From: OC GCP Questions
To: [redacted]
Subject: GCP Question: TMF
Date: Friday, February 20, 2015 12:10:51 PM

Good afternoon –

I sent your question to FDA's BIMO Inspection Expert. Please see his response below.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

Here is my response:

FDA's inspectional approach in the BIMO Program area has not changed in regards to inspection/review of electronic records. Firms are still required to maintain source records (including electronic records) in accordance to applicable regulations. As mentioned by Mr. Briddock below " …during FDA sponsor inspections, all individual TMF documents have been requested by the inspector and provided in paper format or on an electronic medium such as a CD, or documents in electronic systems have been shown to the inspector by an expert user, but direct and independent access to the actual TMF electronic system was not required…". This inspectional approach and policy remains unchanged and its applicable to any inspection in the BIMO Program area (and any FDA inspection in general). All parties involved recognize this is very challenging given the continuous changes in technology; different study conduct and record keeping approaches; and resources and time constraints. As usual, any changes on this regard, if implemented in the future, will be communicated to the industry accordingly.

Regards,

Héctor J. Colón Torres, MPH
LCDR, US Public Health Service
CSO, BIMO Program Expert
FDA/ORA/Office of Operations
Office of Medical Products and Tobacco Operations

12420 Parlawn Drive,
Element Bldg., Rm. 2135,
Rockville, MD 20857
Tel: +1 (301) 796-3899
Fax: +1 (301) 827-4090
hector.colon@fda.hhs.gov

From: [redacted]
Sent: Thursday, February 19, 2015 2:27 PM
To: OC GCP Questions
Subject: GCP Question: TMF

Dear Sir / Madame,

I have heard recently that during an FDA GCP sponsor inspection at a major pharmaceutical company in the US, direct access was requested to the company's electronic Trial Master file (TMF), i.e. the inspectors reviewed documents electronically and independently using a laptop supplied to the inspectors.

Traditionally during FDA sponsor inspections, all individual TMF documents have been requested by the inspector and provided in paper format or on an electronic medium such as a CD, or documents in electronic systems have been shown to the inspector by an expert user, but direct and independent access to the actual TMF electronic system was not required.

Is this a new inspection approach? If so, is this process referenced in any regulation or guideline? Would issues with direct and independent accessibility be an inspection finding?

Kind regards,
[redacted]