From: OC GCP Questions
To: [redacted]
Subject: Disaster Recovery Question
Date: Monday, April 02, 2018 12:32:00 PM
Attachments: [redacted]

Good afternoon –

The sponsor would have to retain records and make them available for inspection for the period of time specified by the regulations. See for example, 21 CFR 312.57 and 21 CFR 312.58. This would be true whether the documents were maintained in paper for electronic format. For electronic records we have a guidance on Computers Used in Clinical Trials. Advice in the guidance concerning backup and recovery of electronic data is a follows:

Backup and recovery procedures should be clearly outlined in the SOPs and be sufficient to protect against data loss. Records should be backed up regularly in a way that would prevent a catastrophic loss and ensure the quality and integrity of the data.

Backup records should be stored at a secure location specified in the SOPs. Storage is typically offsite or in a building separate from the original records.

Backup and recovery logs should be maintained to facilitate an assessment of the nature and scope of data loss resulting from a system failure.

If you have specific questions related to a particular study, CI and sponsors may directly contact the FDA review division that is overseeing the study. If the information for a particular study is lost or destroyed , this may compromise the study data. Sometimes under unusual circumstances trial data is lost (such as through fire, flood or other natural disaster). I this situation does occur, we highly recommend that you and/or the sponsor of the study contact the assigned reviewing division(s) for further advisement.

Please see FDA's Emergency Operations Plan
https://www.fda.gov/downloads/EmergencyPreparedness/EmergencyPreparedness/UCM230973.pdf

Emergency Preparedness > Natural Disaster Preparedness and Response (Drugs)

Emergency Preparedness > Contact Information for Questions about Clinical Investigations Affected by Natural Disasters

Kind regards,

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U.S. FOOD & 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: Monday, April 02, 2018 9:23 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Disaster Recovery Question

When drafting a disaster recovery plan and implementing, what are the key items regulatory authorities (FDA, EMEA) would be seeking?