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The translational medicine guide: Asking the right question at the right time

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The translational Medicine Guide (TxM guide) has been developed to help each project team maximize success in achieving clinical Proof of Concept (cPoC) by considering multiple aspects of drug discovery and development. The TxM Guide is a forward looking strategic planning framework for teams to ask "the right questions at the right time" for each of the 3 categories - Target, Dose and Patient: • Target: The target pillar focuses on the critical need to identify the right biological target and increase the understanding of its role in a particular disease. The goal is to identify the right biological target for the selected disease. • Dose: The dose pillar addresses dose, regimen and drug (molecule), focusing teams on the importance of identifying the right molecule for a given biological target that will have the right therapeutic window. The goal is to identify right molecule that delivers the right exposure at the target site of action and elicits the desired target modulation over the stated time period, without compromising patient safety. • Patient: The patient pillar underscores the importance of selecting the right sub-patient population for the investigational drug and identifying the potential use of a companion diagnostic test to select an appropriate sub-disease population. The goal is to identify the right patient group in the selected disease. The presentation will outline how the TxM guide helps teams to build a body of scientific & medical evidence to be better positioned to achieve positive cPoC.

Biography

Laetitia Devy-Dimanche is the Head of Global Early Stage (Discovery to Proof of Concept) Project Management. She ensures with her team that projects are executed on time, within budget and with high quality. She is a professional with 12+ years' experience working in Biotech and Biopharmaceutical industry focusing in the area of novel drug development including antibody and small protein drugs. She has a Pre-Graduate Research Degree in Clinical Pharmacology and a PhD in Biochemistry and Molecular Biology. During her PhD and Post-doctoral fellow, she has acquired extensive expertise in tumor microenvironment, proteolysis and angiogenesis leading to the publication of 28 papers in peer-review journals.

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