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Healthcare leverages on doc management systems

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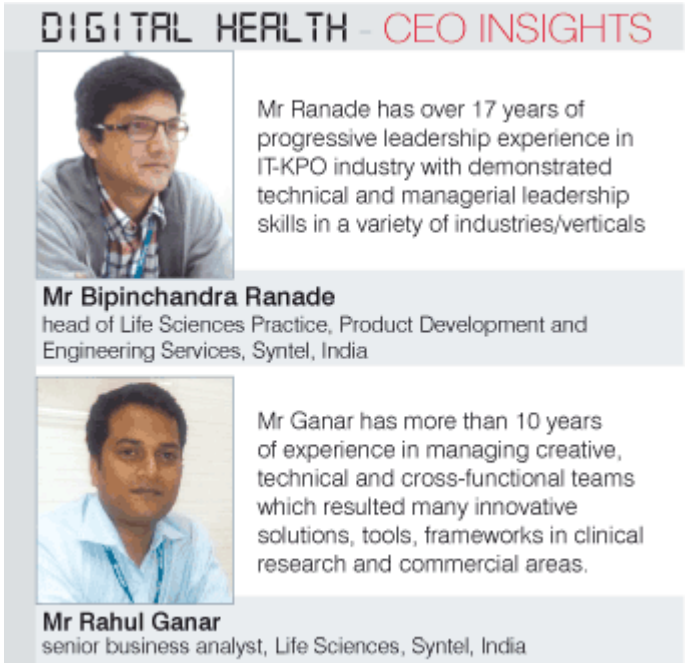

Anyone who conducts clinical trials knows that paper clinical documents and electronic processes consume staffing expenses, storage facilities and complicate compliance. Clinical Documents Management (Clinical DMS) is the practice of identifying, classifying, archiving, preserving, and destroying documents according to a set of pre-defined standards. The primary objective of a Clinical DMS team is to reduce risk through improved regulatory and corporate compliance.

Today's Clinical DMS
Many life sciences organizations have multiple content management systems, which result in costly maintenance fees and put strains on support and development resources. In a 2012 survey conducted by AIIM.Org (The paper free office), 72 percent of respondents indicated that it is harder to find information owned by their organization than information not owned by them.

Future trends
Paperless clinical trials: There are conversations about paperless clinical trials and moving to the cloud with promises of saving time, reducing costs and decreasing risk in clinical research, and many organizations are putting an effort towards it. One strategy to reduce the number of paper-based processes is to combine technologies like cloud, EDMS, CTMS with EDC, which simplifies the collection, storage and transfer of clinical trial data.

Content on cloud: According to the 2012 AIIM.org survey (Content in the Cloud-making the right decision), 42 percent of responding organizations have strategic plans to use some form of third-party cloud content management, while 15 percent have specific policies against cloud content and 42 percent have no current plans.

Outsourcing integrated IT-KPO document management services: An outsourcing vendor can provide end-to-end Document Management Services in addition to IT support. Many organizations are exploring in-house e-Document Control Centers, which function as a central archive for routing, processing and tracking of incoming records from multiple sites, along with validating and standardizing record templates.

Use of intelligence tools: In an eTMF, documents are acquired and stored electronically. Documents may be acquired from the web or email using digital signatures which have been authenticated. Digital signatures are accepted in place of wet signatures in most countries worldwide, including the USA and the EU, thereby averting the need to scan a document.
Wet-signed or non-digitally signed documents are converted from paper documents to document images by scanners or multifunction printers. Optical character recognition (OCR) software may sometimes be used to convert digital images into machine readable and searchable text. Such OCR solutions may either be integrated into the hardware or available as stand-alone software.

Designing Clinical DMS solution of future
At each stage of the Life Sciences clinical research value chain, workers need to document everything they do.

The solution should be flexible enough to adapt to future needs, trends and innovation without affecting day-to-day transactions. The most critical parameter to consider is that the solution must conform to the boundaries of regulatory compliance. The Clinical DMS should enable Life Sciences organizations to extend their core capabilities by applying project accelerators, best practices, industry expertise, migration, configuration and validation capabilities for clinical documents.

Some requirements that need to be addressed during the construction of a Clinical DMS solution are:
â€¢ Enable direct information entry by CROs - CROs should be able to upload documents directly to the web-based platform.
â€¢ Clinical Documents Management team should perform a QA role, as opposed to data entry.
â€¢ Accurate document indexing- The indexing rules should be automated in the tool as per standards onto staging and long term repository as two different entities. This enables a single window view of information for end users to perform an accurate search of the content repository. A co-existing collaborative document management platform and a more process-centric system will balance user needs and different content applications.

A Clinical DMS solution should be built on a solid business case of hard dollar savings and cost avoidance - accomplished by taking servers out of the data center, not renewing software licenses and maintenance, and by reducing costs for legacy system support resources. Success will be measured by how quickly an organization is able to decommission and replace legacy systems without affecting the day-to-day business.

Key success factors
Focus on business value and innovation: Choosing the right technology is very critical. Every organization will has an ECM solution and the IT leadership will encourage their team to utilize the investment that has already been made. One useful step is to create a comparison matrix between document platforms to help explain the requirements and the tools that can assist.

Manage risk: The solution should be robust, scalable and open ended to adapt to future trends and requirements. (e.g. the trend toward using mobile apps for most business processes)

Core vs non-core content valuation exercise: A content migration effort will require the business to pare down the amount of content. As part of this assessment, it's possible to identify documents and processes that may not be required in five years. Such documentation can be put into long term archival storage without expending the time and effort to standardize and move it into the new system.
Collaboration: A collaborative approach to designing the processes and documentation across the organization and firewall will ensure well organized document lifecycle management.

Find the right partner: Search for a partner with the right kind of experience building Clinical DMS solutions from the ground up. You will be able to derive significant value by drawing on their experience choosing the right technology, addressing change management, mitigating technology, cultural and other risks, and managing regulatory compliance.
To be effective, stakeholders must be able to access and interact with information and knowledge throughout the organization. Keep in mind that a true enterprise information integration solution does not expect all information to be captured in a single location. It anticipates an organization's unique needs and builds infrastructure to fill the information gaps. Organizations should research these requirements and utilize the expertise gained to make enterprise information integration successful on all fronts.

Some of the features that a Clinical DMS solution should posses are:
â€¢ Single collaborative platform for information and knowledge exchange, which reduces application diversity

â€¢ The ability to connect with multiple applications, irrespective of technologies

â€¢ Enables informed decision making - manage complexity, variety, quality of information and 'Boundary-less' solution - should be able to cope with a rapidly changing environment