

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Risk based monitoring approach  
**Date:** Monday, September 21, 2015 2:14:20 PM

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Good afternoon ---

This guidance document might be helpful to you or you can contact someone in the Center for Drugs (CDER) at [CDER-OSI-GCPReferrals@fda.hhs.gov](mailto:CDER-OSI-GCPReferrals@fda.hhs.gov)

Oversight of Clinical Investigations --- A Risk-Based Approach to Monitoring  
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf>

I hope this information is helpful. Please contact us again at [gcp.questions@fda.hhs.gov](mailto:gcp.questions@fda.hhs.gov) should you have additional questions.

Kind regards,

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Senior Health Policy Analyst  
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.

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**From:** [REDACTED]  
**Sent:** Monday, September 21, 2015 10:47 AM  
**To:** OC GCP Questions  
**Subject:** Risk based monitoring approach

Hello,

My company is developing an approach to risk-based monitoring along with a software product. My clients are concerned about whether this approach would be accepted by the FDA. Who would I contact or how would I go about talking with the relevant person(s) at the agency to confirm that this approach is an appropriate approach to risk-based monitoring that the agency would accept as and when they review a submission where the monitoring and oversight were based on it?

Thanks for your help!

Regards,  
[REDACTED]