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Successful conduct of clinical trials to prove biosimilarity by defining a best fit outsourcing strategy

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Biosimilar studies need to be conducted according to ICH-GCP and international regulations independent of the markets where Biosimilars will be registered. Especially small to midsize companies (sponsors) in the Biosimilar industry are challenged with the selection of a partner, mainly a Contract Research Organization (CRO) to conduct their Bioequivalence and Phase III studies to fulfill the international requirements. Outsourcing of these studies could be a solution. CROs are generally chosen to complement the sponsor's own resources. CROs specialized in conducting biosimilar studies are able to cover the international regulatory requirements and can therefore provide practical experience to efficiently conduct the required clinical trials. However, the outsourcing process needs to be carefully prepared. A clinical trial which is not performed within time and budget has huge cost implications (time to market). Successful outsourcing starts with a predefined selection process, define clear sponsor expectations and the CRO needs to be flexible enough to understand the sponsor's needs. Both parties involved have different perspectives regarding their objectives, deliverables, values and cultures and also different levels of information, which need to be understood by each other during the selection process. Several key success factors play an important role during the selection process. Defining key criteria for the CRO evaluation, level of experience, performance metrics and others are important factors to influence the selection. Transparency and a joint understanding of the expectations, costs and assumptions are critical to avoid unexpected cost increases.

Biography

Heike Schoen is the Managing Director and Co-Founder of LUMIS International GmbH, headquartered in Germany. She has gained more than 20 years of experience in various management positions overseeing the conduct of international clinical trials Phase I to IV in different indications, within CROs and Biotech companies. She is an active member and regular speaker of the DIA (Drug Information Association) and ACRP (Association of Clinical Research Professionals). At ACRP she was 7 years a member of the voluntary Board of Trustees, and their Chairperson in 2010. She has gained Masters in Science (Psychology) and in Business Administration.

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