

policies, procedures, guidelines, and regulations.

These authorities may be redelegated, but not below the level of the Director, Division of Performance and Organizational Programs, Office of Human Capital, CMS or its successor. Exercise of this authority shall be in accordance with established policies, procedures, guidelines, and regulations as prescribed by the Secretary. The Secretary retains the authority to promulgate regulations.

This delegation is effective immediately. I hereby affirm and ratify any actions taken by you or your subordinates that involved the exercise of the authorities delegated herein prior to the effective date of the delegation.

**Robert F. Kennedy, Jr.,**  
Secretary, Department of Health and Human Services.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

[Office of Management and Budget #: 0970-0545]

**Submission for Office of Management and Budget Review; Next Generation of Enhanced Employment Strategies Project**

**AGENCY:** Office of Planning, Research, and Evaluation, Administration for Children and Families, U.S. Department of Health and Human Services.

**ACTION:** Request for public comments.

**SUMMARY:** The Administration for Children and Families (ACF) Office of

Planning, Research, and Evaluation (OPRE) is requesting a one-year extension to one of the data collection activities conducted for the Next Generation of Enhanced Employment Strategies (NextGen) Project, the second follow-up survey (OMB #0970-0545, expiration April 30, 026).

**DATES:** *Comments due May 29, 2026.*

**ADDRESSES:** The public may view and comment on this information collection request at: [https://www.reginfo.gov/public/do/PRAViewICR?ref\\_nbr=202604-0970-008](https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202604-0970-008). You can also obtain copies of the proposed collection of information by emailing [opreinfocollection@acf.hhs.gov](mailto:opreinfocollection@acf.hhs.gov). Identify all emailed requests by the title of the information collection.

**SUPPLEMENTARY INFORMATION:**

*Description:* OPRE is conducting the NextGen Project to test innovative employment programs designed to help people facing complex challenges (such as physical and mental health conditions, criminal justice system involvement, or limited formal work skills and experience) secure economic independence. The project is partnering with the Social Security Administration to incorporate a focus on employment-related early interventions for people with current or foreseeable disabilities who have limited work history and are potential applicants for Supplemental Security Income.

The project includes an impact study, descriptive study, and cost study. The descriptive and cost studies are now complete. The impact study has concluded enrolling participants and fielding the first follow-up survey. OPRE seeks approval for an extension, without change, to one of the currently approved data collection activities for the impact study, the second follow-up

survey. This survey collects data on key outcomes of interest, including service receipt, employment, earnings, economic independence, well-being, health status, substance use, and involvement in the criminal justice system. The second follow-up survey allows the study to assess NextGen programs' impact on these participant outcomes 18 to 21 months after student enrollment, depending on the program. Reporting on the intermediate-term impacts of the programs is critical for fully understanding the programs' effectiveness given that some outcomes are not likely to emerge until 18 to 21 months after program entry. OPRE seeks a one-year extension to capture additional responses to the second follow-up survey and ensure low differential attrition between the treatment and control groups at each NextGen program. Without this extension, participants who enrolled in NextGen most recently would be less likely to have their data captured, which could compromise data quality. The extension is requested to allow all participants to have follow-up periods of similar length (up to six months), which is likely to reduce nonresponse bias in impact estimates of the effectiveness of each NextGen program.

*Respondents:* Individuals enrolled in the NextGen Project.

*Annual Burden Estimates:*

This extension request does not change the average burden per response for the remaining data collection. The total/annual burden estimates under this request are for an additional one year of data collection through April 2027. All other previously approved data collection activities under this OMB number have been completed.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total/annual burden (in hours)
Second follow-up survey—participants .....	160	1	0.83	133

*Authority:* Section 413 of the Social Security Act, as amended by the fiscal year 2017 Consolidated Appropriations Act, 2017 (Public Law 115-31).

**Mary C. Jones,**  
ACF/OPRE Certifying Officer.

[FR Doc. 2026-08308 Filed 4-28-26; 8:45 am]  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2026-N-4390]

**AI-Enabled Optimization of Early-Phase Clinical Trials Pilot Program; Request for Information**

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

**ACTION:** Notice; request for information.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is issuing this request for information to solicit input on a proposed pilot program to assess how artificial intelligence (AI)-enabled technologies can improve efficiency, speed, and quality of decision-making in early phase clinical trials. Early-phase clinical trials represent a critical bottleneck in drug development, often characterized by high uncertainty, limited patient populations, and inefficient decision-

making processes. This pilot program aims to explore how advances in AI and data science can improve trial efficiency, enhance safety monitoring, facilitate dose selection decisions, and enable more informed early go/no-go decisions (e.g., a regulatory decision as to whether a Phase 1 study may proceed) while maintaining FDA's rigorous scientific and regulatory standards and promoting trustworthy AI systems. The pilot program will be guided by principles aligned with the National Institute of Standards and Technology (NIST) AI Risk Management Framework (AI RMF).

**DATES:** Either electronic or written comments must be received by May 29, 2026.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 29, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets

Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA-2026-N-4390 for "AI-Enabled Optimization of Early-Phase Clinical Trials Pilot Program; Request for Information." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management

Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

#### FOR FURTHER INFORMATION CONTACT:

Mallika Mundkur, Deputy Chief Medical Officer, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-8800.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

This request for information provides an opportunity for interested parties and the public to share their input on a proposed pilot program to assess how AI-enabled technologies can improve efficiency, speed, and quality of decision-making in early phase clinical trials.

##### A. Challenges

Early-phase trials face:

- Uncertainty in dosing, safety, and efficacy.
- Limited patient populations.
- Inefficient progression decisions.
- Long timelines and high resource demands.

##### B. Potential of AI<sup>1</sup>

AI may:

- Improve patient recruitment.
- Optimize dose escalation.
- Enhance safety monitoring.
- Enable adaptive designs.
- Support earlier Phase 1 to 2 decisions.
- Improve biomarker assessment.
- Improve biomarker-based patient selection/stratification.
- Validate endpoints.

##### C. Trustworthy AI

- FDA supports AI use by external sponsors/investigators aligned with NIST AI RMF<sup>2</sup> principles: valid, safe, secure, accountable, explainable, privacy-protective, and fair.

- FDA will apply considerations previously outlined in draft guidance

<sup>1</sup> 15 U.S.C. 9401(3) (also cited in FDA's Draft Guidance for Industry on Considerations for the Use of AI to Support Regulatory Decision-Making for Drugs and Biological Products):

The term "artificial intelligence" means a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations or decisions influencing real or virtual environments. Artificial intelligence systems use machine and human-based inputs to—

(A) perceive real and virtual environments;

(B) abstract such perceptions into models through analysis in an automated manner; and

(C) use model inference to formulate options for information or action.

<sup>2</sup> The NIST AI RMF is available at <https://www.nist.gov/itl/ai-risk-management-framework>.

regarding the use of AI to support regulatory decision-making.<sup>3</sup>

#### D. Industry Alignment

- Industry practices include AI governance, assurance, and risk management frameworks. FDA aims to enhance the use of AI by industry in the conduct of clinical trials in line with such practices.

#### E. Pilot Program

- The pilot will involve the recruitment of sponsors that are currently or will be pursuing early phase clinical trials through product applications submitted to the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Oncology Center of Excellence.

- The pilot will be coordinated by the Deputy Chief Medical Officer within the Office of the Commissioner.

## II. Expanded Considerations for Pilot Development

FDA seeks input on the questions below. To help FDA review comments efficiently, please identify the question to which you are responding by its associated category and number. If you are responding to more than one question, please identify each question to which you are responding, and categorize each response by question.

#### A. Pilot Program Design and Implementation

FDA seeks input on how to structure the pilot to maximize learning, feasibility, and impact:

##### 1. Scope and Focus

- Which trial types or trial issues might benefit most from the application of AI (e.g., first-in-human, oncology dose escalation, rare disease trials)?

- Should the pilot target specific therapeutic areas or remain broadly applicable?

- Should priority be given to specific AI use cases (e.g., recruitment, safety monitoring)? If so, which?

##### 2. Participant Selection

- What criteria should FDA use to select sponsors, trials, or technologies?

- How can the pilot ensure representation across organization size, capability, and therapeutic areas?

##### 3. Collaboration Models

- What partnerships (e.g., sponsor-tech vendor-academic-FDA) are most effective?

- How can FDA facilitate pre-competitive collaboration and knowledge sharing?

- What role should patient groups and investigators play in AI governance?

##### 4. Operational Structure

- What support (e.g., regulatory engagement, technical guidance) should FDA provide?

- What infrastructure is needed (e.g., secure data environments, shared tools)?

- How can the pilot accommodate varying levels of AI maturity across participants?

##### 5. Timeline and Milestones

- What is an appropriate duration for the pilot?

- What interim milestones or checkpoints should be included (e.g., enrollment, safety review, interim analyses)?

- How should FDA balance rapid insights with rigorous evaluation?

##### 6. Knowledge Sharing

- How should lessons learned be captured and disseminated?

- What mechanisms can promote transparency while protecting proprietary information?

#### B. Evaluation Metrics and Success Criteria

FDA seeks input on appropriate metrics and approaches to evaluate the pilot program, including:

##### 1. Trial Efficiency and Speed

- How should improvements in trial efficiency be measured (e.g., time to initiation, enrollment, or completion)?

- What metrics should be used to assess reductions in time from Phase 1 completion to Phase 2 initiation?

- How can improvements in participant screening, recruitment efficiency, and participant retention be quantified?

##### 2. Decision Quality

- How can the quality and timeliness of go/no-go decisions be evaluated (both FDA regulatory decisions and sponsor-internal decision points)?

- What methods can assess concordance between AI-supported and traditional decision-making?

- How should reductions in late-stage trial failures attributable to improved early-phase decisions be measured?

##### 3. Participant Safety and Data Integrity

- What metrics should be used to evaluate the detection and response time for safety signals?

- How should the impact of AI on adverse event rates or protocol deviations be assessed?

- What measures can assess improvements in data completeness, accuracy, and consistency?

##### 4. AI System Performance

- What metrics are most appropriate for evaluating AI model accuracy, robustness, and generalizability?

- How should AI system stability over time be measured, including detection and mitigation of model drift?

- How can performance be evaluated across different patient populations, trial sites, and therapeutic areas?

##### 5. Trustworthiness (Aligned With NIST AI RMF)

- What evidence should demonstrate that AI systems are valid and reliable in clinical trial contexts?

- How should safety and risk mitigation associated with AI systems be evaluated?

- What metrics can assess transparency and explainability for different stakeholders, and are there metrics available that would be applicable to both sponsor-developed and proprietary systems?

- How should privacy protections and data governance practices be evaluated?

- What approaches should be used to assess fairness across demographic and clinical subgroups?

##### 6. Comparative Evaluation

- What comparators are most appropriate (e.g., historical controls, concurrent non-AI trials, simulation studies)?

- How should differences in trial design, complexity, or therapeutic area be accounted for in comparisons?

##### 7. Qualitative Outcomes

- How can stakeholder trust in AI-enabled trial approaches be assessed (e.g., investigators, participants, regulators)?

- What methods can evaluate usability and integration into clinical workflows?

- How should perceived value, scalability, and operational feasibility be measured?

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2026-08281 Filed 4-28-26; 11:15 am]

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<sup>3</sup> Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-use-artificial-intelligence-support-regulatory-decision-making-drug-and-biological>.