

From: OC GCP Questions
To: [REDACTED]
Subject: Question: Can regulatory docs be stored electronically on a local shared drive?
Date: Wednesday, October 18, 2017 9:15:27 AM
Attachments: [REDACTED]

Good morning –

FDA's current regulations and guidance documents on electronic records and signatures permit the interchangeable use of electronic and paper records for the archiving and protection of records, provided that the records are maintained in a manner such that all regulatory requirements under the primary ("predicate") rules are met (e.g., records are maintained for 2 years after the marketing application is approved, as required by 21 CFR 312.57(d), 312.62(c), 812.140(d) or other applicable regulations) and the copies of the required records preserve the content and meaning of the original records. Please refer to FDA's "Guidance for Industry Part 11, Electronic Records; Electronic Signatures- Scope and Application" (www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm126953.pdf), and FDA's "Guidance for Industry Computerized Systems Used in Clinical Investigations" (www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf)

In particular, see Guidance for Industry Part 11, Electronic Records; Electronic Signatures- Scope and Application, Section 4, "Copies of Records." I have pasted it into this e-mail for your convenience:

4. Copies of Records

The Agency intends to exercise enforcement discretion with regard to specific part 11 requirements for generating copies of records (§ 11.10 (b) and any corresponding requirement in §11.30). You should provide an investigator with reasonable and useful access to records during an inspection. All records held by you are subject to inspection in accordance with predicate rules (e.g., §§ 211.180(c), (d), and 108.35(c)(3)(ii)). We recommend that you supply copies of electronic records by:

- Producing copies of records held in common portable formats when records are maintained in these formats
- Using established automated conversion or export methods, where available, to make copies in a more common format (examples of such formats include, but are not limited to, PDF, XML, or SGML)

In each case, we recommend that the copying process used produces copies that preserve the content and meaning of the record. If you have the ability to search, sort, or trend part 11 records, copies given to the Agency should provide the same capability if it is reasonable and technically feasible. You should allow inspection, review, and copying of records in a human readable form at your site using your hardware and following your established procedures and techniques for accessing records.

E-mails documenting trial-related information and decisions about the study be preserved. Keeping a protocol-specific e-mail folder and/or burning a CD at the end of the study, converting e-mails into a PDF format, or adopting a procedure to make certified copies of the e-mails are all acceptable methods to achieve this. (FDA does not have any regulatory requirements as to the type of CD or DVD that might be used to preserve information (presumably to meet the regulatory requirements concerning clinical data/records). A company just needs to make certain that whatever media it uses does so in a manner that preserves the integrity of the original data/information.

Retention of study related e-mails at clinical sites and sponsors is also supported by FDA's official guidance, ICH E6 "Good Clinical Practice: Consolidated Guidance;" section 8.3.11 states that investigators and sponsors maintain "Relevant communications other than site visits." See: www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf.

There are no regulatory requirements for encrypting clinical trial data. What is required by the regulations is that studies have adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data, where appropriate.

It is quite understandable that, when transmitting data from one system to another (especially one outside of your system), one might want to encrypt data to make ensure confidentiality of the data. When it comes to storing data on your hard drive, it is more important that controls be in place that limit access to the data to authorized persons only. This type of control can be accomplished in ways other than through data encryption. For example, requiring that data be entered and accessed through password protected, individual user accounts is a reasonable way to address subject confidentiality issues.

When it comes to controlling access to records, I look at electronic records in the same way I do paper records when it comes to issues related to access.

It's not necessary to keep clinical trial records in "locked" file cabinets, but it is a good idea to keep records in a filing system that ensures record accountability and that the records are available to staff on as "as needed basis". Similar controls need to be used for electronic records; namely one needs to employ controls that ensure that only those people who are authorized to enter and access clinical trial data in e-records do, in fact, have access to them. Likewise, there need to be controls in place that "capture" information about who entered/accessed data, what data they entered/changed, and when they entered the data.

Kind regards,

Doreen M. Kezer, MSN
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Office of the Commissioner, FDA



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: Tuesday, October 17, 2017 2:21 PM
To: OC GCP Questions
Cc: [REDACTED]
Subject: Question: Can regulatory docs be stored electronically on a local shared drive?

To Whom It May Concern,

Would you mind providing guidance on the below good clinical practice question?

Do regulatory essential documents (e.g., protocol, investigator brochure, financial disclosures, etc.) for clinical trials stored electronically on a "local shared" drive need to be 21 CFR Part 11 compliant? From our understanding, a local shared drive does not meet the criteria for compliance with 21 CFR Part 11.

For example, an essential regulatory document would be stored electronically on the local shared drive as the “official” document (not a copy), and printed for monitors or auditors during a visit if requested. Thus, a paper record would not be maintained as the “official” document.

Thank you for your direction.

Take care,

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