

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services**

[Document Identifier: CMS-10545]

**Agency Information Collection Activities: Submission for OMB Review; Comment Request****AGENCY:** Centers for Medicare & Medicaid Services, HHS.**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by September 12, 2018.

**ADDRESSES:** When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 *OR*, Email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786-1326.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

**Information Collection**

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Outcome and Assessment Information Set (OASIS) OASIS-C2/ICD-10; *Use:* This request is for OMB approval to modify the Outcome and Assessment Information Set (OASIS) that home health agencies (HHAs) are required to collect in order to participate in the Medicare program. CMS is seeking OMB approval for the proposed revised OASIS item set, referred to hereafter as OASIS-D, scheduled for implementation on January 1, 2019. The OASIS D is being modified to: include changes pursuant to the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act); accommodate data element removals to reduce burden; and improve formatting throughout the document. *Form Number:* CMS-10545 (OMB control number: 0938-1279); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 12,149; *Total Annual Responses:* 18,161,942; *Total Annual Hours:* 9,943,140. (For policy questions

regarding this collection contact Joan Proctor at 410-786-0949).

Dated: August 8, 2018.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2018-17302 Filed 8-10-18; 8:45 am]

BILLING CODE 4120-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2018-D-2777]

**Expansion Cohorts: Use in First-In-Human Clinical Trials To Expedite Development of Oncology Drugs and Biologics; Draft Guidance for Industry; Availability**

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics." The purpose of this draft guidance is to provide advice to sponsors regarding the design and conduct of first-in-human (FIH) clinical trials intended to efficiently expedite the clinical development of cancer drugs, including biological products, through multiple expansion cohort study designs.

**DATES:** Submit either electronic or written comments on the draft guidance by October 12, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

*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-2018-D-2777 for "Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics." Received comments 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.

- **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.gpo.gov/fdsys/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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002, or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Lee Pai-Scherf, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2314, Silver Spring, MD 20993-0002, 301-796-3400; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for industry entitled "Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics." The purpose of this draft guidance is to provide advice to sponsors regarding the design and conduct of FIH clinical trials intended to efficiently expedite the clinical

development of cancer drugs, including biological products, through multiple expansion cohort study designs. These are study designs that employ multiple, concurrently accruing, patient cohorts, where individual cohorts assess different aspects of the safety, pharmacokinetics, and anti-tumor activity of the drug. This guidance provides FDA's current thinking regarding: (1) Characteristics of drug products best suited for consideration for development under a multiple expansion cohort study; (2) information to include in investigational new drug application submissions to justify the design of individual expansion cohorts; (3) when to interact with FDA on planning and conduct of multiple expansion cohort studies; and (4) safeguards to protect patients enrolled in FIH expansion cohort studies.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

##### **II. Paperwork Reduction Act of 1995**

This draft guidance refers to previously approved collections of information found in FDA regulations. 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. 3501-3520). The collections of information in the draft guidance have been approved under 21 CFR part 312 at OMB control number 0910-0014; the guidance for industry entitled "Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products" under OMB control number 0910-0429 is available at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM590547.pdf>; the guidance for clinical trial sponsors entitled "Establishment and Operation of Clinical Trial Data Monitoring" under OMB control number 0910-0581 is available at <https://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm127073.pdf>; the guidance for industry entitled "Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring"

under OMB control number 0910–0733 is available at <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm269919.pdf>; 21 CFR parts 50 and 56 under OMB control number 0910–0755; the guidance for industry entitled “Expedited Programs for Serious Conditions—Drugs and Biologics” under OMB control number 0910–0765 is available at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358301.pdf>; and the ICH guidance for industry entitled “E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)” under OMB control number 0910–0843 is available at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM464506.pdf>.

### III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, or <https://www.regulations.gov>.

Dated: August 8, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–17273 Filed 8–10–18; 8:45 am]

BILLING CODE 4164–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2018–N–2455]

#### Patient-Focused Drug Development Guidance: Methods To Identify What is Important to Patients and Select, Develop, or Modify Fit-for-Purpose Clinical Outcome Assessments; Public Workshop; Request for Comments

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

**ACTION:** Notice of public workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a 2-day public workshop to convene a discussion on methodological approaches that may be used to identify what is most important to patients and caregivers with respect to burden of disease, burden of treatment, and the benefits and risks in the management of the patient’s disease, and best practices for selecting, developing, or modifying

fit-for-purpose clinical outcome assessments (COAs) to measure the patient experience in clinical trials. This workshop will inform development of patient-focused drug development guidance as required by the 21st Century Cures Act (Cures Act) and as part of commitments made by FDA under the sixth authorization of the Prescription Drug User Fee Act (PDUFA VI). FDA will publish discussion documents approximately 1 month before the workshop date. FDA is interested in seeking information and comments on the approaches proposed in the discussion documents. FDA is also interested in input on examples, which could be illustrated in the draft guidance, where the approaches proposed in the discussion document have been successfully applied.

**DATES:** The public workshop will be held on October 15 and 16, 2018, from 9 a.m. to 5 p.m. Submit either electronic or written comments on this public workshop by December 14, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public workshop will be held at FDA’s White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>. Workshop updates, agenda, and discussion documents will be made available at: <https://www.fda.gov/Drugs/NewsEvents/ucm607276.htm> prior to the workshop.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 14, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of December 14, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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–2018–N–2455 for “Patient-Focused Drug Development Guidance: Methods to Identify What is Important to Patients and Select, Develop or Modify Fit-for-Purpose Clinical Outcome Assessments; Public Workshop; Request for 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.

- **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