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Re-engineering the clinical development process

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The bio-pharmaceutical industry is struggling to optimize the clinical development process and generate a sufficient return on investment. The critical factors that are challenging the operating landscape include: high protocol complexity, long clinical cycle time, rise in development cost and silo-based operating models. These challenges make it difficult to achieve enrollment targets, leading to protocol amendments and rework on the clinical development plan (CDP). Currently the pharmaceutical industry contains fragmented operating models based only on study level enrollment predictions. There is a need to re-engineer these silo-based study level operating models and create an integrated CDP operating model. This integrated program level operating model will capture all CDP scenarios, draft launch labels, target product profiles and estimated cost in a central location. It will enable higher cross-functional collaboration, planning and execution. It also helps the clinical development teams analyze multiple program level scenarios to determine the risk, cost and time tradeoffs. The integrated CDP operating model methodology signifies an innovative approach to re-engineering the current clinical development process. Combining the siloed study level enrollment predictions, enables the business to compare program level scenarios for better decision making. This approach can be an asset for high level clinical planning, boost efficiency, reduce trial spend and serve as a collaborative operating model.

Biography

Anvita Karara is a Life Science Professional with expertise in Clinical Trial Design and modeling. She pursued her Master's in Biotechnology and Management from Carnegie Mellon University, USA. She has worked prior in this area with leading bio-pharmaceutical companies such as Genentech (a Roche company) and Onyx Pharmaceutical (an Amgen subsidiary).

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