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Recruitment challenges in patients based pharmacokinetics studies

Vikas Kumar
Fresenius Kabi Oncology Ltd., India

Timelines for the patients based pharmacokinetics (PK) studies are often extended as compared to the healthy volunteer based PK studies with obvious reason of recruitment challenges in former case. Patient Identification, selection and appropriate screening are key parameter to enroll the patients and to assess the validity of clinical phase of such studies. This is especially important in case of patients based bioequivalence (BE) studies where most of the times protocol is designed to mimic the innovator product regimen for selection of patients. Inclusion criteria in such cases tend to be very restrictive as compared to normal cancer clinical trials.

Paucity of the cancer patients along with lack of interest of the investigators in patients based PK studies makes conducting such studies challenging as compared to healthy volunteers BE studies. Various types of cancer population pose different challenges in terms of recruitment. For example, in a trial of drug indicated for myelodyplastic syndrome (MDS) which 30% of the time act as a precursor to leukemia's such as acute myeloid leukemia (AML) and chrome myelomonocytic leukemia (CMML), patient diagnosis with exact disease and stable status of patient is a key aspect. For high grade glioma trial designs changes in histopathological grading of patients {for examples from grade III (Anaplastic Astrocytoma, AA) to grade IV (Glioblastoma, GBM)} is one major vault amongst others in patient's recruitment.

In this presentation different recruitment challenges in case of patients based PK studies for proving BE of generic drugs with innovator product will be discussed.

Biography

Vikas Kumar has completed his M. Pharm (Pharmaceutics) at the age of 24 years from Punjabi University, Patiala, India. He is working as Research Scientist (Global Medical, Clinical and Regulatory Affairs) at Fresenius-Kabi Oncology Ltd, a premier generic oncology pharmaceutical organization. He has previously worked with Ranbaxy laboratories, India. He has rich experience in field of bioequivalence, preclinical and drug metabolism and pharmacokinetics (DMPK) studies required to support generic drug development. He has participated in several conferences.

Vikas.Kumar@fresenius-kabi.com