From: OC GCP Questions

To: Subject:

Clinical Study Data Standards

**Date:** Thursday, August 29, 2013 9:35:41 AM

## Good morning -

Please see the link below.

http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM261514.pdf

Kind regards,

Doreen M. Kezer, MSN 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.

**From:** [Redacted]

Sent: Thursday, August 29, 2013 9:27 AM

**To:** OC GCP Questions

**Subject:** Clinical Study Data Standardsat

To Whom It May Concern:

I am a Clinical Data Manager, and am beginning to work on [redacted] clinical trials. I am needing to access the catalogue of data standards to ensure that we are accurately creating data collection items for a study.

Please advise me on how I can "quickly" reference the catalog of data standards.

Thank you, in advance, for your help!

Kind regards,

[redacted]