



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 11, 312, and 812

[Docket No. FDA-2017-D-1105]

Use of Electronic Records and Electronic Signatures in Clinical Investigations Under Part 11--  
Questions and Answers; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed Rule; notification of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Use of Electronic Records and Electronic Signatures in Clinical Investigations under our regulations--Questions and Answers.” The draft guidance provides guidance to sponsors, clinical investigators, institutional review boards (IRBs), contract research organizations (CROs), and other interested parties on the use of electronic records and electronic signatures under our regulations in clinical investigations of medical products. The draft guidance expands upon recommendations in the guidance for industry entitled “Part 11, Electronic Records; Electronic Signatures--Scope and Application” issued in August 2003 (referred to as the 2003 part 11 guidance) for recommendations that pertain to FDA-regulated clinical investigations conducted under our regulations.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft

guidance 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: <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-2017-D-1105 for “Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11--Questions and Answers; Draft Guidance for Industry; Availability.” 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.

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 the 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; or the Office of the Center Director, Guidance and Policy Development, 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Cheryl Grandinetti, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3348, Silver Spring, MD 20993-0002, 301-796-2500; 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; or Irfan Khan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3563, Silver Spring, MD 20993-0002, 301-796-7100.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Use of Electronic Records and Electronic Signatures in Clinical Investigations under 21 CFR Part 11-- Questions and Answers.” The draft guidance provides guidance to sponsors, clinical investigators, IRBs, CROs, and other interested parties on the use of electronic records and electronic signatures under part 11 in clinical investigations of medical products. The draft guidance thus expands upon recommendations in the 2003 part 11 guidance for recommendations that pertain to FDA-regulated clinical investigations conducted under parts 312 and 812 and is limited to the scope and application of part 11 requirements to such clinical investigations.

Since 2003, advances in electronic technology have expanded the uses and capabilities of electronic systems in clinical investigations. In addition, electronic systems and technologies are used and managed in novel ways, services are shared or contracted between organizations in new ways, and electronic data flow between parties is more efficient and more prevalent. The standards and capabilities of electronic systems have improved, and features--such as audit trails, automated date-and-time stamps, appropriate validation, and the ability to generate copies and retain records--are standard components of many electronic systems.

FDA’s overall approach to the 2003 part 11 guidance was to provide a narrow and practical interpretation of part 11 requirements. FDA continues to support and promote such a

narrow and practical interpretation in the draft guidance, including our intent to exercise enforcement discretion regarding specific part 11 provisions for validation, audit trails, record retention, and record copying. FDA reminds sponsors, however, that records must still be maintained or submitted in accordance with the underlying predicate rules, and the Agency can take regulatory action for noncompliance with such predicate rules. In addition, FDA continues to encourage sponsors and other regulated entities to use a risk-based approach, as introduced in the 2003 part 11 guidance and further described in the draft guidance, when deciding to validate electronic systems, implement audit trails, or archive required records for clinical investigations. The draft guidance clarifies and expands upon recommendations for applying and implementing part 11 requirements, as appropriate, in the current environment of electronic systems used in clinical investigations.

The draft guidance discusses the following: (1) Procedures that may be followed to help ensure that electronic records and electronic signatures meet FDA requirements and are considered to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper, and (2) the use of a risk-based approach when deciding to validate electronic systems, implement audit trails for electronic records, and archive records that are pertinent to clinical investigations conducted under parts 312 and 812.

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 the use of electronic records and electronic signatures for FDA-regulated clinical investigations conducted under parts 312 and 812. 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 applicable statutes and regulations. This is not a significant regulatory action subject to Executive Order 12866.

## II. Paperwork Reduction Act

This draft guidance refers to previously approved collections of information that are found in 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). This draft guidance pertains to sponsors, clinical investigators, IRBs, CROs, and other interested parties who use electronic records, electronic signatures, and electronic systems in FDA-regulated clinical investigations and who send certain information to FDA or others or who keep certain records and make them available to FDA inspectors. The collections of information in part 11 have been approved under OMB control number 0910-0303; the collections of information in part 312, including §§ 312.41, 312.57, 312.58, 312.62, and 312.120, have been approved under OMB control number 0910-0014; and the collections of information in § 812.140 have been approved under OMB control number 0910-0078. The use of electronic records, electronic signatures, and electronic systems (as described in the draft guidance) would not result in any new costs, including capital costs or operating and maintenance costs because sponsors and others already have experience using computer-based equipment and software necessary to be consistent with the draft guidance.

## 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/Guidances/default.htm>,

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>, or <https://www.regulations.gov>.

Dated: June 15, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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