CASE STUDY

Interim Pharmacokinetic Analysis to Enable Rapid Decision Making

Background and Problem

A food-drug interaction could cause increased or decreased systemic exposure/pharmacokinetics (PK) of the drugs, which may lead to impacts on efficacy and safety. Therefore, results of a food-effect study are often critical early in drug development for informing dosing recommendations for oral drugs to guide the practical instructions and dose(s) for a Phase 2 study in patients.

A client engaged Allucent to prepare a food-effect study protocol, analyze interim PK data, and author a clinical information amendment for submission to regulatory authorities. The conduct and reporting of PK results of the food-effect study was on critical path to initiation of a Phase 2 clinical study. The challenge for the client was that the protocol, PK data analysis, and PK clinical information amendment for regulatory submission needed to be prepared in a very short timeframe.

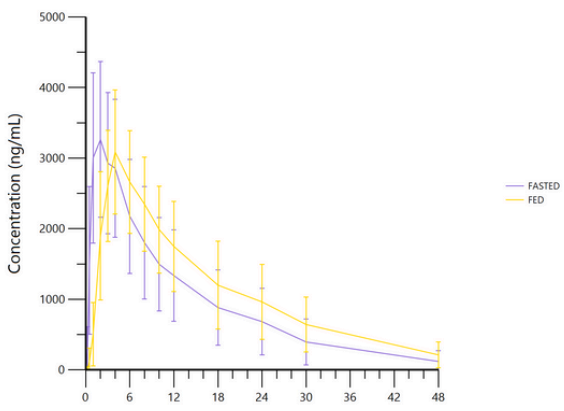
Our Solution

Allucent's Clinical Pharmacology Modeling and Simulation (CPMS) technical writing group drafted the protocol under tight timelines. Protocol details included study rationale, sample size, dose, PK sampling scheme, and PK and statistical methods. Within 5 business days, the protocol was written and internally reviewed by the CPMS team. Allucent's protocol template ensured quick authorship, timely site selection, and data transfer agreement. Good communication with the client's bioanalytical group enabled seamless assessment of interim PK.

Outcome

From the time the bioanalytical data was received, Allucent's CMPS experts analyzed the PK results and prepared the first draft of the clinical information amendent within 5 business days. Due to the high quality of the draft, the client was able to finalize the amendment within 12 business days. The clinical information amendment included key PK results on the effects of food ingestion on the oral bioavailability and PK of the drug, including inferential statistics. A modest food effect was observed, showing approximately 36% increased exposure when the drug was administered with food (**Figure 1**). The drug was well tolerated following administration of

Figure 1: Mean (±SD) Drug Plasma Concentration Over Time in Fed and Fasted States (Food-Effect)



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Helping bring new therapies to light

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the studied dose in the fasted and fed state. Therefore, this study confirmed acceptability of ingestion of food with the investigational drug.

The prioritization of the client's immediate needs as well as efficiency within Allucent's CPMS team of experts led to short turnaround times for the protocol, PK analysis, and clinical information amendment, which was essential for the client's goals to efficiently progress in their program.

About Allucent

We have the same mission as you: To develop and deliver essential medicines to the patients who need them. We do this through deep collaboration to understand your needs, increasing your confidence in decision making, and delivering innovative strategies. By translating data into actionable insights that inform PK/PD/dose, study designs, modeling and development strategies, the Allucent CPMS team can help deliver on your drug development needs.

To learn how Allucent can improve and support your clinical pharmacology studies, analyses, or strategies, **click here**.

For related Allucent content, check out these additional resources:

Strategically Aligned for Streamlined Interim Pharmacokinetic Analysis

Compartmental Modeling in Pharmacokinetics

Noncompartmental PK (NCA) Services