



Non-Compartmental Analysis of Pharmacokinetic Data

The evaluation of the pharmacokinetic (PK) data gathered in preclinical and clinical stages of drug development helps researchers understand how quickly and how much of the drug is getting into and out of the body. In more specific terms, it provides insight into the rate and extent of drug absorption, distribution, metabolism and excretion, factors critical to the definition of a safe and efficacious dose, thereby streamlining the drug development program.

Non-compartmental analysis (NCA) methods are widely used for quick evaluation of the PK data when the primary requirement is to determine the systemic exposure of the drug following administration. As opposed to a compartment modeling approach, which requires some assumptions regarding the number of compartments to be made and validated, NCA analyses don't require such assumptions, thus they are time- and cost-efficient, resulting in fewer deviations in terms of final output when compared across studies, analysts and software. NCA are also used to examine the linearity vs non-linearity of the drug, allowing researchers to make dose escalation decisions and to assess the results of bioavailability and bioequivalence studies.

A key PK parameter is the Area Under the Concentration-Time Curve (AUC), which indicates the extent of exposure. In addition to AUC, parameters such as C_{max} (maximum observed concentration), T_{max} (time to reach maximum concentration), total clearance and volume of distribution are reported. These parameters are crucial in calculating the dosage needed to achieve target average plasma concentration at steady state, the dosing interval needed to achieve target fluctuation between maximum and minimum plasma drug concentration at steady state, and the loading dose needed to achieve target average plasma concentration at steady state.

Thus, PK parameters estimated from NCA methods have a significant role in supporting regulatory filings to evaluate and inform decision making both during development and during the approval process.

At Synteract, we use NCA methods extensively during pre-clinical and clinical drug development to help our clients in understanding the PK characteristics of their drug compounds by estimating PK parameters as well as characterizing the underlying exposure following drug administration, allowing for proper and accurate dose-escalation decisions.

[Contact us](#) today for more on how we can help with your clinical trials.

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