

From: [REDACTED]
Subject: Question Regarding ICH Guideline for GCP E6(R2)
Date: Friday, February 28, 2020 9:57:06 AM

Good morning –

Thank you for your email. Please note - it is not necessary to make certified paper copies of original electronic records if the original electronic record is available and accessible for viewing by the monitor, auditor, or FDA inspector upon request.

Certification is needed when making copies of paper or electronic documents. Certified paper copies of electronic documents, as you state in ICH E6(R2), should be generated through a validated process or verified (e.g., by a dated signature) as an exact copy having all of the same attributes and information of the original documents, including any associated metadata (e.g., units of the data, date and time stamps, data originator, and other audit trail information associated with the data). If screenshots or paper printouts of an EMR are used to serve as a paper record and that record fails to capture important metadata and audit trail information that are recorded in the electronic system, such paper records would be regarded as incomplete unless the accompanying metadata and audit trail information are included. FDA would require access to the electronic system used to produce those data to review the complete record (see 21 CFR 312.58, 312.68, 812.140, and 812.145).

So, you can see from this definition of, a source document can any record where original observations/data are recorded and/or certified copies of these original documents. For example, when using paper to record information, the source document is that piece of paper where an original observation or figure obtained from a measurement (e.g., a body temperature reading obtained from a thermometer) is recorded. The paper document can be part of a hospital medical chart where many observations/recordings about a subject are originally recorded; a sponsor-provided case report form; a form designed by the clinical testing facility; a bound notebook; or any other record that will be preserved (as the original paper or as a certified copy of the original paper).

The concept of "certified" copies or transcriptions. What this means is that a copy of the "original" record can be relied upon to meet regulatory obligations in the same manner as the original record provided the copying process has been "verified" as producing a copy that contains all of the attributes and meaning of the original document. Perhaps a useful example to consider is that of making a photocopy of the original document. If you verify through a validated process (such as visually comparing information that's present on the original document with the photocopy) that the photocopying process captured all of the attributes (e.g., ink color, stamped information) and content of the original record on the photocopy itself, you can rely on the photocopy to meet your regulatory requirements. Based on the ICH definition of source document, this photocopy would be considered equivalent to the original

record.

You apply the same concepts when using electronic records. The first recording of information on an electronic record constitutes the creation of an "original" or source document. When you then convert the source e-document to a pdf version of the record, using a process that has been proven to capture all of the source document attributes and information, (e.g., by verifying the content through a visual comparison of all of the data/information that was on the original paper record with the pdf electronic version of that record), you now have a copy that can be relied upon as if it was the "original" document.

Again, It is not necessary to maintain paper copies of the EMR if the original EMR can be accessed electronically. However, if you plan to retain and archive the paper copy of the EMR (e.g., if the original EMR is no longer accessible), then the certification process should ensure that copies of electronic originals have the same attributes and information as the original, including any associated metadata (e.g., units of the data, date and time stamps, data originator, and other audit trail information associated with the data).

Additionally, FDA does not intend to assess EHRs for compliance with part 11. For more information on this topic, please see draft guidance for industry on the use of EHR data in clinical investigations.

<https://www.fda.gov/media/97567/download> It would be helpful to you to review this guidance document.

The guidance "Computerized Systems Used in Clinical Investigations" (<https://www.fda.gov/media/70970/download>) Certified Copy: A certified copy is a copy of original information that has been verified, as indicated by a dated signature, as an exact copy having all of the same attributes and information as the original.

There is also a guidance document that mentions certified copies of source documents in several places, "Electronic Source Data in Clinical Investigations" (<https://www.fda.gov/media/85183/download>)

If I have not adequately answered your question, please consult the Center for Drugs (CDER), Office of Medical Policy (OMP) directly at CDEROMP@fda.hhs.gov as they are considered the experts on electronic records and systems in clinical trials.

Kind regards,

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U.S. Food and Drug Administration

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [REDACTED]
Sent: Thursday, February 27, 2020 3:31 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Question Regarding ICH Guideline for GCP E6(R2)

Hello,

My question pertains to section 1.63 of the ICH Guideline for GCP E6 (R2), specifically regarding the use of the term "validated process". This section defines a certified copy as a "copy of the original record that has been verified (i.e., by a dated signature **or by generation through a validated process**) to have the same information...". What would qualify as a validated process? We would like to print records kept electronically in an Electronic Medical Record system using this EMR's print function. Would the print function provided be considered a validated process, thereby ensuring that printed copies are certified copies without the need of a dated signature? Would we be the ones who would need to validate the EMR print function, or the developers of the EMR? What evidence do we need to provide that the process was validated?

Thank you so much for your clarification.

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