Pharmacokinetic Data Submission in the CDISC Environment

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Creating Structure datasets for SDTM and ADaM

Overview

In the pharmaceutical industry, pharmacokinetic (PK) analysis plays a crucial role in understanding the behavior of drugs in the body. To ensure regulatory compliance and facilitate the submission of PK results to the FDA, the use of standard data submission frameworks is essential. CDISC (Clinical Data Interchange Standard Consortium) provides such frameworks, including SDTM (Structured Query Language for Tabular Data) and ADaM (Analysis Data Model), which are designed to standardize clinical trial data documentation.

INTRODUCTION

In the context of clinical trials, the goal is to generate electronic submission-ready analysis data (supported by data documentation) in a standardized format. This process involves the creation of SDTM and ADaM datasets, which are designed to support individual subject listings with a complete set of study data. Analysis Data Model (ADaM) standards are complemented by the SDTM dataset. This paper describes the process of creating well-formed data (SDTM and ADaM) that contain all information needed to understand study results.

METHODS

The key goal is to generate electronic submission-ready analysis data (supported by data documentation) in a standardized format. Two-step Data-driven Define.xml Creation Using Proc Template involves the following steps:

1. **Domain Level Define.xml Created by the Second Step**
   - Create a dataset that includes all the necessary metadata and variables.
   - Use theDefine.xml data document and code list.
   - Set up SAS data sets for SAS define data.

2. **Process to Create SDTM and ADaM Dataset**
   - Celerion, Inc. standard procedure to create ADaM datasets for PK analysis in clinical trials.
   - The ADaM PC dataset is created based on the SDTM structure dataset, SDTM PC dataset, and ADaM ADaM/Domain Level Define.xml. ADaM ADaM dataset supports PK parameter calculation.
   - ADaM ADaM dataset is created based on the SDTM structure dataset, SDTM PC dataset, and ADaM ADaM/Domain Level Define.xml.

RESULTS

The current process overview emphasizes how the use of input metadata files (used for his expert leadership on SDTM, ADaM, and Define.xml) and the Use of SAS define data sets for his expertise on SDTM, ADaM, and Define.xml. The second step is the production of six SAS format define data sets by mining the data for unique information. The six define data sets include six levels of study information, which include data set, analysis level, variable level, when required, data documentation, and code list. The second step is the integration of the ADaM define data into an existing framework through a custom approach driven by the input metadata file. The six SAS define data sets are structured and transferred to a general group of users and need to be defined. Below are the specifications of an example for SDTM define and ADaM.

CONCLUSIONS

The approach outlined in this paper is designed around CDISC dataset specifications and standards and can accelerate PK analysis and reporting for efficient agency review.

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