

**From:** OC GCP Questions  
**To:** [REDACTED]  
**Subject:** eTMF  
**Date:** Monday, March 27, 2017 10:15:00 AM  
**Attachments:** [REDACTED]

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Good morning –

There are no restrictions on which documents are maintained electronically or signed with e-signatures, including eTMFs. While we cannot endorse any outside organization DIA is well respected.

Please see:

Part 11, Electronic Records; Electronic Signatures — Scope and Application

[www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072322.pdf](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072322.pdf)

For general information on the use of computer systems in clinical trials in FDA regulated clinical trials, please reference the following guidance:

[www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf)

Or draft e-Source Guidance:

[www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM239052.pdf](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM239052.pdf)

You may also wish to perform a web search. There is much information available on eTMFs.

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.

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**From:** [REDACTED]  
**Sent:** Sunday, March 26, 2017 8:50 PM  
**To:** OC GCP Questions  
**Subject:** eTMF

Greetings,

I am trying to determine the FDA requirements for electronic trial master files for a pharmaceutical clinical study. Is the DIA model acceptable to the FDA or is ICH E6(R2)? Can you point me in the right direction?

Regards