FALL PREVENTION ATTENDANCE LOG

| Comment | Response |
|---|---|
| A suggestion was submitted to add a column for the total number of classes attended and a check box if the participant was considered a completer. | ACL adopted the suggestion add a column for the total number of classes attended.<br>ACL did not adopt adding a box to check if a participant was a completer due to the variability of definition of a completer across programs. |
| A suggestion was submitted to add space for the date of each session and names of leaders/coaches. | ACL did not adopt this suggestion. The form can be modified by the grantee. |
| Some comments suggested that for ease of data entry, the participant identification number is too long. | ACL acknowledges these comments. |

COMMENTS RELEVANT TO ALL FORMS

| Comment | Response |
|---|---|
| Some commenters suggested changes to the collection of data, *i.e.,* prefilled forms and positive remarks to prevent falls. | ACL will provide the documents in Word format. If resources allow, we will provide fillable PDFs for grantee use. |
| One respondent commented that the burden of data entry falls on the program coordinators taking hours to enter different forms. | ACL acknowledges the comment. |

*Estimated Program Burden:* ACL estimates the burden of this collection of information as follows:

| Respondent/data collection activity | Number of respondents | Responses per respondent | Hours per response | Annual burden hours |
|---|---|---|---|---|
| Program leaders (Program Information Cover Sheet, Attendance Log). | 480 leaders | Twice a year (one set per program). | .50 | 480 |
| Data entry staff (Program Information Cover Sheet, Attendance Log, Participant Information Survey, Participant Post Program Survey). | 48 data entry staff | Once per program × 938 programs. | .50 | 469 |
| Program participants (Participant Information Survey) | 12,265 | 1 | .10 | 1,226 |
| Program participants (Participant Post Program Survey) | 7,359 | 1 | .10 | 735 |
| Total Burden Hours | | | | 2,910 |

Dated: April 10, 2024.

**Alison Barkoff,**

*Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.*

[FR Doc. 2024–08009 Filed 4–15–24; 8:45 am]

**BILLING CODE 4154–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2024–N–1336]**

### Center for Drug Evaluation and Research Center for Clinical Trial Innovation

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing this notice to announce the establishment of the Center for Drug Evaluation and Research (CDER) Center for Clinical Trial Innovation (C3TI). C3TI aims to be a central hub within CDER that supports innovative approaches to clinical trials that are designed to improve the quality and efficiency of drug development and regulatory decision making. C3TI's mission is to promote existing and future CDER clinical trial innovation activities through enhanced communication and collaboration. Existing CDER clinical development innovation programs will continue to operate according to their established processes with C3TI serving to synthesize lessons learned across those programs. C3TI will also be providing additional opportunities for sponsors of innovative clinical trials in the project areas described below to interact with CDER staff with the goal of fostering knowledge sharing both internally and externally.

**DATES:** The applicable date of this notice is April 15, 2024.

**FOR FURTHER INFORMATION CONTACT:** Kevin Bugin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6312, Silver Spring, MD 20993–0002, 301–796–2302, *Kevin.Bugin@fda.hhs.gov* or *CDERClinicalTrialInnovation@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

CDER guides and fosters drug development by providing scientific and regulatory advice and direction. Evolving understanding of disease biology and molecular pharmacology, advancements in drug discovery, and growth in novel therapeutics have the potential to transform the development of promising new therapies. These changes in the drug development landscape can be further facilitated by novel clinical trial designs, innovative strategies for trial execution, and the expanding range of drug development tools. Similarly, later stages of development, including in the postmarketing setting, can benefit from innovative approaches to study design and analysis. These innovative approaches can include adoption of new statistical approaches, incorporation of pragmatic trial elements, the implementation of point-of-care trials, and wider adoption of selective safety data collection.

With this changing landscape in mind, CDER has many ongoing efforts to advance innovation in clinical trial design and conduct. These CDER efforts have led to improvements in more efficiently designing and conducting

clinical trials that are intended to generate evidence of safety and effectiveness of therapies that in turn showcase the value of clinical trial innovations. CDER leads or co-leads several ongoing programs to advance innovation, and CDER recognizes that additional innovative areas would benefit from the enhanced interactions that are the staple of these programs.

CDER also recognizes that opportunities exist to further enhance the adoption of clinical trial innovations, including the amplification of lessons learned across CDER's robust clinical innovation programs. On October 17, 2023, CDER solicited public comments on the barriers and facilitators to incorporating successful or promising innovative clinical trial approaches in drug development programs. These public comments were discussed as part of a public workshop led by the Duke-Margolis Institute for Health Policy, under a cooperative agreement with FDA, on March 19 and 20, 2024. Topics addressed during the workshop included, but were not limited to, those listed below:

- Evolution of clinical research and the current state of trial innovation
- Regulatory and compliance considerations
- Patient-centric and recruitment considerations
- Infrastructure and organizational considerations
- Global regulatory collaboration on clinical trial innovation
- Collaborations across industry, academia, and FDA to leverage innovation
- Future directions on clinical trial innovation

As a result of these discussions and internal deliberation, FDA is establishing C3TI to further enhance clinical trial innovation for drug development and regulatory decision making. C3TI will serve as a central hub to (1) facilitate the sharing of lessons learned across CDER's existing clinical trial innovation programs, (2) communicate and collaborate with external parties about innovative clinical trials, and (3) manage a C3TI Demonstration Program that will expand opportunities for sponsors of innovative clinical trials in the areas described below that are under a pre-investigational new drug application (pre-IND) or IND to interact with CDER staff.

## II. Goals of C3TI

Specifically, C3TI aims to:

- Assist stakeholders 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
- Enhance the quality of clinical trial data
- Accelerate the development of safe and effective new drugs
- Serve as a central hub for knowledge management and coordinating lessons learned across CDER's clinical trial innovation programs
- Establish a C3TI Demonstration Program that will include case examples from ongoing development programs in the project areas described below to spur innovation across therapeutic areas

## III. Activities of C3TI

C3TI provides a single CDER location to engage stakeholders and assist with non-product-specific questions on innovative clinical trial approaches. C3TI maintains a website at *fda.gov/C3TI* to centralize information on existing and new CDER clinical trial innovation efforts, including links to existing websites and resources. C3TI can be contacted at *CDERClinicalTrialInnovation@fda.hhs.gov.* Additionally, C3TI will coordinate and act as a liaison to facilitate information sharing with external stakeholders, as appropriate and permitted by law, when they engage CDER on general clinical trial innovation matters. It will also support knowledge sharing internally through various mechanisms, such as discussion forums and communications, and a centralized knowledge repository. This repository will curate knowledge about completed CDER clinical trial innovation activities and maintain a comprehensive portfolio of ongoing efforts and knowledge resources.

A critical component of C3TI is expanding the subject areas that could benefit from enhanced communication between CDER and sponsors and serve as case examples to spur further innovation. Therefore, C3TI will manage a demonstration program that includes three initial subject matter/project areas described below. The program is for selected sponsors of innovative clinical trials in certain initial project areas under a pre-IND or IND with CDER that are intended to support new drug product approvals or changes to approved drug product labeling and that will serve as case examples that can be shared both internally and externally to foster innovation across therapeutic areas. If selected, sponsors will have the opportunity for enhanced communication and interaction with CDER staff. Because the goal of selecting these case examples from clinical trials under a pre-IND or IND is to ultimately share lessons learned more broadly with the clinical trial community, participating sponsors and FDA will agree on aspects of the development program that FDA can disclose even before a drug is approved.

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. More information about the C3TI Demonstration Program, including how to participate and how the program differs from existing clinical trial innovation programs, is available on the C3TI website: *fda.gov/C3TI.*

## IV. Paperwork Reduction Act of 1995

For the C3TI Demonstration Program, FDA will request information from no more than nine sponsors. Initial statements of interest from sponsors interested in being evaluated for participation in the C3TI Demonstration Program are not ''information'' in accordance with 5 CFR 1320.3(h)(1). Thus, this notice contains no new collection of information.

This notice also refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014. The collections of information relating to formal meetings between sponsors or applicants and FDA has been approved under OMB control number 0910–0001.

Dated: April 9, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–07829 Filed 4–15–24; 8:45 am]

**BILLING CODE 4164–01–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

**[Document Identifier: OS–0990–0330]**

## Agency Information Collection Request; 30-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork