Sudhakar Bangera, J Bioequiv Availab 2013, 5:3
http://dx.doi.org/10.4172/0975-0851.S1.015

OMICS Group Conferences
Accelerating Scientific Discovery

4th World Congress on
Bioavailability and Bioequivalence:
Pharmaceutical R&D Summit
May 20-22, 2013 DoubleTree by Hilton, Beijing, China

# Challenges in conducting bioequivalence studies in Indian patients

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BA-BE studies are conducted in India by foreign sponsors for various reasons, including availability of patients, timelines, quality and cost. Many of the Investigators, Ethics Committee members, Patients, Contract Research Organizations (CROs) and other stakeholders though familiar with the requirement(s) for the conduct of the clinical trials of new chemical entities in India, do not thoroughly understand the requirements for the conduct of BA-BE studies. Many of them often consider BA-BE studies as a synonym for phase 1 clinical trial. With this background, I would like to share my experience in terms of challenges encountered in the conduct of BA-BE studies in India with an example of a case study, and also suggest solutions to overcome these challenges. This includes education of all the stakeholders. The case study is a BA-BE Study sponsored by a US based pharmaceutical generic company, in order to first-to-file' ANDA application under Paragraph IV of the 1984 USA Hatch-Waxman Act.

## Biography

Sudhakar Bangera is a MD and has done MMedSc (Clinical Trials Methodology) from The University of Hong Kong. He has over 20 years of work experience in healthcare, CRO, ARO, SMO, Medical Imaging, BA-BE Centre, and a global Pharmaceutical company. In his last work assignment, he was Sr. Vice President and Country Head for Daiichi Sankyo India Clinical Development.

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