Standardizing Data within the Inspection Site Selection Process

Overview

Welcome to the FDA/PHUSE Project "Inspection Site Selection Standard Data Elements". Our Project's completed document on the gap analysis between expectations and current CDISC standards is published below. Also below you can find descriptions of various aspects of our project and activities.

Link to deliverable

Project Scope

The past two decades have witnessed a dramatic growth in the size and complexity of the clinical trials enterprise, posing challenges for FDA in maintaining its traditional inspectional approaches. These challenges include, but are not limited to: an increasing number of sites per clinical trial, an increasing number of foreign clinical trial sites, finite resources limiting the number of inspections, PDUFA timelines requiring a high level of efficiency, and variation in the current site selection methodology. To address these challenges, FDA is working to modernise and enhance the efficiency and effectiveness of its inspection processes. For example, FDA's Center for Drug Evaluation and Research (CDER) has developed and is piloting a risk-based inspection site selection tool. This tool combines data from sponsor and FDA databases to quickly analyse and assess clinical site level data contained within an application to identify clinical sites for inspection early in the review process. This need has been addressed in the published draft guidance, "Guidance for Industry: Providing Submissions in Electronic Format — Summary Level Clinical Site Data for CDER's Inspection Planning." The specific data elements were identified in a companion technical document entitled "Specifications for Preparing and Submitting Summary Level Clinical Site Data for CDER's Inspection Planning".

While some of the information detailed in the guidance may be available within an NDA or BLA, it may not be in a format that allows it to be readily repurposed into a dataset to be used for analysis in CDER's Clinical Site Selection Tool. A PHUSE project was formed in March 2012, and charged to do a detailed analysis of each of the proposed elements that have been requested by CDER. The group focused on a couple of key points:

- Providing a clear definition of each of the data elements that CDER needs to complete it's site-selection analysis. This will facilitate generation of the information by enabling sponsors to unambiguously identify the sources of the information and will support consistent interpretation across sponsor companies
- Providing an assessment of whether the requested data elements are consistent with already established clinical data standards CDISC SDTM and ADaM