

At PhinC Modeling, 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.

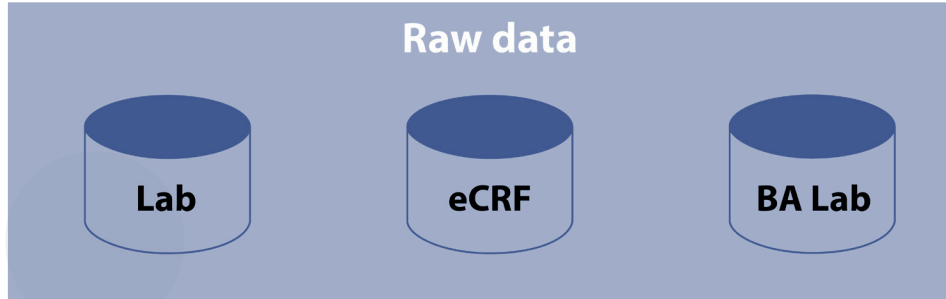
The main challenge is first to efficiently coordinate with all stakeholders in the CDISC process: data management, bioanalysis and regulatory submission.

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).

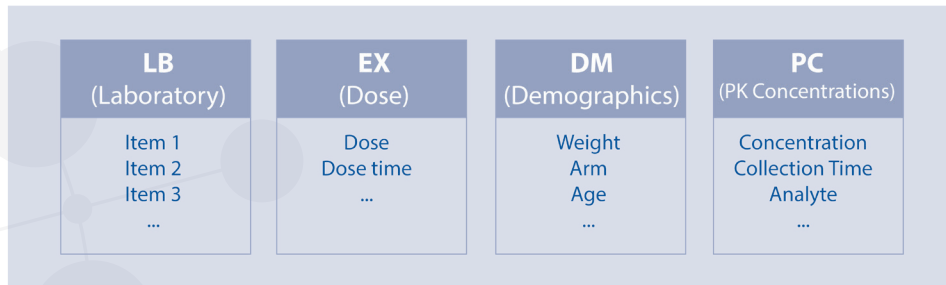
# ACHIEVE COMPLIANCE AND TAKE ADVANTAGE OF THE CDISC STANDARDS FOR PHARMACOKINETIC MODELING

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.

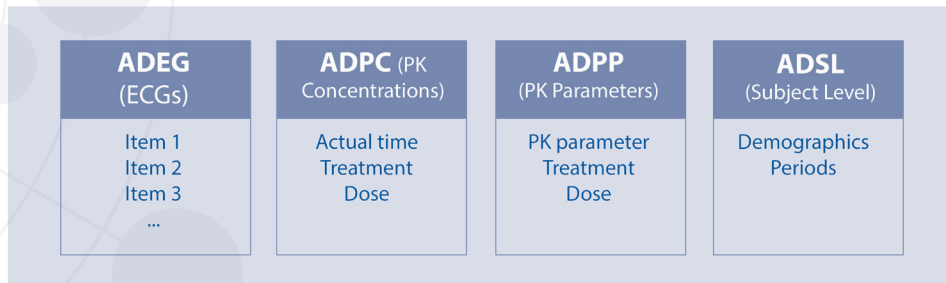
**1** **CDASH**  
Data acquisition



**2** **SDTM/SEND**  
Data Tabulation



**3** **ADaM:**  
Analysis-ready dataset



**4** Analyses



**5** TFLs/ Reporting



**Regulatory submission**



## CONTACT US TODAY TO GET A QUALIFICATION APPOINTMENT



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