ADME and Drug-Drug Interactions: In Vitro/In vivo Considerations During Drug Development, bioinformatic models any future advance?

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Abstract

Statement of the Problem: Preclinical Drug development assigns the characteristics to the molecules by testing in vitro/in vivo tests like (DMPK) drug metabolism and pharmacokinetics test. They estimate ADME absorption, distribution, metabolism, excretion, and DDI Drug-Drug Interactions studies. They go on with clinical tests till the drug is labelled. ADME/DDI studies provide a basic understanding of the molecule. Afterwards, their data assess compliance with regulatory guidance. They prepare molecules for clinical studies. During my late practice in pharmaceutical regulatory expertise, I have been challenging these items to assess the basic toxicity and efficacy of pharmaceuticals. I am now working to guarantee the promptness of these features on labelling files to obtain the regulatory evaluation and so on the commercial validation after clinical tests. Lab bioassays and all the other tests e.g., enzyme induction and inhibition, reaction phenotyping, metabolite ID production, and pharmacokinetic profile set the data I need to collect and insert in the evaluation to set clinical test and then by their results labelling files.

Conclusion & Significance: Careful preclinical (DMPK) drug metabolism and pharmacokinetics evaluation carries out the data to start clinical tests and obtain clinical evidence on product efficacy and safety. Preclinical studies are basic mostly to obtain a clear molecule profile. Further could be done by building metrics on mathematical methods by bioinformatic models to assess (DMPK) drug metabolism and pharmacokinetics test as also all the other necessary tests though *in silicio* screening.

Recent Publications

A.Steardo "Cannabidiol in inflammatory bowel diseases: a brief overview." Phytotherapy Research. 2013 May;27(5):633-6. doi:10.1002/ptr.4781.

A.Steardo "Differential cannabinoid receptor expression during reactive gliosis: a possible implication for a non-psychotropic neuroprotection." Scientific World Journal. 2009 Mar 31; 9:229-35. DOI: 0.1100/tsw.2009.31.

A.Steardo "Palmitoylethanolamide improves colon inflammation through an enteric glia/toll-like receptor 4-dependent PPAR-α activation." Gut. 2014 Aug;63(8):1300-12. DOI: 10.1136/gutjnl-2013-305005.

A.Steardo "Cannabis-derived products: Agronomic production categorization to the best improvement" Vol. 10 (1), pp.05 -08, March 2022 Prime Scholars Library

A.Steardo "How to Prepare a Protocol for a Clinical Trial? 5 Step Advice" Published: 28.03.2022, DOI: 10.35248/2229-4708.22.13.224 Pharm Methods, 2022; 13(1): 11-13



Biography

Doctor Antonio Steardo specialized in Pharmacology and graduated in Pharmacy and Pharmaceutical Chemistry. He has now gained years of experience since 2002 in the pharmaceutical products trade sector as he could have been behind the counter of the Steardo pharmacy from an early age. Already in elementary school, his curiosity for chemistry manifests itself during his games and continues lectures at the department of science at the University of Salerno. Therefore, during the cycle of studies, he prefers biochemistry and biochemistry of drug action, graduating in July 2007 with a thesis on the functioning of the endocannabinoid system on Alzheimer's disease in pharmacology. Following the beginning of his pharmaceutical chemistry studies, he stopped for a competition as a postgraduate in pharmacology at the University of Rome La Sapienza in July 2014. Expecting constant improvement as a professional update, he enrolled in the continuing professional training department at the University of Oxford to follow courses in Experimental and Translation Therapy and Medical Research. His desire to improve leads him to attend international conferences and seminars.

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