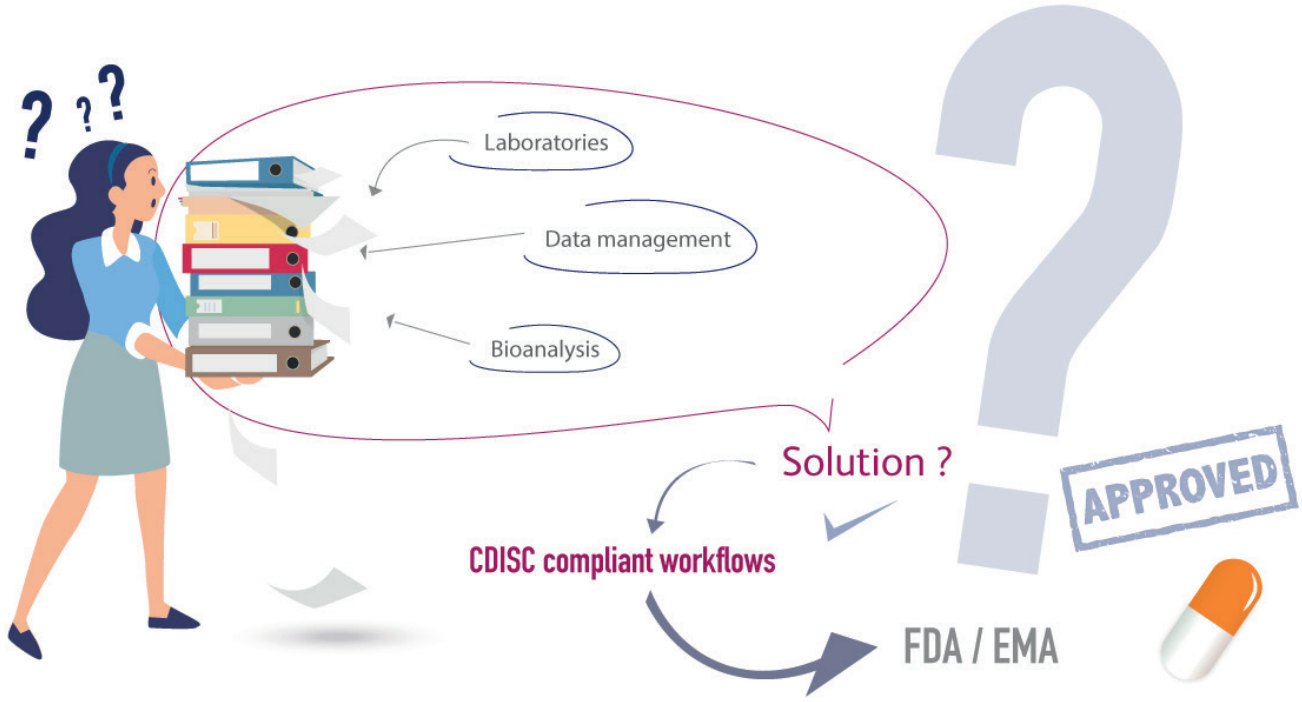

At PhinC Development, we help you identify, mitigate and overcome all the challenges you may face during your drug development process

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.

The main challenge is first to efficiently coordinate with all stakeholders in the CDISC process: data management, bioanalysis and regulatory submission.

Hence, 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).

PhinC Development

ACHIEVE COMPLIANCE AND TAKE ADVANTAGE OF THE CDISC STANDARDS FOR PHARMACOKINETIC MODELING

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.

1 CDASH
Data aquisition

Raw data

- Lab
- eCRF
- BA Lab

2 SDTM/ SEND
Data Tabulation

LB (Laboratory)	EX (Dose)	DM (Demographics)	PC (PK Concentrations)
Item 1 Item 2 Item 3 ...	Dose Dose time ...	Weight Arm Age ...	Concentration Collection Time Analyte ...

3 ADaM:
Analysis-ready dataset

ADEG (ECGs)	ADPC (PK Concentrations)	ADPP (PK Parameters)	ADSL (Subject Level)
Item 1 Item 2 Item 3 ...	Actual time Treatment Dose	PK parameter Treatment Dose	Demographics Periods

4 Analyses

PK Analyses

ECG Analyses

5 TFLs/ Reporting

Tables, figures & listings

Report

Regulatory submission

CONTACT US TODAY TO GET A QUALIFICATION APPOINTMENT

Immeuble Le Classéa
36 rue Victor Basch
91300 Massy
France

+33 1 76 91 24 60

contact@phinc.fr

Follow us on social media:

PhinC Development