Society for Clinical Trials 31st Annual Meeting

Workshop P4
The Role of Standards: Vocabulary and Data Elements to Support Clinical Trials

Sunday, May 16, 2010
8:00 AM - 12:00 PM
Kent BC

Workshop P4

Title: The Role of Standards: Vocabulary and Data Elements to Support Clinical Trials

Precis:
This is an interactive session for attendees who have an interest in the identification and use of clinical trial variables, and in the critical role of controlled vocabulary/terminology needed to create and register data elements. Use cases taken from the National Cancer Institute (NCI) Cancer Biomedical Grid (caBIG®) Case Report Form Standardization and Harmonization initiative will be reviewed and analyzed for their ability to collect clinical data that can be aggregated and analyzed across sites and trials. The caBIG® CRF initiative has been harmonized with the CDISC data collection standard (CDASH v1.0) to produce a library of Case Report forms that can be used across NCI and industry trials. Attendees will participate in exercises that use modules of data elements to assemble CRF templates that can be extended with trial-specific variables. The products of the caBIG® CRF Initiative will be evaluated using metrics intended to measure both the success of and challenges to the implementation of standards. Attendees will also have the opportunity to compare their own CRF variables to the registry of research metadata maintained by the NCI.
Presenters:

I. Learning Objectives:

By the completion of this session, the attendee will be able to:

1. Trace the development of a consensus-based data standards initiative used to produce standards for the collection of clinical trial data
2. Discuss how the processes of harmonization and standardization can contribute to the creation of a set of community-accepted clinical trial standards
3. Identify the role of controlled vocabulary/terminology in the development of a set of clinical trial data standards
4. Analyze a set of clinical trial data collection variables for their potential to be used across organizations

II. Clinical Trial Case Report Forms

a. Background and importance to Oncology Trials
b. Content versus Format
c. Harmonization and Standardization
d. Examples of NCI caBIG® Harmonized CRF Modules
    i. Demography
    ii. Adverse Events
        1. Serious Adverse Events
    iii. Enrollment
    iv. Registration
    v. Protocol Violation
    vi. Medical History
    vii. Physical Examination

III. Semantic Analysis – Terminology

a. Use of Controlled Vocabulary
    i. NLM Semantic Types
    ii. NCI Enterprise Vocabulary Services
b. Vocabulary Candidates to support Oncology Standards
    i. NCI Thesaurus
    ii. LOINC
    iii. SNOMED
    iv. Additional Vocabularies
c. Reference Tools
    i. NCI Metathesaurus
    ii. NCI Terms Browser

IV. Semantic Construction of Variables

a. The caBIG® CRF Harmonization and Standardization Initiative
b. Review of Variables/Data Elements
c. Use of Existing Variables
    i. Semantic analysis
    ii. Oncology requirements for Variables
d. Construction of Variables using Controlled Vocabulary
e. Registration and Maintenance of Variables
f. Vetting Data Elements for Community Standardization
    i. Community review
    ii. Stakeholder Consensus-building
g. Harmonization with CDASH variables

V. Using Variables to construct Case Report Forms

a. Data entry workflow considerations
b. Use of Validation rules
c. Discrepancy Management

VI. The Business Case or 'Why is this Important to our Organization'?

a. Experience from other organizations
b. The role of the Early Adopter(s)
c. Measurement of Success using Metrics
d. Creating value for Stakeholders
    i. Impact on Data Quality
    ii. Consistency and Quality Control
    iii. Speeding Trial setup and activation
    iv. Management of Expectations

VII. Use Case Presentation: Audience Participation in the review and analysis of use cases

a. The use of Data Standards
b. Using Controlled Terminology
c. When Solutions Fail: when then?

d. The role of the Trial Sponsor
e. The bottom line: Documenting success and next steps

VIII. Audience Invitation to Contribute Use Cases
a. Review of Case by Owner and Audience
b. Analysis of Processes and Content
c. Lessons Learned
d. Measures of Success
e. Application to other Organizations

IX. Summary of Discussion and Lessons Learned

X. References and Readings

1. Komatsoulis GA, Warzel DB, Hartel FW, Shanbhag K, Chilukuri R, Fragoso G, Coronado S, Reeves DM, et al. caCORE version 3: Implementation of a model driven, service-oriented architecture for semantic interoperability. 1: J Biomed Inform. 2008 Feb; 41(1):106-23.

2. Lu Z. Technical challenges in designing post-marketing eCRFs to address clinical safety and pharmacovigilance needs. Contemp Clin Trials. 2010 Jan;31(1):108-118.

3. Nahm MM, Pieper CF, Cunningham MM. Quantifying data qualify for clinical trials using electronic data capture. PloS One. 2008 Aug 25;3(8); e3049.

4. National Cancer Advisory Board. Report of the Clinical Trials Working Group of the National Cancer Advisory Board: Restructuring the National Cancer Clinical Trials Enterprise. 2005.

5. Ohmann E, Kuckinke W. Future developments of medical informatics from the viewpoint of networked clinical research, Interoperability and integration. Methods Inf Med. 2009;48(1):45-54.

6. Papatheodorou I, Crichton C, Morris L, Mccallum P, MATABRIC Group, Davis J, Brenton JD, Caldos C. A Metadata Approach for Clinical Data Management in Translational Genomics Studies in Breast Cancer. BMC Medical Genomics. 2009, 2:66-80.

7. Reeves DM. Clinical Data Management Systems. Manual for Clinical Trials Nursing 2nd Edition, (Eds: Angela Klimaszewski, Monica Bacon, Heidi Deininger, Bertie Ford, and Joan Westendorp. Oncology Nursing Society Publishing Division, 2008, 289-292.