From: OC GCP Questions
To: [redacted]
Subject: Clinical trial software qualification
Date: Friday, April 08, 2016 7:28:05 AM

Good morning --

FDA has not previously addressed servers housed in the cloud. I can offer you the following information on validation.

Part 11, Electronic Records; Electronic Signatures – Scope and Application
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf

The guidance link about represents the Agency's preliminary thoughts on the processes needed to validate software.

Briefly, as conveyed in this guidance, the Agency anticipates the need for software vendors as well as the end-users of that software to adequately validate its use in the end user's computing environment. Software developers need to: 1) establish end user needs and intended uses for the software; 2) document the software validation plan, validation procedures and validation report; and 3) dynamically test the software via such approaches as structural testing, functional testing, and modular testing.

End users can evaluate the software's structural integrity by: 1) conducting research into the program's use history; 2) evaluating the supplier's software development activities to determine its conformance to contemporary standards; and 3) performing functional testing of the software that covers all functions of the program that the end user will use.

Another guidance that may be helpful (although it is intended for software that is either regulated as a medical device, or it is used to design, develop or manufacture medical devices) is that entitled " General Principles of Software Validation; Final Guidance for Industry and FDA Staff" dated January 11, 2002. You can find this guidance at the following web address:
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085371.pdf

Other FDA guidances that are listed below may also be helpful to you.

Computerized Systems Used in Clinical Investigations -

www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf

Electronic Source Data in Clinical Investigations -

www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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Office of Good Clinical Practice
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.

-----Original Message-----
From: [redacted]
Sent: Thursday, April 07, 2016 2:33 PM
To: OC GCP Questions

Subject: Clinical trial software qualification

Hi- our company SOP requires all servers that are in house be qualified prior to use. What is requirement or guidance on qualifying servers that are cloud based? As an example, a lesion measurement tool that is validated by the company and server is housed in Amazon cloud what is FDA position if we as sponsor accepted the validation records for the tool only?

I'm hoping to get input on this prior to using the tool so your response will be much appreciated.

Thanks so much!!

[redacted]