4 Ways to Know PKPD Is Right for Your Trial

Pharmacokinetics (PK) and pharmacodynamics (PD) modeling address both how the human body processes a drug and the interactions between that drug and the human body. PK studies the efficiency of drug absorption, how it's distributed throughout the body compartments (bloodstream, tissues, etc.), how it's metabolized and transported, and how quickly the body eliminates it. PD focuses on the relationship between the drug and its impact on the body or intended target (such as pathogens or receptors).

PKPD is an alternative analysis to dose analysis; rather than studying drug dose impact, PKPD applies mathematics and statistics to identify the sources of variability (intrinsic or extrinsic factors) and ultimately reduce the number blood draws by using the sparse sampling strategy which reduces the cost associated with clinical studies required to be conducted. At Synteract we use 4 different platforms, including Non-Compartmental Analysis (NCA), which is 21 CFR Part 11 compliance analysis, PKPK using Phoenix Winnonlin, Polulation PK/PKPD using Nonmem and NLME, Physiological based Pharmacokinetic modeling (PBPK), using PKSim/MoBi all in validated environment, following regulatory guidelines. Here's when to consider PKPD analysis:

- ☐ **Do you have a small patient size?** PKPD applies mathematical models to determine variable impact (both intrinsic and extrinsic), optimizing formulation, predicting drug to drug interaction potential, food effect etc., thus reducing the need for a large sample population.
- ☐ **Moving from Phase I to next stage of your trial?** PKPD evaluates both the body's impact on the drug as well as the drug's impact on the body, to establish the proof of concept (PoC) and provide assessment to give a "sneak peek" to characterize what the next set of clinical study planning and protocols could look like in order to optimize the Phase 3 dose.
- ☐ **Does your trial include special patient populations?** With rare disease trials, or pediatric and senior populations, for example, finding the right dose for the right age group, as well as the reduced need for sampling can be beneficial from a patient perspective — optimizing the safe and efficacious dose and reducing the need for multiple sample draws thus reducing the need for multiple clinic visits are cost efficient.
- ☐ **Are time and efficiency critical for your drug program?** Although PKPD may seem like an extra step, by performing these analyses, you're reducing uncertainty and refining your information. Because most trials are based on variability around an endpoint, by using PKPD mathematics, you're able to reduce uncertainty by addressing those variables head-on.

PKPD can help increase the efficiency and confidence in your trials, streamline the approval process, increase cost effectiveness, and help give assurance that your product will have a positive effect on a broad population.

Contact us today to find out how we can bring your next clinical trial to life.

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BRINGING CLINICAL TRIALS TO LIFE™