information to freeze and seize financial assets more quickly and efficiently.

On December 19, 2025, ACF published a notice in the **Federal Register** Volume 90, Number 242, Page 59525 to announce that the Office of Child Support Services (OCSS) is now the Office of Child Support Enforcement (OCSE). Any reference to OCSS is changed to OCSE in the collection materials. Further, OCSE revised the MSFIDM handbook to include additional guidance for connectivity, testing, and production. The FAST Levy specifications also underwent other revisions to remove obsolete text and to clarify file name requirements.

Respondents: MSFIs and State CSAs.

Annual Burden Estimates

The burden estimates were updated to reflect current estimates for the respondents and responses over the next 3 years. The burden reduction is attributable to a reduction in the estimated number of financial institutions electing to join FAST Levy because they use programming on their end and not a transmitter to send their files. Over the last 3 years, only one financial institution has joined FAST Levy; therefore, we changed the projection from 2 to 1 for each year. Also, the number of financial transmitters using the Child Support Portal decreased from 263 to 160. Many of the transmitters switched to an automated process through Secure File Transfer Protocol while others no longer transmit at all. The prior burden was 5,029.3 hours, the current burden is 3,384.1 hours, and this amounts to a burden reduction of 1,645.2 hours, or 32.71 percent.

Information collection instrument	Total annual number of respondents	Total annual number of responses per respondent	Average annual burden hours per response	Total annual burden hours
Financial Data Match Record Specifications Match File Upload/Download: Portal Users	160	4	0.083	53.12
Election Form	10	1	0.5	5.00
FAST-Levy Response Withhold Record Specifications: Financial Institutions	1	1	1,716	1,716.00
FAST-Levy Request Withhold Record Specifications: State Child Support Agencies	1	1	1,610	1,610.0

Estimated Total Annual Burden Hours: 3,384.12.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 652(l); 42 U.S.C. 666(a)(2) and (c)(1)(G)(ii); 42 U.S.C. 666(a)(17)(A); 42 U.S.C. 652(a)(7); and 45 CFR 303.7(a)(5).

Samantha L. Illangasekare,

ACF/OPRE Certifying Officer.

[FR Doc. 2026–18841 Filed 9–14–26; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–10165]

Statistical Considerations for the Design of Rare Disease Clinical Investigations; Establishment of a Public Docket; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for information and comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is establishing a public docket to collect feedback on statistical considerations for rare disease clinical investigations. This docket is open in conjunction with a Rare disease Innovation, Science, and Exploration (RISE) Workshop on the same topic. Feedback is welcome both on the attached pre-read documents and on the content covered in the Workshop itself.

DATES: Either electronic or written comments on the notice must be submitted by November 13, 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 November 13, 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–10165 for ''Statistical Considerations for the Design of Rare Disease Clinical Investigations; Establishment of a Public Docket; Request for Information and Comments.'' 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: Philipa Friedman, Rare Disease Innovation Hub, *rdinnovationhub@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The RISE Workshop series, co-convened by the FDA Rare Disease Innovation Hub and the Duke Margolis Institute for Health Policy, brings together innovators in drug development, rare disease research, patient advocacy, and regulatory science to discuss challenges in the development of medical products for rare diseases that are common to multiple rare diseases or a class of diseases and for which evolving science offers innovative solutions. The workshops focus on cross-cutting or common issues and do not cover specific products under review by the Agency.

The September 29, 2026, RISE Workshop focuses on statistical considerations for rare disease clinical investigations. Statistical considerations affect numerous aspects of drug development, testing, and review, including clinical trial design and measurement of product effectiveness. Statistical review for rare disease products can be particularly complex, and it requires significant attention to the nuance of the disease state and specific product. Small patient populations constrain sample sizes, limit statistical power, and increase the risk of inconclusive results, yet the urgency of patient need makes timely, reliable evidence critically important. Every clinical investigation design decision involves trade-offs between efficiency and reliability, as well as feasibility and rigor. Meeting this challenge requires both scientific innovation and a shared commitment to transparency about those trade-offs.

II. Issues for Consideration and Request for Information

FDA is seeking feedback from the public—including rare disease medical product developers, disease advocates, and researchers—on the appropriate use of tailored approaches to statistical review of rare disease medical products. FDA has developed two pre-read documents that inform the September 29, 2026, RISE Workshop; one document discusses statistical considerations for clinical trials of rare disease drugs and biologics, and the other document covers statistical considerations for clinical studies of rare disease medical devices. FDA welcomes feedback on either or both of the pre-read documents, as well as feedback related to the content discussed in the RISE Workshop itself.

The pre-read documents are attached in their entirety, and FDA is specifically seeking information that addresses the following discussion questions from the pre-read documents:

For Drugs and Biologics

1. To what extent should we consider adjusting standard success criteria (*e.g.,* significance thresholds) in a rare disease trial and how should disease severity, feasibility constraints, and the availability of corroborating evidence factor into that decision?

2. What would make randomized designs more acceptable and feasible to patients and sponsors in rare disease settings and what role can enhanced medical care for participants in the control arm, patient engagement, and innovative design features play in addressing the concerns of patients and advocacy communities? Examples may include:

a. Ensuring that participants on the control arm always receive treatment and care that meets or exceeds the standard of care they would receive in clinical practice if they did not participate in the study.

b. Incorporating sequential analyses to ensure that the study stops as soon as possible if there is convincing evidence of efficacy or continues if results are promising but not yet sufficient to inform reliable conclusions.

3. Endpoint selection in rare diseases involves balancing what matters most to patients, what is statistically feasible, and what regulators can accept as evidence of benefit. Where does the rare disease and statistical community see the greatest unmet need in this space—and what would most help move the field toward endpoints that are both meaningful to patients and credible to regulators?

4. Which efficiency-enhancing strategies offer the most feasible and meaningful gains in rare disease studies—and what practical barriers currently stand in the way of their wider adoption?

For Medical Devices

1. For new Class III devices for small patient populations, what are important considerations for the premarket-postmarket data shift specific to products serving small populations?

What mechanisms (*e.g.,* registries, electronic health records, post-approval studies) would best support timely, reliable postmarket data collection? *(Note: the pre-read document uses brain-computer interface (BCI) devices for amyotrophic lateral sclerosis (ALS) as a case example.)*

2. Under what clinical situations and statistical conditions can a single-arm device study with a performance goal or external control provide acceptable evidence of reasonable assurance of safety and effectiveness for devices for small patient populations—and what pre-specifications are needed to ensure such designs provide reliable and acceptable evidence? *(Note: the pre-read document uses BCI devices for ALS as a case example.)*

3. What design features would make an external data source appropriate for future pivotal studies in small populations? What infrastructure should be built proactively and by whom? *(Note: the pre-read document uses BCI devices for ALS as a case example.)*

4. What sources of prior information—feasibility studies, natural history data, international experience, prior device generations—are most appropriate and credible in small patient populations, and can hierarchical borrowing and Bayesian adaptive designs meaningfully improve efficiency and accelerate reliable evidence generation in this space?

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–18805 Filed 9–14–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, Optimization of the Health Services Workforce, October 08, 2026, 09:00 a.m. to October 09, 2026, 06:00 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on September 08, 2026, 91 FR 57156, Doc. No. 2026–18193.

This meeting is being amended to change the meeting from a 2-day to a 1-day meeting on October 8, 2026. The meeting is closed to the public.

Dated: September 11, 2026.

Rosalind M. Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–18874 Filed 9–14–26; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Oncology 2—Translational Clinical Integrated Review Group, Translational Immuno-oncology Study Section, October 15, 2026, 09:00 a.m. to October 16, 2026, 06:30 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on September 01, 2026, 91 FR 56151, Doc. No. 2026–17896.

This meeting is being amended to change the meeting from a 2-day to a 1-day meeting on October 15, 2026. And the start time to change from 9 a.m. to 8:30 a.m. The meeting is closed to the public.

Dated: September 10, 2026.

Rosalind M. Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–18825 Filed 9–14–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Engineered Cell Therapies for the Treatment of HPV 16 E6-Expressing Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the patents and patent applications listed in the **SUPPLEMENTARY INFORMATION** section of this notice to MedGene Therapeutics, Inc. (''MedGene''), a company located in Silver Spring, Maryland, the United States of America.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before September 30, 2026 will be considered.

ADDRESSES: Inquiries and comments relating to the contemplated Exclusive Patent License should be directed to: Andrew Burke, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240) 276–5484; Email: *burkear@mail.nih.gov.*

SUPPLEMENTARY INFORMATION:

INTELLECTUAL PROPERTY

Reference No. (with country code)	Application No.	File date	Patent No.	Issue date
E–495–2013–0–US–01	61/846,167	7/15/2013		
E–495–2013–0–PCT–02	PCT/US2014/046480	7/14/2014		
E–495–2013–0–JP–07	2016–527006	1/15/2016	6628719	12/13/2019
E–495–2013–0–US–08	14/905,108	1/14/2016	9,822,162	11/21/2017
E–495–2013–0–US–09	15/786,966	10/18/2017	10,329,339	6/25/2019
E–495–2013–0–US–11	16/408,939	5/10/2019	10,913,785	2/9/2021
E–495–2013–0–JP–19	2019–219105	12/3/2019	6959970	10/12/2021
E–495–2013–0–US–22	17/142,486	1/6/2021	11,697,676	7/11/2023
E–495–2013–0–JP–23	2021–166407	10/8/2021	7223822	2/8/2023
E–495–2013–0–US–02	18/323,493	5/25/2023	12,187,779	1/7/2025