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Phase 1: An Upcoming Series of White Papers for Successful Early Clinical Development

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The scope and importance of early-phase clinical trials in drug development has increased over the past decade. The imperative for earlier Go-/No-Go decisions has led to more complex study designs and aggressive timelines. The increase in complexity has led to intensified pressure on sites, not only for conducting the trial but for resourcing and capabilities surrounding design, regulatory strategy, and data analysis and management. Sponsors want to maximize objectives in studies to address an extensive range of questions, often above and beyond the traditional safety and tolerability, and pharmacokinetic design of old. At the same time, the sponsor is pushing to have the studies done faster and in a cost-effective manner. With this landscape, subject safety and data integrity are key concerns. Even after several measures have been implemented to ensure subject welfare, incidents like the recent Bial study conducted at Biotrial still occur, highlighting the need for thorough preclinical evaluation and consideration for first-in-human study design.

In the absence of an FDA FIH/phase 1 guidance, early-phase studies have been designed and performed based upon industry precedence. Training for individuals performing functions in this arena has been largely through apprenticeship, evolving and scarce academic programs, ''private party'' training courses, and organizational offerings such as the DIA annual meeting and webinars.

For continued support of the DIA membership and colleagues in the field, the Clinical Pharmacology Community will be contributing a series of articles to TIRS describing the successful design and conduct of phase 1 studies. Representatives from the CRO and sponsor perspective with years of experience in early-phase drug development will share best practices and potential pitfalls.

The series, to be published 3Q2017, will define key components for study design and start-up, successful conduct of early-phase studies, essential elements of study close out and reporting with considerations regarding safety for phase 1 studies included throughout. The benefits of early interactions between preclinical and clinical teams within the sponsor organization, between the site and the sponsor, and between the regulatory authorities and the sponsor will be highlighted. The optimization of study design to achieve program objectives and reach Go-/No-Go decisions earlier in development, as well as the implementation of appropriate endpoints will be addressed. Although phase 1 is thought to be straightforward by those not that familiar with it, this setting has its own challenges and difficulties, which will be underscored. The series will address potential concerns for subject safety, sites and sponsors, and strategies to mitigate risks. White papers for the series will be submitted by leaders in early clinical development from site, sponsor, and regulatory perspectives.

Stay tuned!

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