Supplementary information

Article title

Absorption, Distribution, Metabolism, and Excretion (ADME) of Therapeutic Proteins: Current Industry Practices and Future Perspectives

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TABLE S1. Summary of Issued Regulatory Guidance Documents Addressing ADME of NCEs from ICH, FDA, EMA and PMDA

Title	Year	Issuing body	ADME aspects addressed
Safety testing of drug metabolites	2020	FDA	Safety testing of drug metabolites
ICH M3 R2 Non-clinical safety studies for the conduct of human clinical trials for pharmaceuticals	2009 (Q&A) 2012	ICH	Safety studies to be conducted, Metabolite coverage in safety studies
EMA Guideline on the investigation of drug interactions (CHMP/EWP/560/95/Rev. 1, 2012) Sections 5.2.3, 5.2.4, App. V	2012	EMA	Required DDI assessments, mass balance study in humans
In vitro drug interaction studies – Cytochrome P450 enzyme- and transporter-mediated drug interactions	2020	FDA	In vitro assays and data interpretation for characterizing drug interaction potential
Clinical drug interaction studies – Cytochrome P450 enzyme- and transporter-mediated drug interactions	2020	FDA	Timing, design, and conduct of clinical drug interaction studies
Guideline on drug interaction for drug development and appropriate provision of information	2019	PMDA	Drug interactions in absorption, tissue distribution, drug metabolism, and excretion. Clinical drug interaction studies.