DATE: March 22, 2012
SUBJECT: Data Standards

The Problem

One of the inefficiencies in clinical trials is that data collected by different pharmaceutical companies as well as academic research sites is highly variable. The wealth of data from research holds great potential to advance scientific and regulatory work, but the lack of standardized data creates significant challenges. Variable data can impede a FDA reviewer's ability to perform integral tasks such as rapid acquisition, analysis, storage and reporting of regulatory data. Improved data quality, accessibility and predictability will give reviewers more time to carry out complex analyses, ask in-depth questions and increase review consistency. www.fda.gov/.../FormsSubmissionRequirements/ElectronicSubmissions/UCM214120.pdf -

The Solution

Data standards provide a uniform approach for collection, transfer, analysis, reporting and archiving of data. The benefits of using common data standards include improved learning and knowledge generation and a reduction in time, resources and costs. Both FDA CDER and CBER are encouraging the use of data standards by industry into an accepted format such as that created by the Clinical Data Interchange Standards Consortium (CDISC) or Health Level Seven International (HL7).
http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm
http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/ucm209137.htm

Another potential for use of standardized data is the ability to create larger databases from smaller clinical trials and increase statistical power. Collecting AD data into large databases that can be mined will enable improved clinical trial design and patient selection for research, qualification of biomarkers for use in research, and decisions on the effects of novel therapeutics. An example of how a large database built on pooled AD data can contribute to the knowledge base is the use of modeling and simulation to provide a quantitative model of AD progression as performed by the Coalition Against Major Diseases (CAMD). Indeed, opportunities afforded by AD data standards and data sharing have the potential to reduce costs of clinical trials and accelerate the translation of research into new therapies for the millions of patients and their loved ones affected by Alzheimer's Disease. Making data publically available allows more scientific investigators to perform AD research and provide new insights. A public database can increase collaboration and initiative from multi-disciplinary experts.

Medical research data on Alzheimer's patients should be collected in uniform data standards that are the same if the studies are done in San Francisco, Shanghai or Sydney.

Recommendations

AD Data Standards

Require or strongly encourage all new and ongoing federally-funded and industry-sponsored AD clinical trials to use the same AD CDISC data standards to facilitate data sharing and regulatory authority (FDA and EMA) review.

Remap data AD clinical trial data rich in biomarker data, as ADNI and ADCS, to the same common AD CDISC data standards.

Develop common data standards and measurements for questionnaires that assess cognition and functional status. Engage copyright holders of AD questionnaires to allow an additional layer to capture recording of these instruments into AD CDISC data standards.

Foster the development of standardization of methods for imaging modalities and assays of CSF analytes and establish a resource of appropriate reference samples and reference standards.

Post data from federally-funded and industry sponsored AD clinical trials and recorded in AD CDISC data standards into a common AD database (as the CAMD database) available for qualified research use. Include data from placebo and if possible, active intervention arms

Promote the use of AD data standards in clinical practice/ Electronic Health Records (EHR) to collect data seamlessly that can be aggregated and analyzed for research.