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Clinical development aspects of gene therapy medicinal products

Joachim Scholpp
Boehringer Ingelheim, Germany

While for clinical development of Gene Therapy Medicinal Products (GTMPs), the general scientific and ethical principles of drug development and available guidelines related to specific therapeutic areas and indications apply, there are a number of unique challenges when developing a GTMP. For instance, the choice of an optimal vector system for a specific condition is critical and needs to be justified. As gene therapy is a relatively new treatment modality, and clinical experience with these approaches is limited, the benefit-risk analysis considering the target indication and alternative treatment options is of special importance. In addition, specific aspects like the delivery method, often requiring surgery or any other invasive procedure, have to be considered early. Monitoring of subjects exposed in clinical trials needs to account for the risks of the specific GTMP and for the persistence of the GTMP and/or its pharmacological effects. As preclinical data usually is less informative in comparison to NCEs or NBEs the design of a first-in-human clinical trial does have unique challenges, including the determination of the optimal starting dose and an adequate dose escalation scheme. Taking these aspects into account, a first-in-human clinical trial with a GTMP does have specific design features differing from a typical first-in-human clinical trial with an NCE or NBE.

Biography

Joachim Scholpp is a Physician with more than 20 years professional experience spanning careers in Academia, Clinical Medicine and the Pharmaceutical Industry, where he held several leading positions in drug development. He has experience in all phases of drug development across several therapeutic areas. His core expertise is in the field of CNS drug development, development of ATMPs, exploratory clinical development and Clinical Pharmacology. He leads a group of clinical program leaders within BI's Innovation Unit responsible for clinical aspects of developing new treatment modalities like ATMPs and indications beyond BI's established core indications. He is board certified in Clinical Pharmacology, board certified in Anaesthesiology and Intensive Care, holds a Diploma of the European Society of Anaesthesiology and is an authorized Physician for speciality training in Clinical Pharmacology (Chamber of Physicians, German Medical Association).

joachim.scholpp@boehringer-ingelheim.com

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