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Achieve compliance and take advantage of the CDISC standards for pharmacokinetic modeling

As many sponsors can attest, the preparation of CDISC-compliant datasets is time-consuming and costly. It is important to consider current and future data regulations when planning studies for your development program.

"At PhinC, we can help you by using a native CDISC process for PK analyses, we ensure the seamless delivery of CDISC compliant results (such as SDTM datasets) that are easily reproducible and consider all the aspects of the analysis."

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Pharmacometrician & CDISC Expert

This article, written by Michael Boily, defines CDISC, deliver its advantages and explains how PhinC can help you implementing the standards within your data. Michael is a pharmacokineticist with a special interest in data modeling as an approach for optimisation of pharmacometrics and pharmacokinetics workflows.

Gathering efficiently data for PK analysis and modeling purposes

When performing either a classical PK/PD analysis or developing a model with pharmacometrics tools, one of the first step usually involves retrieving all the relevant data from one or multiple clinical studies. Historically, recovering and merging the appropriate information from an increasingly large amount of data collected during clinical studies and further tabulating analyses results, involved a laborious process often leading to uneven results from study-to-study (think multiple vendors, scientists and companies all using different standards). Today, using **universal standards**, such as CDISC standards, to tabulate, analyse and exchange study data between vendors/authorities has become a key element in the drug development process.

CDISC for PK and pharmacometrics

From its first meetings in the late 90's, the CDISC consortium (Clinical Data Interchange Standards Consortium)- a panel of experts from small to large pharmaceutical compagnies and FDA observers- has developed and continuously improved a set of such standards. This includes SDTM (Study Data Tabulation Model), a data model/standard now required by the FDA for regulatory submissions (i.e. INDs, ANDAs). SDTM is separated in various domains, each representing a specific type of data.
The PC domain, containing PK concentrations, and the PP domain, containing PK parameters data calculated by PK scientists, are two examples of key SDTM domains for PK analyses and pharmacometrics.
At PhinC, we understand that using CDISC standards, while representing additional cost, can be used to the sponsor's advantage by:

1. Standardizing analysis and reporting of data
2. Facilitating pooling of data for future analyses such as PK population modeling
3. Facilitating study data review by regulators
4. Improving transferability of study results (including PK)

Implementing PK CDISC standards

The main challenge is first to efficiently coordinate with all stakeholders in the CDISC process: data management, bioanalysis and regulatory submission.
While preparing, those PK domains may appear quite simple at first. Indeed, the CDISC implementation guides, such as the SDTMig, offer all the specifications and a great variety of examples. However, our experience have shown that complex PK studies often present particular challenges to clinical programmers and CDISC vendors. It is, for instance, important to ensure correct allocation of reference timepoint for PK samples collected in a study in relation with study design and PK endpoints. **Therefore, we always suggest involving experienced PK scientists early in the process, to ensure good communications between players and to avoid having the different teams working in isolation (in silos).**

How PhinC can help?

- By involving pharmacometricians and PK experts in the process of data transfers, as well as analysis dataset creation (processes typically reserved to data managers and clinical programmers). PhinC ensures that transferred data comprise all the essential elements required for performing analyses/modeling. This reduces delays after analysis start by reducing back and forth and increases the compliance to CDISC standards. For instance, we have observed that very few CDISC/data management teams process the internal resources to ensure delivery of high-quality PK datasets in CDISC format, particularly for complex PK studies.
- By using a native CDISC process for PK analyses, we ensure the seamless delivery of CDISC compliant results (such as SDTM datasets) that are easily reproducible and consider all the aspects of the analysis (e.g. reasons why some PK parameters are not calculable, flags, populations). Both the source (bioanalysis) data and the analysis results (pharmacokinetics) are generated directly in CDISC format as opposed to the alternative approach of retroactively converting data to a CDISC format (mapping), a process which is prone to errors and may reduce the reusability value of the PK results.

CONTACT

Let's talk about how we can help you in your drug development research