CLINICAL PHARMACOLOGY

# Optimizing PK/PD Data with CDISC: Enhancing Regulatory Readiness

## The Relationship between CDISC and PK/PD

Clinical Data Interchange Standards Consortium (CDISC) formatting guidelines help enable a more efficient submission and review process by providing regulatory agencies with clean, consistent, and standardized data. Implementation of CDISC standards can decrease timelines and costs during drug development by expediting the regulatory processes, leading to a faster marketing authorization.

Within CDISC, an important subset of clinical trial data is pharmacokinetic data. Pharmacokinetics (PK) is the study of a drug's time course profile within the human body via the processes of absorption, distribution, metabolism, and excretion (ADME). Pharmacodynamics (PD) is the study of how drugs affect the human body given their mechanism of action. PK/PD describes the relationship between drug concentration (PK) and the resulting physiologic effect (PD). The analysis of PK/PD data is an important aspect of clinical trials that helps define a drug's concentration, exposure, response, and other PK parameters.

## Why Allucent?

Allucent is an industry leader in PK/PD CDISC standards and has extensive experience with generating datasets for legacy, planned, and ongoing studies. We help ensure your program's datasets are in compliance with the FDA's required CDISC standards.

## Scan here to learn more about Allucent's Clinical Pharmacology solutions:

Allucent®
Helping bring new therapies to light

# Allucent Services:

- Interim PK/PD data review
- Noncompartmental PK analysis (NCA)
- CDISC dataset generation (validated for FDA Compliance using Pinnacle 21 Enterprise)
  - SDTM datasets - direct reformatting of raw source data
    - Pharmacokinetics Concentrations (PC)
    - Pharamcodynamics Concentrations (PD)
    - Pharmacokinetics Parameters (PP)
    - Pharamcodynamics Parameters (PDP)
    - Related Records (RELREC) - describes cross-domain relationships
    - Immunogenicity Specimen (IS) Assessments
    - Supplemental (SUPP--) domains as needed
  - ADaM datasets provide data in analysis-ready format
    - Analysis Dataset for Pharmacokinetics Concentrations (ADPC)
    - Analysis Dataset for Pharmacokinetics Parameters (ADPP)
    - Analysis Dataset for Pharmacodynamics Parameters (ADPD)
    - Analysis Dataset for Immunogenicity (ADIS)
    - Analysis Dataset for NCA (ADNCA)
- Tables, Listings, and Figures (TLFs)
  - Proprietary validated source code that quickly turns ADaM datasets into data summaries and graphics
- Data specifications for facilitation of Define.xml files
- Abbreviated Reviewer's Guides (RGs)

**For additional content on PK/PD and CDISC visit the www.allucent.com**

**or**

**Read our blog on Understanding How PK Data and CDISC Work Together**