

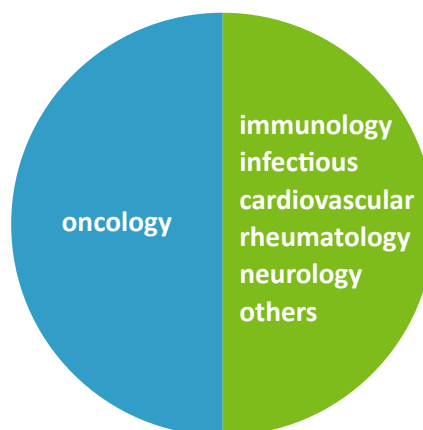


Venn Life Sciences

part of Open Orphan plc

Clinical PK and PD Service at Venn Breda

- » For more than 20 years, the clinical pharmacokinetic (*PK: understanding the kinetics of a drug in terms of absorption, distribution, metabolism and elimination [ADME]*) and pharmacodynamic (*PD: the biochemical and physiological effects of a drug*) team of Venn Life Sciences have supported (model-independent) noncompartmental (NCA) PK and PD analyses for many pharmaceutical companies.
- » Venn has experience in supporting PK/PD analyses over a wide range of therapeutic areas, with about 50% for oncology and the remaining 50% in the area of immunology, infectious, cardiovascular rheumatology, neurology and other diseases. Venn is supporting a wide range of new molecular entities, such as small molecules, antibodies, RNA, but also cellular based.
- » PK/PD analyses, required for regulatory submissions, have been performed for all types of phase 1 studies, including first-in-man, ADME studies, drug-drug interaction studies, bioequivalence and bioavailability studies, studies in special populations and other PK and PD studies during Phase 2/3 of drug development.



3 years

approximately
125 PK/PD
analyses after
final DBL

and over 300
preliminary/
interim PK/PD
analyses

450 PK/PD analyses



Over the past 3 years, Venn supported more than 450 PK/PD analyses of which approximately 125 PK/PD analyses after final DBL (database lock) among other requests (interim, preliminary, and ad hoc analyses).

- » Each PK/PD analysis is performed by qualified staff, according to high-quality ICH GCP based Standard Operating Procedures (SOPs, from Venn or Sponsor) using validated software (PhoenixTM WinNonlin[®], SAS). All data, calculations, tables, figures, and resulting PK/PD report are reviewed for scientific content and QC-ed internally.
- » The Clinical PK/PD team in Breda consists of a total of 24 members (14 PK/PD analysts, 9 PK/PD consultants and a PK/PD project manager).

Clinical PK and PD Service at Venn Breda

- » This experienced clinical PK/PD team enables high flexibility to support our Sponsors with high quality PK/PD data for each analysis within the pre-agreed timelines.
- » Each PK/PD analysis is supported by 2 PK/PD data analysts & 2 PK/PD consultants (lead & reviewer) from Venn or a combination of these functions at Venn/Sponsor.



Figure 1: Typical flow of a clinical study involving PK/PD analysis at Venn Life Sciences

Case study

Venn Life Science provided support in the pharmacokinetic, pharmacodynamic and immunogenicity analysis of the client's first-in-class bispecific antibody in an oncology trial. For this trial multiple administration routes and various escalating doses were explored in several hundred subjects. The Venn Life Science PK team performed the complicated and challenging NCA on this study with high numbers of PK profiles and large amount of deviations and adverse events, associated with trials in oncology patients. Due to the preparations involved and ample experience in managing similar oncology trials, the Venn Life Science PK team managed to complete the NCA, and provide the PK report and output within tight timelines, to meet regulatory submission timelines.



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