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Novel exploratory approaches to define clinical Absolute Bioavailability and other ADME properties

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Abstract

Novel exploratory clinical approaches to address questions on definitive pharmacokinetics and absolute bioavailability have come to the fore in recent years. Some of this has been enabled through technological advances such as the emergence of Accelerator Mass Spectrometry in biomedical science and extensive adoption of the microtracer design (concomitant administration of an intravenous microdose with a therapeutic level oral dose). The ease of conducting such studies has been assisted via production of regulations to support the concept of microdosing to humans. A summary of the applications of microtracer approaches for exploratory clinical investigations both in early and late stage clinical development will be presented, including assessment of a variety of ADME (absorption, distribution, metabolism and excretion) endpoints.

Biography

Graeme Young gained a MSc in Forensic Science at Strathclyde University, Glasgow, Scotland (1986-1987). Graeme then joined Glaxo Group Research in 1987 and now has >25 years experience within departments of Drug Metabolism. Graeme acted as a "champion" of the AMS technique in GlaxoWellcome and GSK, and since 2004 has been charged with responsibility for bringing AMS in-house and applying it to projects within GSK. Graeme is lead or contributing author to several papers published on the subject of AMS and its application to Drug Metabolism and Bioanalysis. Graeme is currently the manager of the Accelerator Mass Spectrometry group at GSK, in the DMPK division.