must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: December 18, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–28244 Filed 12–21–23; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2021–D–1128]**

### Digital Health Technologies for Remote Data Acquisition in Clinical Investigations; Guidance for Industry, Investigators, and Other Stakeholders; 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 final guidance for industry, investigators, and other stakeholders entitled ''Digital Health Technologies for Remote Data Acquisition in Clinical Investigations.'' This guidance provides recommendations on the use of digital health technologies (DHTs) to acquire data remotely from participants in clinical investigations that evaluate medical products. DHTs for remote data acquisition in clinical investigations can include hardware and/or software to perform one or more functions. Use of DHTs as recommended in this guidance may improve the efficiency of clinical trials for sponsors, investigators, and other stakeholders and may increase the opportunities for individuals to participate in research and make participation more convenient. This guidance finalizes the draft guidance of the same title issued on December 23, 2021.

**DATES:** The announcement of the guidance is published in the **Federal Register** on December 22, 2023.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances 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–2021–D–1128 for ''Digital Health Technologies for Remote Data Acquisition in Clinical Investigations.'' 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, 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.

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

Submit written requests for single copies of this 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; the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, 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 guidance document.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Kunkoski, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3332, Silver Spring, MD 20993–0002, 301–796–6439, *Elizabeth.Kunkoski@fda.hhs.gov;* James Myers, 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, *James.Myers@fda.hhs.gov;* Matthew Diamond, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5540, Silver Spring, MD 20993–0002, 301–796–5386, *Matthew.Diamond@fda.hhs.gov;* or Paul Kluetz, Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2223, Silver Spring, MD 20993, 301–796–9567, *Paul.Kluetz@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a guidance for industry entitled ''Digital Health Technologies for Remote Data Acquisition in Clinical Investigations.'' This guidance addresses requirements set forth in section 3607(a) of the Food and Drug Omnibus Reform Act of 2022 (FDORA) and meets a Prescription Drug User Fee Act (PDUFA) Reauthorization Performance Goal to finalize guidance on DHTs (section IV.C.5.b of the PDUFA VII commitment letter).[1] This guidance provides recommendations for ensuring that a DHT is fit-for-purpose (*i.e.,* that the level of validation associated with the DHT is sufficient to support its use, including the interpretability of its data in the clinical investigation), which involves considerations of both the DHT's form (*i.e.,* design) and function(s) (*i.e.,* distinct purpose within an investigation). DHTs may rely on or work with other technologies, such as general-purpose computing platforms (*e.g.,* smartphones) and communication networks, for remote data acquisition in a clinical investigation. Compared to intermittent trial visits, the use of DHTs to remotely collect data from trial participants may allow for continuous or more-frequent data collection. This may provide a broader picture of how participants feel or function in their daily lives. DHTs provide opportunities to record data directly from trial participants (*e.g.,* biomarkers, performance of activities of daily living, sleep, vital signs) wherever the participants may be (*e.g.,* home, school, work, outdoors). The data collection may involve passive monitoring by the DHT or the acquisition of data while participants are actively interacting with the DHT.

This guidance outlines recommendations intended to facilitate the use of DHTs in a clinical investigation as appropriate for the evaluation of medical products. The guidance provides recommendations on, among other things: (1) selection of DHTs that are suitable for use in clinical investigations; (2) the description of DHTs in regulatory submissions; (3) verification and validation of DHTs for use in clinical investigations; (4) use of DHTs to collect data for trial endpoints; (5) identification and management of risks associated with the use of DHTs during clinical investigations; (6) retention and protection of data collected by DHTs; and (7) the roles of sponsors and investigators related to the use of DHTs in clinical investigations.

This guidance finalizes the draft guidance of the same title issued on December 23, 2021 (86 FR 72981). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include clarification regarding the meaning of DHT function(s) for the purposes of the guidance; further explanation of regulatory considerations for DHTs that meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act; clarification regarding the use of participants' own DHTs or other technologies in clinical investigations; inclusion of references to Form FDA 1571 and Form FDA 356h for tracking submissions that include DHT data; revisions to the verification, validation and usability evaluations section; clarification on DHT record protection and retention; clarification on the sponsor and investigator's roles; and further recommendations on handling DHT updates and other changes during clinical investigations. In addition, editorial changes were made to improve clarity.

Section 3607(a) of FDORA requires FDA to, within 1 year of enactment, issue or revise draft guidance regarding the appropriate use of DHTs in clinical trials. This provision of FDORA further requires that, not later than 18 months after the end of the public comment period on the draft guidance, FDA must issue a revised draft guidance or final guidance. This guidance revises and finalizes a draft guidance on use of DHTs in clinical trials issued December 23, 2021. Most of the content required to be included in guidance under FDORA section 3607(a) was included in the draft version of this guidance that was open to public comment and such comments were considered in finalizing this guidance. The few additions to address the remaining FDORA section 3607(a) content requirements are minor. As noted above, you may submit comments on a guidance at any time. As with any guidance, FDA will consider comments received and issue any further revisions that we determine to be appropriate, consistent with 21 CFR 10.115. To ensure that the Agency considers your comments in determining if any further revisions to this guidance are appropriate, submit your comments by February 20, 2024.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Digital Health Technologies for Remote Data Acquisition in Clinical Investigations.'' 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.

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 11 have been approved under OMB control number 0910–0303; the collections of information in 21 CFR part 312, including submissions under subpart E, and 21 CFR 312.41, 312.57, 312.58, 312.62, and 312.120 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; the collections of information under 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information under 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231; the collections of information under 21 CFR part 814, subpart H, have been approved under OMB control number 0910–0332; the

[1] PDUFA VII: Fiscal Years 2023–2027 | FDA available at *https://www.fda.gov/media/151712/download?attachment.*

collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information for the De Novo Classification Process (Evaluation of Automatic Class III Designation) have been approved under OMB control number 0910–0844; and the collections of information in the guidance document entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' have been approved under OMB control number 0910–0756. The collections of information in 21 CFR part 314 (Applications for FDA Approval to Market a New Drug) and 21 CFR part 601 (General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension) have been approved under OMB control numbers 0910–0001 and 0910–0338, respectively. The collections of information in 21 CFR parts 50 and 56 (Protection of Human Subjects: Informed Consent; Institutional Review Boards) have been approved under OMB control number 0910–0130.

## III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 18, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–28262 Filed 12–21–23; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2021–D–1146]**

### Real-World Data: Assessing Registries To Support Regulatory Decision-Making for Drug and Biological Products; 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 final guidance for industry entitled ''Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products.'' This guidance provides considerations for sponsors proposing to design a registry or to use an existing registry to support regulatory decision-making about a drug's effectiveness or safety. FDA is issuing this guidance as part of its Real-World Evidence (RWE) Program and to satisfy, in part, the mandate under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to issue guidance on the use of RWE in regulatory decision-making. This guidance finalizes the draft guidance of the same title issued on November 30, 2021.

**DATES:** The announcement of the guidance is published in the **Federal Register** on December 22, 2023.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances 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–2021–D–1146 for ''Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products.'' 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, 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