



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3579]

Using Technologies and Innovative Methods to Conduct Food and Drug Administration-Regulated Clinical Investigations of Investigational Drugs; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the establishment of a public docket to solicit input from a broad group of stakeholders on the scope and direction of the use of technologies and innovative methods in the conduct of clinical investigations. Specifically, FDA seeks information to understand individual and industry experiences with the use of such technologies to more efficiently conduct clinical research. FDA also seeks stakeholder perspectives on possible barriers to implementing these technologies and methods to conduct clinical investigations.

DATES: Submit electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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-2015-N-3579 for "Using Technologies and Innovative Methods to Conduct FDA-Regulated Clinical Investigations of Investigational Drugs." Please identify the specific question or issue that the comment addresses. Received comments will be placed in the docket and, except for those

submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management 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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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 docket, see 80 FR 56469, September 18, 2015, or access the information at:
<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Nicole Silva, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3341, Silver Spring, MD 20993-0002, 301-796-3419; Aaliyah K. Eaves, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002, 301-796-2948; 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

Clinical investigations that ensure the protection of the rights, safety, and welfare of trial participants and that yield reliable data are critical to FDA's mission to ensure that medical products are safe and effective. The clinical trial enterprise continues to evolve and become more complex, and the scientific and infrastructure challenges of conducting clinical investigations affect the cost and timeliness of medical product development. Challenges in recruiting and retaining sufficient numbers of trial participants to conduct an adequately powered investigation in a reasonable amount of time may contribute to the cost and complexity. Creative uses of technology in conducting clinical investigations have emerged over the previous decade and include advances that have the potential to improve recruitment, participation, and retention of trial participants. New technology and communication infrastructure allow for collection of data and communication wherever the trial participant is located, including at his or her health care provider's location, creating opportunities to overcome geographical and logistical barriers

that otherwise might prevent a potential trial participant from participating in a clinical investigation, as well as facilitating the integration of research with clinical care. In addition to potential convenience for the trial participant, these tools and technologies may present sponsors with the opportunity to capture data more frequently and efficiently than would be feasible if data collection were only conducted when the trial participant visited the study site. This may enhance the sponsor's ability to understand the safety and effectiveness of drugs, biologics, and medical devices; increase additional meaningful data gathering; minimize missing data; and maximize trial participation and retention.

Some of these technologies and methods may be used regardless of the trial participant's location and may include, for example, mobile health technology, telemedicine, and remote sensors. Use of these technologies and methods allows for more flexibility for the sponsor and clinical investigator in the oversight of clinical investigation conduct, data collection, and monitoring of trial participants and clinical sites. Other elements that may be incorporated into clinical investigations to improve trial participant recruitment include online/Web-based eligibility screening, informed consent, and communication between investigators and participants.

II. Purpose of the Docket

FDA is soliciting public input from a broad group of stakeholders regarding technologies and innovative methods for using technology to more efficiently conduct clinical research. FDA is interested in identifying new opportunities to study medical products, as well as receiving comments on barriers, challenges, and relevant considerations that may affect a medical product clinical investigation that uses these technologies and methods.

III. Issues for Comment

In addition to the general information requests in section II of this document, FDA is interested in obtaining information and public comment on the following specific issues:

1. What technologies, communication infrastructure, or innovative methods are being used to conduct clinical investigations? FDA is aware of several groups conducting and interested in conducting clinical investigations using mobile technology and remote methods for data collection. FDA requests feedback on experiences with implementing such methods or models (for example, lessons learned), as well as information supporting the use of any suggested technologies, methods, or models, including any characteristics that would make the technology more or less desirable for use in clinical trials.
2. What are ways FDA could encourage adoption of these technologies and innovative methods in the conduct of clinical investigations?
3. Identify any clinical, cultural, business, regulatory, or other barriers perceived by stakeholders that serve as a disincentive to the use of technology to facilitate the conduct of clinical investigations.
 - a. What challenges do stakeholders anticipate in adoption of these technologies or methods? Are there challenges in complying with regulatory requirements surrounding the conduct of clinical investigations that use such technologies or methods?
 - b. What are the perceived barriers or challenges to obtaining and documenting informed consent or obtaining institutional review board review, approval, and oversight for clinical investigations utilizing these technologies or methods?
4. FDA is interested in obtaining information on potential trial participant acceptance, privacy, and human subject protection issues that may occur as a result of the use of

technologies and innovative methods for the conduct of clinical investigations. In particular, FDA is interested in assessing potential trial participants' interest, tolerance, concerns, and willingness to participate in clinical investigations that involve nontraditional settings or utilize new technologies. FDA is also interested in identifying the factors that affect trial participant awareness, acceptance, enrollment, and retention for these investigations.

- a. Are there specific patient groups or therapeutic areas that could particularly benefit from these types of technologies or methods?
- b. What new opportunities for the conduct of clinical investigations are created through the use of continuous or intermittent remote monitoring and data collection?
- c. What are some of the anticipated risks to trial participants that may occur as a result of the use of these technologies or off-site methods in clinical investigations?
- d. What are some of the anticipated benefits to trial participants that may occur as a result of the use of these technologies or off-site methods in clinical investigations?
- e. Are there perceived challenges to participation in clinical investigations utilizing these types of technologies or methods because of concerns regarding inadvertent disclosure of trial participants' information or breach of privacy? Are there concerns relating to the integrity of data collection or encryption or the secure transmission of information?

- f. Are there unique considerations for ensuring integrity of the source data, for example, authenticity and reliability?
- g. How should validation of participant-operated mobile devices be addressed?
- h. What are the challenges presented when data are collected using the Bring Your Own Device (BYOD) model? BYOD in clinical investigations refers to the practice of trial participants using their own devices, such as smartphones or tablets, for data collection. For example, participants in a clinical investigation may use their own computer devices to access and respond to study-related questionnaires. What are the perceived barriers to pooling data collected from different devices provided by individual trial participants, as well as pooling data from the BYOD model with data collected at the investigational site or on paper forms? How should situations such as mid-study user device switches be handled?
- i. What are the challenges or special considerations with recruiting and/or retaining potential trial participants with low levels of computer literacy or individuals who may have limited or no access to mobile technologies, computer devices, or the Internet? How can these challenges or special considerations best be addressed?

Dated: October 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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