From: OC GCP Questions
To: [redacted]
Subject: Clinical trials database question - MS Excel
Date: Tuesday, February 10, 2015 3:00:25 PM

Good afternoon –

I forwarded your email to the IT experts at the Center for Drugs (CDER). Please see their answer below.

In regards to use of excel, FDA regs do not prohibit the use of excel to collect data, provided there are robust audit trails (that can't be turned off) and restricted authentication (unique IDs and protected passwords).

Kind regards,

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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Monday, February 09, 2015 4:18 PM
To: OC GCP Questions
Subject: Clinical trials database question - MS Excel

Hello,

I'm working for a small start-up company and we have a few initial clinical trials planned which are exempt from 21CFR812. The proposed sample size is about 30 subjects each. We've received some quotes from database vendors, and they may be cost-prohibitive for us at this time. We are considering using MS Excel as a repository for our study data. We would still collect data on paper CRFs enter data into Excel on the sponsor side, using an initial entry and review process. I realize Excel is not Part 11 compliant, but it appears that this shouldn't be an issue for the initial trials we will conduct. Our ultimate goal with these studies is simply to generate some clinical data for a whitepaper or something similar.

We need to operate in the most cost-effective manner possible while following GCP for these types of studies (510k cleared device used in accordance with labeling). Is there any reason we should not use Excel as a data repository, as long as we follow a written process for managing the data? Any guidance or recommendations would be greatly appreciated.

Thanks for your help!