Feasibility of Developing a Standards-based Medical Imaging Repository

DESCRIPTION

FDA's Office of New Drugs and Office of Translational Sciences of the Center for Drug Evaluation and Research (CDER) and FDA's Office of the Chief Scientist within the Office of the Commissioner are seeking perspectives on the feasibility of developing a Standards-based Medical Imaging Repository. **CDER is requesting that interested parties, including potential collaborators, respond to this announcement by submitting a capability statement that comments on each of the numbered items in the SPECIFICATION section of this posting.** The information collected will allow FDA to gain insights into the feasibility of such a repository and gauge potential collaborator interest.

Conceivably, a collaboration under a Cooperative Research and Development Agreement (CRADA) or other agreement mechanism may result in a pilot project to assess an image repository functionality. Under the CRADA, FDA and a third party would cooperatively explore the development, establishment, and maintenance of a Standards-based Medical Imaging Repository. This effort is part of an overarching strategy to support the review of standardized information generated from clinical trials.

BACKGROUND

Clinical trial data submitted to CDER often contain the results of imaging studies performed to assess the safety or effectiveness of a new drug. Following expert interpretation, the results are documented on the case report form (CRF), and the images themselves are not typically submitted. In cases when CDER requests to see the images (e.g. to help reviewers appreciate the nature of the imaging data provided in the case report form), sponsors often provide the images using proprietary hardware and software, resulting in logistical challenges associated with viewing and maintaining the images locally.

SPECIFICATION

CDER would like to obtain information about the feasibility of a “trusted third party” hosting images and providing remote viewing capabilities to FDA review staff. Under one potential paradigm, drug sponsors might choose to “deposit” digital images and associated metadata in a third party image repository. Such images could potentially be linked to the CRF data, and CDER reviewers would then have read-only, on-demand access to:

- The digital images, upon clicking on linked information in the application, including relevant metadata describing when and how the images were acquired;
- Annotations and markups made by the image interpreter (e.g. tumor dimensions using electronic calipers); and
- The image interpretation report.

The near-term objective of this request for information is to obtain perspectives regarding the logistical feasibility of a “trusted third party” hosting an image repository that would allow sponsors to voluntarily supply images for FDA access. Conceivably, this type of repository

might facilitate CDER review staff access (e.g. using existing web technology) to digital images and metadata for improved appreciation of information within the images used in clinical studies.

FDA requests interested stakeholders to comment upon:

1. The potential for a trusted third party to host clinical trial images and provide remote viewing capabilities to FDA review staff;
2. The strengths and limitations of using a third party host for a repository, including any security concerns and how these concerns may be addressed;
3. Data standards for the image repository in order to support and facilitate access and review of images, annotations, and reports by FDA review staff;
4. Ways to maintain secure and de-identified information related to protection of information sensitive to patients and companies developing drugs;
5. Ways to establish and maintain a repository that is interoperable with other biomedical resources as they pertain to clinical trials and biomarker qualification;
6. Ways to develop or adopt templates (e.g. for header fields, case report forms, etc) and consensus terminology;
7. Mechanisms of data storage for the short-term and the long-term; and
8. The potential for short-term and long-term funding for an ongoing public - public collaboration or public – private collaboration that maximizes the value and benefit of a standards-based image repository for all interested stakeholders at minimal to no cost to FDA.

FDA respects the importance of corporate intellectual property and data security while balancing the need to document the benefits of public expenditures. Provisions relating to proprietary information and intellectual property will be set forth in the CRADA if / when a Collaborator(s) is selected.

SELECTION CRITERIA
Responses will be evaluated on their basis of:

- Logistical feasibility of hosting and storing data
- Security mechanisms
- Method of determining standard(s) for the repository
- Interoperability
- Feasibility and sustainability of proposed funding mechanism

ANNOUNCEMENT DATE(S)
Posted November 30, 2012
Closed April 30, 2013

SUBMISSION INFORMATION
All interested parties should submit a description of their capabilities, along with specifications, via email to FDA.images@fda.hhs.gov by 30 April 2013. This is a market survey only, not a pre-solicitation notice. If a formal solicitation is generated at a later date, a solicitation notice will be published. All information is to be submitted at no cost or obligation to the Government.

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