



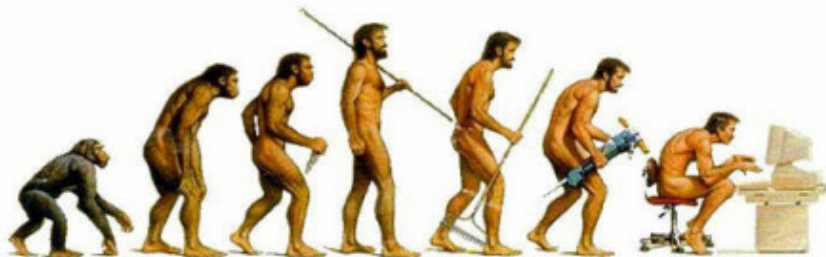
Fast-track PK Analysis

A Simple Approach for the Assessment of Clinical PK

PhUSE 2015, Vienna

Ramanatha Saralaya, Cytel

Introduction



Incremental progress in the field of clinical pharmacokinetics



Cost and time continued to rise over recent times



Improving success rates and reduction in cost and time taken during drug development

Introduction



Rapid and accurate clinical pharmacokinetic result can contribute to overall speed of development



Cytel - Fast Track Pharmacokinetic Analysis (combines multimodal approaches in one "Basket")



This approach helps in rapid turnaround and quick decisions for successive steps.

HOW?

Project management for concurrent execution of tasks



Rapid inputs
for decision



Use of tools to
reduce steps



Reduce the time



Effective teamwork



Fast Track Pharmacokinetics Analysis

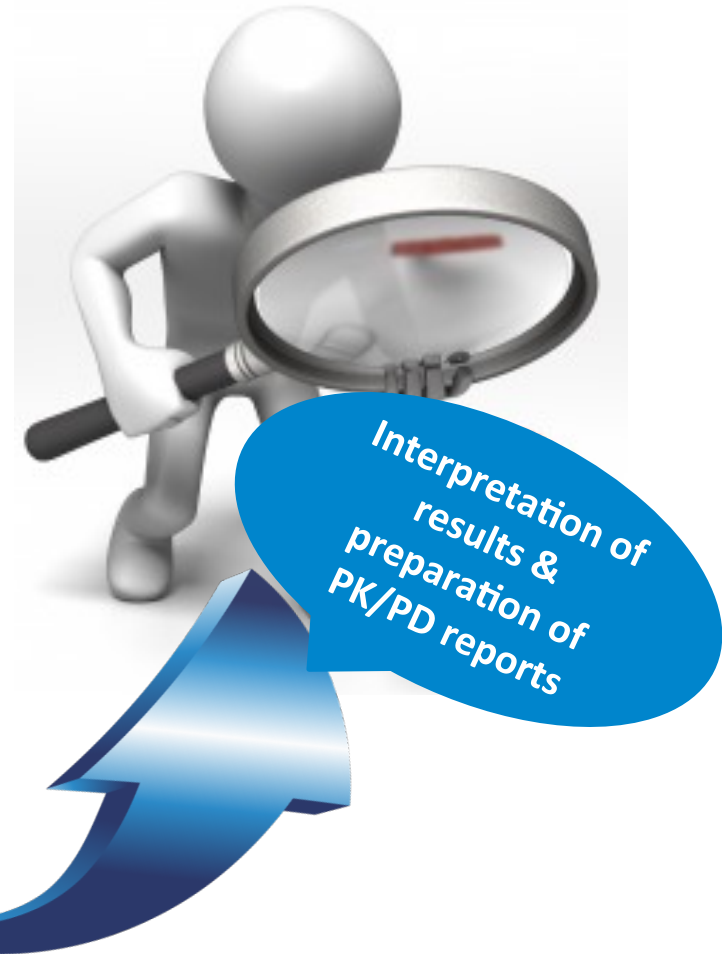
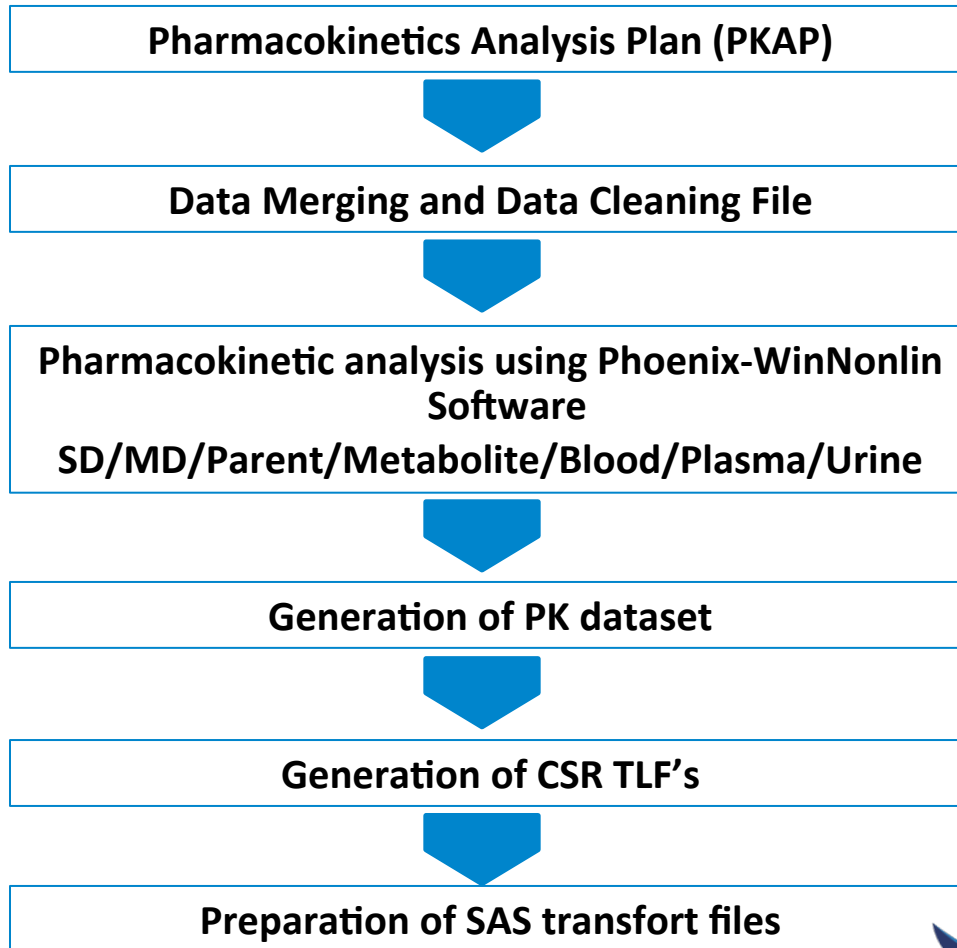


Fast-track Pharmacokinetic analysis provides for parallel progress with different skillsets



Great partnership between a SAS programmer and a Pharmacokineticist to form a multi-disciplinary team

Project Workflow for full CSR



Cytel Approaches



Three different approaches



24 hour turn-around time



Preliminary Analysis



Full PK CSR Analysis

Fast Track Pharmacokinetics Analysis



24 hour turn-around time

Noncompartmental clinical PK analysis with turn-around-times as fast as 24 hours. Reporting in Microsoft Word & Excel.

The goal of this 24 hour turn-around time approach is to provide topline PK/PD parameters for clients along with CSR TLF's

Deliverables (24 hours)

- **Phoenix NCA Workflow**
- **PK Summary Tables**
- **CSR PK TLF**

Fast Track Pharmacokinetics Analysis



Preliminary Analysis

Turn-around-times as fast as 3-5 days. The goal of this preliminary analysis approach is to provide guidance to clients on the PK results and how those results can influence next steps in their development programs.

Deliverables (3-5 Days)

- **PK Analysis Plan**
- **Phoenix workflow w.r.t RNT (1 Day)**
- **PK Summary Tables (1 Day)**
- **CSR PK TLF (1 Day)**
- **Data Set for Statistics team (1 Day)**

Fast Track Pharmacokinetics Analysis



Full PK CSR Analysis

Turn-around-times as fast as 7-10 days. The goal of this provide clients with a submission-ready report that includes a full accounting of PK/PD analysis and data.

Deliverables (7-10 Days)

- PK Analysis Plan
- Data Merged File & Data Cleaning Comments (2 Days)
- Phoenix workflow w.r.t RAT (2 Day)
- PK Summary Tables (1 Day)
- CSR PK TLF (1 Day)
- Data Set for Statistics team (1 Day)
- XPT files (1 Day)
- CSR PK write-up (2 Day)

Lead/Developer will take care of all deliverables and the validator (senior scientist) will review all the deliverables and share the QC checklists with client

Conclusions

- Efficiency in pharmacokinetic analysis, novel use of tools for data analysis and provide quality result.
- These approaches support early and rapid decision-making, thereby saving time and money.



Any Questions...

