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ICS: A new way to manage data

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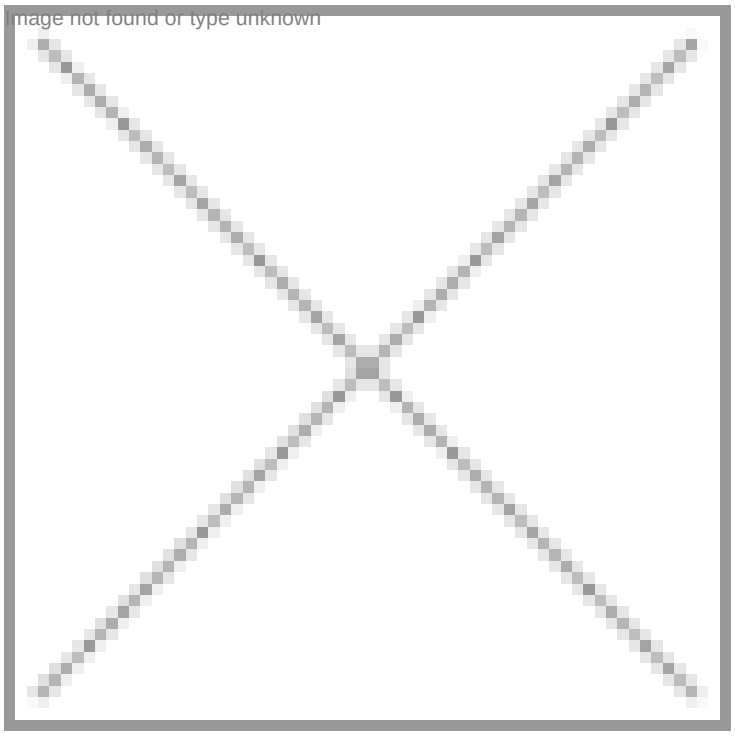

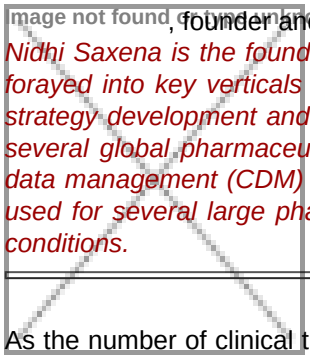

, founder and CEO, Karmic Lifesciences, Maharashtra

Nidhi Saxena is the founder and chief executive officer of Karmic Lifesciences. She founded the company in 2005, and has forayed into key verticals including oncology, neurology and medical devices. She has been involved in pre-clinical/clinical strategy development and execution of over 50 global and local trials, across multiple therapeutic areas, and has consulted several global pharmaceutical corporations on their product development and commercialization strategies. On the clinical data management (CDM) side, she initiated and developed KarmaData 2.0, a Karmic proprietary CDM software, which was used for several large phase IV studies, and is currently designing Kclinion, a state-of-the-art EDC software for Indian site conditions.

As the number of clinical trials increases worldwide, the clinical back office, with its growing complexity and costs, presents a formidable challenge. With ever-increasing volumes of data, a single, fully-integrated clinical system (ICS) is required to encompass the entire clinical workflow and unify multiple stand-alone systems into one. It is time to let some real innovation seep in, and leverage technology to seamlessly capture and integrate data from multiple mediums, in a common portable format, ensure compliance and data integrity leveraging bio-metric recognition technology, and provide real-time data analysis, auto-adaptive design and predictive functionalities.

The last two decades have seen a huge growth in the clinical trial industry. As the industry itself is coming of age, and the clinical back office is evolving, there has been no quantum innovation in the way the clinical data is captured, analyzed and reported. While a lot of hue and cry is being made out of the 21 CFR Part 11 guidelines for computerized systems, this is a basic set of guidelines, and does not provide a benchmark for a truly-evolved clinical back office system. Also, while there has been a definite movement from paper-based data capture to electronic data capture, this cannot be termed as real

‘innovation’. Hence, it is time to re-think the entire clinical data management approach and deliver something truly innovative.

Challenges of clinical back office

As the number of clinical trials increases worldwide, and the volume of clinical data to be managed grows exponentially, the clinical back office presents a formidable set of challenges. First and foremost, there are multiple disparate systems to handle different aspects of the trial. You have clinical data management system (CDMS) to handle paper CRFs; electronic data capture (EDC) to handle web-based electronic data capture; clinical trial management system (CTMS) to handle trial-related metrics and reporting; integrated voice response system (IVRS) to manage investigational supplies; SAS to handle data analysis; pharmacovigilance systems to manage safety reporting and CTD/eCTD to handle the regulatory submissions process.

Each of these systems represent a huge cost to the enterprise, and involve extensive implementation, customization and validation activities, as well as high ongoing maintenance costs. Further, there are several issues in ensuring compliance.While all systems are technically using the Clinical Data Interchange Standards Consortium (CDISC) standards, there are several challenges with data portability from one system to another, and systems integration can be a complex exercise depending on the varying technology platforms, data and table structures.

Importance of ICS

There is clearly a need for a single integrated clinical system (ICS) to handle the entire clinical workflow, from database design to regulatory submission. Such a system should integrate all functionalities of the existing disparate systems, and bring them under a common database and table structure, with unified data views and reporting dashboards. This will bring down the overall IT investment as well as provide a seamless, fully-compliant method of data management. But the question is – what else can be done to create a truly-evolved data management system?

Futuristic clinical technology

Besides what the current systems provide in terms of robust document management and workflow capabilities, electronic signatures, roles-based access and audit trials, when one thinks of a truly-innovative clinical system, he/she visualizes a futuristic, seamless and fully-integrated system that would provide the following key functionalities:

Multiple data capture channels and electronic data: The ICS would be able to accept data from multiple data capture channels including paper, fax, e-mail, electronic Case Report Form (eCRF), EDC, personal digital assistant (PDA) devices, bluetooth-enabled medical and diagnostic devices, and integrated multiple file formats such as document files, image files, medical scans, X-rays, into common file formats as envisioned by the Health Level Seven International (HL7) standard.

Biometric recognition: In order to address concerns about patient record and data integrity, the system would be able to integrate biometrics recognition technology and link all patient data to biometric scans such as finger-print recognition, retinal recognition, and face recognition.

Real-time analytics: In clinical trials, it is all about data-driven decisions. Often, the interim and final analysis related to trial data, take several weeks to complete and provide results, when it is too late to make any changes to the trial design. A system that analyzes data on a real-time basis while maintaining the data blinding can be of immense utility, wherein an unblinding algorithm can be applied to get the interim trial results quickly, and thereby adapt to the trial design as necessary.

Auto-adaptive/predictive capabilities: Drawing from the previous point, an advanced clinical system would have robust auto-adaptive and predictive capabilities, wherein, as the data gets analyzed on a real-time basis, the system would automatically suggest an adaptive go-forward trial design, and have the intelligence to provide predictive outcomes, at any time during the trial based on the existing interim data analysis.

Platform agnostic: The system would use open source technology, and would be completely platform agnostic, wherein, data could be extracted from any system in any format, and plugged seamlessly into the ICS.

The new workflow

For the system functionalities, the following envisages how the data workflow would get modified in the new system, andhow data would be captured in the integrated clinical system:

Step 1: All patient-objective medical parameters would be captured via bluetooth-enabled medical and diagnostic devices, directly onto a remote server. This would substantially obliterate the need for source data verification, and reduce chances of data tampering dramatically.

Step 2: All patient-subjective parameters including assessment scales, quality of life (QoL), global patient and physician

questionnaires, would be captured using 21 CFR Part 11 compliant, hand-held PDA devices.

Step 3: All patient lab data would be directly uploaded onto the remote server using a web-based lab interface. Similarly, all safety and pharmacovigilance data would be uploaded on a real-time basis onto the remote server using a web-based interface.

Step 4: As the system keeps receiving data from multiple sources and in multiple formats, it will keep decoding the data and creating unified patient records in a pre-defined tabular format, that can be made available on a real-time basis.

Step 5: The system would further keep analyzing the data on a real-time basis and interim results at any point in the trial would be available at the click of a mouse.

Step 6: The system would further generate auto-adaptive trial design and predictive models of the trial results using pre-defined algorithms thereby enabling researchers to make real-time changes to the trial.

Step 7: A regulatory interface would further communicate real-time trial results to regulatory agencies and keep pushing updated data files onto the regulatory server if so desired. All these files would get auto-compiled to create a CTD file.

Thus, the system would provide a fully-integrated workflow from start-to-finish of the study. The integrated clinical system is the need of the hour for the pharma and clinical trial industry, and is an innovation worth pursuing. It may change the way we view data, forever.