

## KARMIC LIFESCIENCES IMPLEMENTS PHASE FORWARD'S CLINTRIAL™ 4.6



**Mumbai:** Mumbai based CRO, Karmic Lifesciences has implemented Clintrial™ 4.6, an industry leading clinical data management

software to strengthen its data management back-end and ensure efficient delivery to its global clinical trial customers. As Karmic Lifesciences grew both in volume and complexity of studies, its homegrown data management solution fell short of its growing needs. Karmic needed a new data management solution to increase efficiency, enforce standardization, help manage tight project deadlines, and comply with regulatory and reporting requirements. It was then that Karmic did an extensive evaluation of industry leading solutions and zeroed in on Phase Forward's Clintrial™ CDMS owing to the systems ease of usage, ease of integration, low maintenance, and versatility. The Clintrial™ solution (v4.6) was implemented by the IBM India team with Core and Resolve modules based on an Oracle 10 g platform. The IBM team provided project planning and management, installation services, as well as training and post-implementation support. Karmic further performed the entire validation exercise, i.e., Installation Qualification (IQ), Operational Qualification (OQ), & Performance Qualification (PQ) as per GCP requirements in conjunction with the IBM team to comply with regulatory guidelines including 21 CFR Part 11. Ms. Nidhi Saxena, President & CEO, Karmic Lifesciences, said, "Implementing Clintrial early on turned out to be a wise decision – it has helped us showcase our Clinical Data Management capability to prospective global clients while improving our data management delivery and productivity substantially by automating key CDM activities, helping to manage discrepancies better and provide customized reporting to our clients. This, coupled with robust international regulatory compliance as well as great project management from IBM, will not only help us deliver our current business well but also grow new business at an accelerated pace." On completion of the implementation project, Ms. Jayashree Thacker, Associate Partner, Global Business Services, IBM India/South Asia, said, "IBM is committed to build capabilities to address some very unique business challenges faced by Indian enterprises. We are very excited about the implementation at Karmic Lifesciences and especially the fact that this solution will help them to enhance efficiency, enforce standardization, and help comply with regulatory requirements. The healthcare industry is seeing tremendous growth in India and we believe that a unique solution like this will help organizations like Karmic Lifesciences improve their operational efficiencies by strengthening their competitive edge in the market." Phase Forward's Clintrial™ benefits Karmic's CDM process by providing rapid clinical data entry and management, extensive coding and reporting features, and full CDISC support. The system further ensures easy integration with other softwares including SAS, multiple

lab management softwares and medical dictionaries including MedDRA and WHO-DD. Clintrial's easy-to-use interface minimizes the need for Oracle® database expertise on-staff, thus lowering Karmic's CDMS total cost of ownership (TCO). Clintrial™ ensures full regulatory and audit compliance for Karmic and its global customers.