

Luce, David

To: paula.mckeever@fda.hhs.gov
Subject: Docket No. 2006N-0464 Electronic Submission of Regulatory Information, and Creating an Electronic Platform for Enhanced Information Management

Dear FDA,

The following is part of a larger initiative to reengineer our global research and development and healthcare industries to better meet the demands of aging populations, treatment performance and quality of care needs.

It is with sincere gratitude I submit this information to the many fine individuals at the agency who have always made time to work with industry and collaborate on development of open standards and shared business practices.

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

Establish a much larger globally partnered information technology infrastructure to make efficient collective R&D operations in support of our aging populations and treatment demands.

- 1) This infrastructure will be a Pharmaceutical/Academic/Healthcare R&D Multi-Grid complex that more fully leverages multicore processing to maximize virtualization, better manage redundancy, disaster recovery/business continuity expense as well as pursue the expansion of numerous self-validating interoperable services within the various trusted grids.
- 2) Promote and enforce an industry professional identity management program according to open specification by 2008. People pay for their own drivers licenses and passports. Each professional who works in these industries and grids should pay for their own identity management token/certificate so they can access needed systems from any location. Sponsors/MAHs etc. only provide oversight, service and management as needed.
- 3) Reduce all submitted Final content to two sets of electronic records that meet current and emerging electronic records archive standards (NARA ERA). One set will be for the government. The second set will be for the Sponsor/MAH to be shared with partners, investigators etc., from a central network of document repositories. If some global government agencies only want access to the electronic content, provide a link. If content needs to be changed, reviewed or approved this content remains available as a single new, current and annotated and then approved version within the centrally located repositories.
- 4) Establish a cross industry staffed group that provides application access provisioning, management and support for centralized document repositories that reduces the burden on IRBs/ECs, labs, smaller organizations and health authorities.
- 5) Establish a harmonized cross industry issue/resolution help desk report with common categorization and reporting made available to the industry members with monthly statistics by company, application or system and related business process, i.e. what were you working on when x occurred.
- 6) Support OCLC endorsed standards and vendor technologies that leverage: Dublin Core Metadata Initiative, Open Archival Information Services and Open URL
<http://www.oclc.org/community/standards/default.htm>
- 7) Expand and promote with vendors distributed computing initiatives by leveraging existing work and emerging multicore development and coding efforts.
<http://folding.stanford.edu/>
<http://www.intel.com/technology/computing/multi-core/>

Sincerely,
David M. Luce
President
CommonPractice.org
(609) 332-3199
davidluce@commonpractice.org