

Creating a global clinical development strategy & regulatory roadmap leveraging emerging drug development markets

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With increasing regulatory complexities, timelines and costs for drug development in mature markets, the model of drug development is shifting to emerging markets with robust regulatory systems, lower costs and faster timelines. Indeed we are moving away from a mono-centric and concentrated model to a highly poly-centric and distributed model of R&D. In such a landscape, the biggest strategic tool that companies have at their behest is the local regulatory knowledge and expertise across different markets to be able to create an optimized clinical development and regulatory strategy leveraging multiple global locations.

At Karmic, we have developed a Global Regulatory Rolodex based upon country specific requirements, drug/device categories, accelerated regulatory pathways and ways and means to shorten the development cycles leveraging co-location of clinical studies in emerging markets. We further superimpose a Multi-Centric Clinical Development strategy that provides high-level timelines and budgets as well as co-development and licensing options. This paper seeks to present a few high impact strategies as well tools and techniques for creating a global clinical strategy and regulatory roadmap leveraging emerging drug development markets. It further highlights a few real-life case examples to showcase how these strategies have been applied and the benefit they provided.

Biography

Nidhi Saxena is Founder & CEO of Karmic Life sciences Inc., a high growth global CRO with a 100+ people team and operations in US, South Africa, APAC and India. She comes from an IT background and has worked in large, global IT companies including GE, WNS North America, Wipro Technologies and Hexaware Technologies. She further won the First Generation Women Entrepreneur of the Year 2012 Award from Asia Pharma Leaders and was facilitated by the Governor of Maharashtra last year. She is an MBA from SP Jain, Mumbai as well as a Certified Master Six Sigma Black Belt from KPMG.

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