IASCT
Indian Association for Statistics in Clinical Trials

# PHARMACOKINETICS ANALYSIS WORKSHOP

## Curriculum

Registration – 9:00 AM to 9:30 AM

- Introduction to PK – Overview

- Why PK is needed and importance in clinical trials?
  - ❖ How PK data is collected e.g.: blood collection, dosing data
  - ❖ Linking concentration to different doses (e.g.: 24h, pre concentration)

- Various type of samples (Blood, Plasma &Urine) and analysis depending on samples

- Flagging of PK concentrations vs flagging of parameters
  - ❖ Identifying evaluable samples
  - ❖ Imputation rules

- Concept of merging PK data with dosing information

- Case studies
  - ❖ DDI, FDI, Bioequivalence

- Reporting of PK data
  - ❖ Types of summaries
  - ❖ Reporting ways of various PK Parameters
  - ❖ Significant digits
  - ❖ Software

- Interpretation of PK results

Annual

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**Meet the Trainers – A brief sketch**

**Jagannath Kota**
Group Manager, PK Sciences,
Novartis Institutes for Biomedical Research (NIBR).

**Jagannath Kota** is the Group Manager of the PK Sciences group in India. He started his career at Dr. Reddy's Discovery Research, Miyapur, Hyderabad in Drug Metabolism and Pharmacokinetics department (DMPK) Department. He completed PhD (on "The impact of injection site and animal model on the lymphatic absorption of subcutaneously administered protein drugs") in November 2007 from Department of Pharmaceutics, Monash University, Australia and joined Advinus Therapeutics Private Limited in the DMPK Division. In August 2008 Jagannath joined Novartis, Hyderabad, where he has led and facilitated several PK workshops and trainings within Novartis and externally.
Jagannath loves mentoring people on communication and presentation skills.

**Vinay Kumar Venishetty**
Investigator II, PK Sciences,
Novartis Institutes for Biomedical Research (NIBR)

**Vinay Kumar Venishetty** completed his B.Pharmacy and M.Pharmacy (Industrial Pharmacy) from University College of Pharmaceutical Sciences, Kakatiya University, Warangal. He did his PhD in Pharmaceutics from Indian Institute of Chemical Technology (IICT), Hyderabad and explored some of the novel drug delivery techniques to enhance brain uptake of anticancer drugs. He also worked as Post-doctoral Research Associate at Texas Tech University Health Science Center (TTUHSC), Texas, USA, with a focus on distribution and transport of drugs across the blood brain barrier in preclinical breast cancer induced metastatic brain tumor models using novel drug delivery techniques.
He has more than 6 years of research experience in drug delivery (formulation) techniques, drug discovery and preclinical oncology models. He worked for Piramal Life Sciences as a Senior Research Scientist in preclinical DMPK and involved in initial metabolic and pharmacokinetic screening of new chemical entities using in-vitro models & preclinical species. He has about ten (10) international publications and a book chapter to his credit.

**Prasanna Kumar Nidamarthy**
Principal Biostatistician, Biostatistics for Clinical Pharmacology – Oncology
Novartis

**Prasanna Kumar Nidamarthy** has around 11 years of pharma experience as a Biostatistician (8 years) and Statistical programmer (2.5 years). He holds a Masters in Statistics from Acharya Nagarjuna University. He started his career as a Biostatistician at GVK BIO sciences Pvt Ltd, Hyderabad. He joined Novartis in 2008 and currently working as a Principal Biostatistician in Oncology Clinical Pharmacology department and supporting Clinical Pharmacology studies in both healthy volunteers and in patients. He also worked as Biostatistician for Phase IV studies.

**Chandrasekhar Bhupathi**
Sr. Principal Statistical Programmer, Statistical Programming,
Global Development Operations (GDO),
Novartis.

**Chandrasekhar Bhupathi** is managing the Clinical Pharmacology programming group in India**.** He has close to 10 years of programming experience in Clinical Trials. He has been with Novartis since 8 years. He holds a Masters in Statistics from Osmania University, Hyderabad and currently pursuing his Ph.D program as a part time student with Osmania University.