

Requirements of drug-drug interaction studies in the USA and Europe based on recent regulatory FDA and EMA guidelines

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Drug-drug interactions (DDI) can be a very important aspect during drug development as an important factor for drug action and safety. During the past 2 decades the background knowledge about DDI has greatly increased, in particular regarding the mechanisms of drug transport. This in turn has evoked new regulatory guidance on DDI studies in 2012 by both the FDA and the EMA in large documents of 79 and 60 pages, respectively. Both guidance are scientifically driven and provide a well-structured overview on the complex field on DDI via drug-metabolizing enzymes and drug transporters with valid examples given. Much detailed information is contained for specific inhibitors, inducers and probe drugs to ease the selection of well-known drugs to be used in specific DDI studies. Guidance also addresses the impact of genetic polymorphisms of enzymes and transporters. This talk will 1) provide an overview on the scientific background and how to read and understand these large documents, 2) explain the decisions whether at all, why and when a DDI study will become necessary, 3) explain the impact of DDI studies with historical examples including their scientific background, and 4) provide an overview how to plan a DDI study in view of well characterized probe drugs. This talk will also include recent strategies such as “drug cocktails”, population pharmacokinetics or modeling approaches.

Biography

Karl Ludwig Rost started in clinical pharmacology with postdoctoral studies at the Schering AG, Berlin, before he continued his career at the Charité, Benjamin Franklin for 9 years with studies on pharmacokinetics and genetics including DDI studies. After he qualified as a university lecturer, he was the main consultant at Parexel int. for 14 years, responsible for planning of nearly 800 early-phase studies. Since 4 years he acts as a free consultant focused on drug development, pharmacokinetics and drug submissions. He has published 30 papers in reputed journals, 85 congress abstracts and made contributions to 16 books.

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