



## COMSYS Clinical



# PK/PD Programming Support

Pharmacokinetic and Pharmacodynamic (PK/PD) analyses are a critical component in the Discovery and Clinical Development Phases of Pharmaceutical Research. Yet, PK/PD remains a highly specialized area with unique skill-set requirements. With more and more emphasis being placed on biomarkers as surrogate endpoints, the need for PK/PD expertise continues to grow. At COMSYS Clinical, we have a highly trained and experienced group of PK/PD programmers who function above and beyond the role of programmer.

## Experience and Efficiency

The individuals on the PK/PD programming team at COMSYS have a wealth of specific PK/PD experience. Typically, it takes a non-PK/PD programmer months to be independently working on these types of projects. We have a highly specialized group in place with many years of experience that can be up and running much quicker than a non-experienced PK/PD programmer. They have formed trusted working relationships and continue to mentor each other and share expertise. This internal network allows them to problem-solve quickly so that your analysts and clinicians are presented with solutions rather than questions.

## Unique PKPD Skillsets

The nature of PK/PD datafile creation demands broader and more varied experience than the typical non-PK/PD programming assignment. Some of these unique skills are listed below:

- They are very knowledgeable in NONMEM and NCA data standards and possess an in-depth understanding of PK concentration and date/time data.
- Communication-COMSYS PK/PD programmers currently work directly with the analyst/kineticist and hold programming

plan meetings with them so there are fewer chances for misinterpretation of specifications which reduces draft iterations and gets your clinical team to a final dataset sooner and more efficiently.

- Our PK/PD programmers routinely discover data issues that were missed by data management and Tables and Listings (TLG) programmers. In most instances, problem data issues affect more than one study so the potential quality and time-savings impact is far-reaching.
- Our PK/PD group is adept at converting Excel files to SAS data sets, merging data from several different data modules at the same time and developing programs before having all of the input data sets since PK concentration data often comes later than the other data.
- They work on studies in all Phases of development and Therapeutic Areas and support multiple studies and compounds at the same time.

## Quality and Continuous Improvement

Because of our in-depth industry experience, our specialized programmers can help you optimize the PK/PD dataset development process. Our teams work cohesively to share knowledge and to find new and more efficient ways of dealing with traditionally difficult data.

If you're looking for a true partner with deep experience in PK/PD programming, look no further than COMSYS Clinical. We have over 27 years of providing quality and timely pharmaceutical services and solutions to our clients across North America.