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An Industry perspective on drug transporter-mediated drug interaction studies

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Recently, the US FDA (Food and Drug Administration) and EMA (European Medicines Agency) have issued new guidances for industry on drug interaction studies, which outline comprehensive recommendations on a broad range of *in vitro* and *in vivo* studies to evaluate drug-drug interaction (DDI) potential. Both of the latest guidance documents contain much more extensive recommendations on in vitro and in vivo studies and approaches to evaluate DDIs mediated via drug metabolizing enzymes and drug transporters. In this presentation, we present an industry perspective in applying the regulatory guidance to support drug discovery and development, and case examples to demonstrate complexities in applying at an early stage of drug development the proposed transporter decision trees to derive actionable information. In contrast to CYP-mediated DDIs where knowledge gained over the past 20-30 years has established a foundation for more quantitative predictions of drug clearance and potential for DDI, our understanding of the potential for DDI arising from interactions with transporters is still in emerging, requiring additional research to fill in knowledge gaps.