event	Location
September 4, 2024	11:00 am - 3:00 pm	FDA NIH : Regulatory Do's and Don'ts: Tips from FDA	Webinar
September 12, 2024	8:45 am - 4:45 pm	Electronic Drug Registration and Listing (eDRLS) Using CDER Direct - 2024: Earn 6.5 CE Hours	Webinar
September 24 -25, 2024	8:30 am - 4:30 pm	Advancing Generic Drug Development: Translating Science to Approval 2024 - Special Room Rate Ends August 30!	Workshop
October 9, 2024	1:00 pm - 3:00 pm	ICH M12 Drug-Drug Interaction Studies Final Guidance	Webinar
October 16, 2024	1:00 pm - 2:30 pm	Global IDMP Implementation - Getting Closer to the Goal	Webinar

CDER Small Business & Industry Assistance (SBIA)

*A Comprehensive Resource for Information on Human Drug Development in
Regulation*



REGULATORY REFERENCES, TRAINING, AND RESOURCES



Regulatory References

Find information on drug development, applications, submissions, manufacturing & quality, safety, labeling and more



SBIA Learn Online Training Repository

Search for conferences, webinars, online courses, newsletters and podcasts



SBIA on LinkedIn

Stay connected and receive regulatory updates and event notifications



SBIA Learning Library on YouTube

Browse conference and webinar recordings on YouTube

CDER Small Business and Industry Assistance (SBIA) Learn

Online Training Repository



Use filters and search box to find resources

Advanced search (combine topic and search terms)

Type

Topic

[Clear Filters](#)

Search Show 11 entries

Summary	Type	Issued/Updated	Topic	Substituted en Español
Global ICDP Implementation - Getting Closer to the Goal	Webinar	10/16/2024	Data Standards, Drug Shortages, Labeling, Electronic Submissions, Pharmacovigilance, Regulatory Submissions	No
ICH M12 Drug-Drug Interaction Studies Final Guidance	Webinar	10/9/2024	Drug Interaction, New Drug Development, IND	No
Advancing Genetic Drug Development: Translating Science to Approval 2024	Conference/Workshop	9/24/2024	ANDA, Complex Generic Drug, Product Specific Guidances, Generic Drug Development, Regulatory Assessment	No
Electronic Drug Registration and Listing (eDRL) Update CDER Direct - 2024	Conference/Workshop	9/12/2024	Import/Export, International, Registration and Listing	No
FDA, MH, Regulatory Ops and Devs: Tips from FDA	Webinar	9/4/2024	Biologics, Chemistry, Manufacturing and Controls (CMC), Clinical Trials and Research, Early Product Development, Devices, Digital Health Technologies, Drug Development	No

CDER Small Business and Industry Assistance (SBIA) Learn



Online Training Repository

Oncology Therapy Development Workshop: Pivotal Steps and Avoiding Pitfalls for Start-ups

MARCH 30 - 31, 2021

Scheduled

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On This Page

- [Meeting Information](#)

Date: March 30 - 31, 2021

Day1: Tue, Mar 30 9:00 AM - 4:30 PM ET

Day2: Wed, Mar 31 9:00 AM - 4:30 PM ET

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Email Subscriptions



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CONFERENCES

Regulatory Education for Industry (REI) Annual Conference 2024

Innovation in Medical Product Development

Hybrid
May 29 – 30 | 8:30 AM - 4:30 PM ET

No Fee Registration

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DRUGS, DEVICES, AND BIOLOGICS

TRACKS WILL OFFER AN OPPORTUNITY FOR 1:1 QUESTIONS FOR ONSITE ATTENDEES.

Learn directly from the FDA's regulatory experts in medical product centers: drugs, devices, and biologics. This course is designed to provide participants with a strong, basic foundation in the FDA's regulatory requirements, and also create awareness of current activities



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INDUSTRY NEWS

FDA establishes CDER Center for Clinical Trial Innovation (C3TI)

Today, FDA's Center for Drug Evaluation and Research (CDER) [announced](#) the launch of the CDER Center for Clinical Trial Innovation (C3TI). C3TI's mission is to promote CDER clinical trial innovation activities through enhanced communication and collaboration, both internally within CDER and externally.

"CDER's long-standing efforts to embed innovation in clinical trial design and conduct into our regulatory work have been crucial in bringing new therapies to areas of unmet medical need," said Patrizia Cavazzoni, M.D., director of CDER. "We are eager to build on this foundation by launching C3TI to further spur the adoption of clinical trial innovation across industry and within CDER."

For years, CDER has championed innovation, and our activities to foster and support innovation span drug development programs, therapeutic areas, and disciplines. These CDER efforts have led to improvements in the design and conduct of clinical trials that are intended to efficiently generate evidence on the safety and effectiveness of new therapies in ways that meet the growing demands of drug development.

Recently, we sought to understand the impact of these efforts by holding interviews, listening sessions, and a public workshop with both internal and external parties, and soliciting comments to a public [docket](#). Based on these engagements, we recognize an opportunity to enhance the implementation of our innovative efforts and maximize the impact on drug development.

C3TI will be a central hub within CDER that supports innovative approaches to clinical trials that are designed to improve the efficiency of drug development. C3TI will facilitate the sharing of lessons learned across CDER's existing clinical trial innovation initiatives and will communicate and collaborate with external parties. C3TI will also manage a demonstration program that will expand opportunities for sponsors of innovative clinical trials to interact with CDER staff and for these trials to serve as case examples to spur further implementation. The three initial project areas under the C3TI Demonstration Program are 1) point-of-care or pragmatic trials; 2) Bayesian analyses; and 3) trials using selective safety data collection.

This new center within CDER will enable both internal and external parties to access information on clinical trial innovation efforts more easily, engage in collaborations, identify resources that can further support the use of innovative modalities, and identify development programs where a concerted approach to the use of clinical trial innovations would be impactful. The goals of these efforts are to assist those involved in clinical research in staying current with clinical trial innovations, improve the efficiency and effectiveness of clinical trials, help increase the participation of diverse populations in clinical trials, and, in turn, accelerate the development of safe and effective new drugs.

For more information about C3TI, including how to participate in a project in the C3TI Demonstration Program, explore the [C3TI webpage](#). Visit the [CDER Conversation](#) with Dr. Kevin Bugin, deputy director for operations in CDER's Office of New Drugs and lead for C3TI to learn more about the impetus for establishing C3TI and the center's forward-facing goals and objectives.

Email Subscriptions



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Center for Drug Evaluation and Research (CDER)

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Resources



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Summary and Call to Action



- Email or call SBIA with your regulatory questions
CDERSBIA@fda.hhs.gov | 866-405-5367 or 301-796-6707
- Bookmark www.fda.gov/cdersbia and www.fda.gov/cdersbialearn
- Browse the [CDER SBIA playlists](#) on FDA's YouTube channel
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- Subscribe to the [SBIA listserv](#)

Today's Moderator



Nora Lim, PharmD, BCPS

Lieutenant Commander (LCDR)

United States Public Health Service (USPHS)

Small Business and Industry Assistance (SBIA)

Division of Drug Information (DDI)

Office of Communications (OCOMM)

Center for Drug Evaluation and Research (CDER) | FDA

Today's CDER Presenters



Paresma Patel, PhD

Division Director

Office of Product Quality Assessment III (OPQA III)
Office of Pharmaceutical Quality (OPQ) / CDER

Today's CDER Presenters



Emily Wearne, PhD

Pharmacologist/Acting Nonclinical Team Leader
Division of Hematology Oncology Toxicology (DHOT)
OOD | OND | CDER

Caitlin Tydings, MD

Pediatric Hematologist/Oncologist
Medical Officer, Division of Oncology 3
OOD | OND | CDER



An Oncology Drug Development Mindset First Steps

Jeff Summers, MD

Associate Office Director

Office of Oncologic Diseases (OOD)

Office of New Drugs (OND) | CDER

