

Department of Health and Human Services

Food and Drug Administration

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[Docket No. 2006N-0464

Electronic Submission of Regulatory Information, and Creating an Electronic Platform
for Enhanced Information Management; Public Hearing

NOTICE OF PARTICIPATION AND REQUEST FOR ORAL PRESENTATION

REQUEST: 30 MINUTES

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DISCUSSION TOPICS

A. Electronic Submissions

1. Transition from paper submissions to electronic submissions

Currently under development is software to replace paper source documents while complying with all elements of 21 CFR Part 11. Multiple benefits will be realized such as elimination of a majority of data queries as well as direct transfer of source data to an eCRF platform without dual entry.

2. Cost

Because eSource documents would exist both at the research site and in a secure web environment, clinical monitors could view them remotely in order to verify source data in relation to eCRF data. In addition, in-house data managers could view said documents in order to clarify data questions. An additional benefit would be that some FDA inspection activities could also be done remotely if

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desired. The cost savings to the conduct of clinical trials as well as data management would be enormous. This transformation of source documents would be a natural evolution of the current electronic platforms that facilitate the transfer of data from clinical sites. The cost of implementing such a method would be minimal in comparison to the savings.

3. Implementation

This technology would be easy to implement at clinical sites because it would utilize tablet pc / digital form technology that would closely approximate the paper forms that are currently used to collect source data. In addition, because data would not have to be re-entered into paper or electronic case report forms, errors of omissions of data would be eliminated

B. Third Party Entities

1. Private third party entities can develop this technology, however partnering could speed the transition. In any case, cooperation from Pharmaceutical companies' data management would be required. The recent efforts on behalf of the CDISC e-SDI group to create data sharing standards makes adopting this technology easier.

2. A word of caution to the agency:

ADOPTION OF VALIDATION GUIDELINES NEED TO BE SUPPORTIVE OF, NOT BARRIERS TO, THE DEVELOPMENT OF THIS TECHNOLOGY. GUIDELINES NEED TO BE CLEAR SO THAT STAKEHOLDERS OF MARKETING APPLICATIONS CAN HAVE THE CONFIDENCE THAT REGULATORS WILL WELCOME PROPERLY VALIDATED SYSTEMS.