Abstract

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Design and conduct considerations for first-in-human trials of biologics

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Abstract

Current drug development research is generating many new approaches for using biologics in diverse therapeutic areas. However, the TeGenero disaster spurred a fundamental rethinking by regulators. Special rules have been developed for pre-clinical and first-in-human clinical trials. However, due to the complexity of these drugs, the severity of their potential side-effects, and their therapeutical areas, it is often difficult to plan first-in-human clinical trials. Defining relevant animal models for in vivo pre-clinical studies, calculating the initial start dose and maximal dose in human trials, and implementing appropriate safety-monitoring assessments remain a challenge. These factors should be considered in planning any first-in-human clinical trials.

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Biography

Sara Armani, M.D, pharmacist, and board-certified clinical pharmacologist, has over 18 years of experience in international drug development and has planned and conducted clinical trials for numerous pharmaceutical companies. She has held multiple leadership positions in various clinical research centers. Currently, she is Medical Director and head of the Medical Affairs Division at CRS Clinical Research Center in Berlin, Germany. She has extensive experience in planning and conducting first-in-human clinical trials. Sara holds a degree in pharmacy from the Free University of Berlin and a M.D. degree from Berlin's Charité University of Medicine. In Germany, she is authorized to train and educate assisting doctors in the field of clinical pharmacology.

