PHARMA AND LIFE SCIENCES TECHNOLOGY SPECIAL

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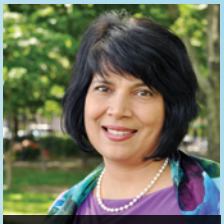
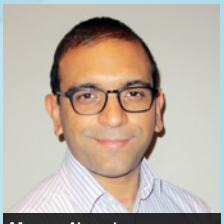
Entrepreneur of the Month



Janaki Joshi
CEO, Iris Interactive

Company of the Month



Murtuza Abuwala
CEO, Orbytel Group

MaxisIT: Unlocking Information Across Clinical Value Stream

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Maulik Shah
CEO

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CIO Tech Solution Providers to Pharma and Life Sciences Industry 2014
20 Most Promising Tech Solution Providers to Pharma and Life Sciences Industry

MaxisIT: Unlocking Information Across Clinical Value Stream

By Raj Kumar

A young and determined Maulik Shah organically built MaxisIT with only one thing in his mind, to be the harbinger of innovation and change. After earning an MS in Computer Science, Shah began working in large consulting and software companies in the healthcare sector that gave him an exposure and perspective of how drugs were developed and delivered to patients. Having picked up a keen interest in pharmaceutical and life sciences industry, he analyzed the market scenario further and found that poor technology adoption and lack of apt solutions were the reasons behind soaring drug costs, risks and untimely market delivery. This spurred the conception of MaxisIT and gave birth to the idea of building an "Integrated Clinical Development Platform."

MaxisIT is a premier provider of a true cloud-based integrated platform solution that is focused on the entire life cycle of clinical trials. Leveraging sweat equity alone, the technology strategist in Shah steered MaxisIT into a successful global and profitable business within a short time.

"Taking personal interest in building the software and delivery platform that is inline with the industry needs of today and tomorrow has helped us position ourselves as a successful organization today," says Shah, co-founder and CEO, MaxisIT. With a mission to improve the ways businesses leverage information and make decisions that impact key stakeholders and the global community at large, MaxisIT utilizes a lean and agile business practice, allowing them to achieve their objective and deliver innovative technology solutions. "Our technology allows businesses to stay agile and lean while making better and informed business decisions that will allow them to witness the progress," emphasizes Shah.

The Winds of Change

The awareness that a drug portfolio must now "carry its own weight," and the impending patent expiration of several blockbuster drugs across the industry, have increased the competitive pressures, with the focus on cost controls and decreased the level of innovation today. As an effect, companies

Maulik Shah
Co-Founder and CEO

are looking into a variety of solutions to leverage information that will help them bring their products to market quicker and also avoid the costs of trials that are not delivering results. With the acknowledgment that completed trials, in conjunction with ongoing trials represent a huge corporate asset with valuable potential that should be leveraged, companies intend to implement Clinical Data Warehouses and metadata repositories.

"The need for analytics is growing almost exponentially, as organizations look into the large variety of data being extracted, standardized, and mined, while still maintaining Intellectual Property concerns and overall data security," says Shah. "Furthermore, there is an overall sense of urgency in terms of timing. The longer a trial runs without producing meaningful information, the costlier it becomes for the sponsor organization."

MaxisIT, via the creation of CTRenaissance®–MaxisIT Integrated Clinical Development Platform–offers a variety of in-stream analytical processes that provide increased levels of information processing, timeliness, and availability. The platform is capable of quick implementation of solutions, allowing organizations to take advantage of information deployed, integrated, and aggregated in a number of formats across the entire value chain, thereby enabling swift and accurate access to data for decision-making and insightful analysis.

CTRenaissance®, the Holistic Platform

The pharmaceutical and life sciences industry is experiencing a new phase of regulation, oversight, patent expirations, mergers, and acquisitions. The traditional method of conducting clinical trials is no longer adequate in this paradigm. In order to shorten duration and reduce the cost of conducting trials while still maintaining expected levels of data quality and integrity, the metadata repository is an investment that institutions should make, but the conventional piecemeal approach, which is typically resource-intensive and time-consuming is not going to cut it.

MaxisIT has positioned their product to function as a true cloud-based integrated platform solution focused on the entire life cycle of clinical trials right from study start up through final submission to a regulatory authority. They accomplish this by having several individual components work together to streamline data collection, data integration, metadata, data standardization, data harmonization, data utilization, along with static and interactive data analysis and reporting in a secure manner. This ease of access to standardized and integrated data with appropriate controls, dramatically impacts an organization's capability to increase the number of trials run and reduce the overall time-to-market for new products in the pipeline.

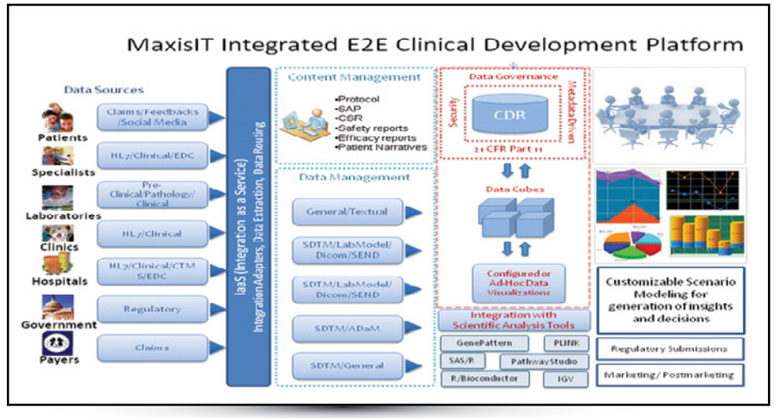
The company's CTRenaissance® offers a "one-stop-shop" for the pharmaceutical, life sciences and healthcare industry that enables the entire clinical trial activities to be deployed and conducted in a single platform and environment, streamlining the time and effort required to execute a clinical trial. This approach brings an added benefit when it comes to composite trials. The Clinical Data Management and Biostatistics functions enable

integration of data across multiple trials—allowing downstream pooling of standardized data into composite reports and visualizations. This process also combines legacy trial data with ongoing active trial data.

> **"Our technology allows businesses to stay agile and lean while making better and informed business decisions that will allow them to witness the progress"**

Rising Above the Rest

MaxisIT also builds and delivers an "Out-of-the-box Solution as a Service Model" as an alternative to traditional approaches that result in subpar success rates, inconsistent quality, non-transparent processes and increased costs in spite of offshore outsourcing. Their approach, which is manifested by their "Integrated Clinical Development Platform," facilitates a sponsor organization to leverage a multitude of functional and outsourcing features consisting of Study Setup and Support, Data Integration and Mapping, Standards Support, Clinical Data Management, Statistical Analysis, Scenario Planning and Generation, Operational Support, and Metrics Generation, that are available to be executed by a sponsor's own internal team, the MaxisIT Clinical Allied Services Team, or a partnership with a third party such as a CRO. This flexibility also allows MaxisIT to deliver outsourcing and functional services in the most effective, efficient, transparent and qualitative manner with reduced overall costs and improved compliance. Perceiving alliances as sharing



of capabilities between two or more firms to enhance overall competitive advantages and create new business without losing respective strategic autonomy, the company has a established a mature Alliance Framework across numerous other CROs and software companies.

CTRenaissance® offers a tremendous amount of flexibility in the pharmaceutical software and services arena via a series of modular solutions. These can either be selected individually or combined into an entire in-stream clinical trial delivery and conduct model in a completely cloud-based environment including, a robust global services delivery and implementation model, thereby achieving business, technical, IT, resource, and cost savings in a single package.

Some of CTRenaissance's key differentiating factors that maintain and heighten MaxisIT's position in the marketplace are its complete integration of metadata repository, which eliminates the need for an external repository; technology agnostic vision; quick deployment capability; cost containment; and its ability to offer functionality across the entire lifecycle of a clinical trial.

Content Customers

MaxisIT has built several solutions for small to large pharmaceutical, life sciences and healthcare organizations on a global scale. Some of the success stories include billion dollar pharmaceutical companies in the Oncology and Neurology space with several studies in different phases. The organizations had redundant data points leading to inefficiencies, duplication of effort, delayed decision-making and decreased productivity. The multiple vendor-based systems that were in place resulted in complex processes, longer cycle time from data capture, lack of visibility, and reliance on external resources to respond to critical and urgent business queries.

MaxisIT implemented their Integrated Clinical Data Platform in less than 7 months and provided an out-of-the-box solution for industry data standards like CDISC (Clinical Data Interchange Standards Consortium), data integration and decision support, even with the integration of over 10 different data points involving image data, genomics data, clinical data and healthcare data. The highly flexible and scalable platform allowed cost control by facilitating minimum programming, provided centralized access and tracking of data, a strong functionality for execution of repetitive code and processes, and completely integrated the processes from data to information to decisioning. The customers saw increased efficiencies and level of automation, combined with decreased costs and resource utilization. "Our customers are targeting to realize an average savings of $9 million to $10 million per year across data management, data loading, data transformation and standardization, and data review processes for an average of 100 studies per year," says Shah. Above all an integrated processes that is rather automated, will help them gain at least 30 percent to 40 percent of time efficiency across the data flow from source to decisioning.

Looking Beyond the Horizon

"The pharmaceutical and life sciences industry has arrived at an overall realization of their 'core competencies'," says Shah. "Two recent examples are the industry-wide migration from a cumbersome paper-based vehicle to data capture into today's EDC systems, and the development of clinical data repositories and integrated analytics solution from source systems to explore new opportunities and avoid risks."

As mergers, acquisitions, consolidations, patient-centric views and philosophies increase, companies will foray into new grounds that they were reluctant in the past. "MaxisIT's roadmap for the coming years is based on an ongoing evolving analysis of the pharmaceutical, life sciences and health care industry," says Shah. It consists of geographical expansions in line of sales and services delivery growth, as well as technology updates with a series of functional upgrades and enhancements that meet the evolving industry needs. Future iterations of their platform will have increased levels of automation, upgraded integration options for the completely integrated Data Hub feature, increased support for translational medicine and adaptive trials, superior study design and setup processes, and more, which will increase efficiencies while reducing costs and timeframes. "We will also be implementing technical enhancements to support increased levels of cloud-based access and larger datasets in the healthcare space," adds Shah.CR