Nonclinical Historical Controls

Project Scope

The Nonclinical Historical Control (HC) Project is part of the of the FDA/PHUSE Computational Sciences Nonclinical Working Group. We gathered interested participants from industry, academia, and governmental organizations to identify the most promising projects related to historical control data at various levels of aggregation. With the rise of electronic nonclinical datasets, is it time to consider how we might more effectively harness decades of untreated control data? The kinds of questions were considered included:

- Is there utility in agreeing upon a format for such data for easier sharing?
- How can historical control data be harnessed to speed drug development?
- Is it possible to aggregate data at various levels and retain validity?
- Can historical controls supplement or supplant concurrent controls?

Deliverable

The Working Group drafted a survey covering various aspects of nonclinical historical control data and distributed it to a wide variety of stakeholder groups. There were 352 respondents. Results were presented in a poster at the 2014 FDA/PHUSE Computational Science Symposium in Silver Spring, Maryland. The paper describing the survey and its results has been accepted for publication.

Milestones

1. Identify established definitions of historical controls (by June 2012). This should include categorizations of common types of historical control data.
2. Gather suggestions for improvements in HC data and perceived uses/benefits of HC at different levels of aggregations (by June 2013)
3. Identify the highest priorities of these uses based on utility, feasibility, and validity (by March 2014)

Tasks

Completed

1. Identify participants and project leads
2. Gather published definitions of HC data or from other sources and relevant papers evaluating uses of HC data
3. Created an industry survey to distributed to a broad nonclinical audience through various personal and industry contact lists
4. Agreed to Instem electronic survey tools to publish survey, gather responses and analyze results
5. Agreed on survey questions, and mechanisms for surveying relevant stakeholders
6. Drafted electronic survey courtesy of Instem
7. Distribute survey and collect responses
8. Assigned participants to write White Paper sections
9. Evaluate responses according to agreed upon parameters and prioritize list
10. Draft white paper
11. Circulate white paper to WG6:HC members for comments
12. Publish in appropriate forum (Draft has been recommended for publishing)

Background

During a broad survey of needs and challenges related to nonclinical data, issues related to historical control data were a top concern of stakeholders across organizations. There is a perception that there may be additional ways to make further use of historical control data to enhance studies or submissions across industry, academia, and government.

During the working sessions of the FDA/PHUSE Computational Sciences Symposium, participants discussed options for identifying the highest priority projects in this area. There was agreement that the idea of "historical control data" had several connotations which should be clarified prior to proceeding with this project.

Goal

Develop recommendations for high priority projects regarding the use of historical control data. These recommendations could include identification of areas where additional aggregation or analysis of historical control data may be useful or identification of data standards to develop and pilot for exchange of historical data.

Deliverables

March 2014

- List of prioritized HC data projects and recommendations of next steps.