Automation in Clinical Trials

Increasing Sophistication Requires Strategies for Adoption

As clinical trials have become more complex with more moving parts, so too have the requirements on technology and specifically on automation. Automation comes in various forms; new capabilities, integrations, and Robotic Process Automation (RPA) are examples. These technologies provide a consistent, deterministic means of automating repetitive and predictable tasks. As automation needs become more complex, the sophistication required of automation has also increased. Artificial Intelligence (AI) and Machine Learning (ML) have aided in managing this complexity through "learning while automating".

RPA enables us to quickly automate processes to the extent that the initial automation can be iterated upon, continually improving and extending the positive impact. For example, at ICON we have enabled automation using RPA across a wide range of disciplines: finance, Trial Master File loading, locking of clinical databases, and managing help desk tickets, to name a few. These processes are both clinical and administrative in nature, enabling consistency, timeliness and quality to remain as the focus.

A key challenge to the adoption of automation in clinical trials is the preservation of compliance with regulatory requirements, particularly as RPA can be continually updated as business needs change and new requirements are discovered.

Some key components of the approach described by the FDA in their Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning document, published in 2018, are:

1. The establishment of a quality system and best practice for development.
2. Demonstration of safety and effectiveness through a pre-market review so that patient risk can be managed throughout the lifecycle.
3. Ongoing monitoring of the device to incorporate risk management in the development, validation, and execution of any changes, managed through tightly controlled change management practices.
4. Use of post market real-world performance reporting to maintain the continued assurance of safety and effectiveness.

The discussion document from the FDA focuses on Software as a Medical Device. The same concepts could be applied to a validated process for the implementation of sophisticated RPA automation. Given the speed of development associated with RPA, how can it be controlled, and the evidence gathered in such a way to prove the efficacy/benefit associated with the specific automation? Similar decision points could be used to determine what level of re-validation may need to be executed based on updates to inputs, processes/algorithms and intended use.

What can individual organisations do to ensure they are compliant with regulation?

1. Embed a culture of quality into organisations where everyone is responsible for quality in application lifecycle management by asking questions at the conception stage:
   a. Can the requirements be specified in such a way as to be directly measurable and testable?
   b. Where is the data and how robust is the integration plan and design to allow for high quality including performance?
2. Expand the use of automated test tools to cover more of the application ecosystem. This enables quality to be continually verified and baked into the core of the application/solution. This will give a baseline for the software and the ability to continuously monitor the performance of the software in real-world circumstances.

3. Use a standard method of specifying requirements and their regulatory impact to identify and then focus on the critical features of applications that may present the highest risk to the patient. This will enable a risk managed approach.
4. Use technology to curate and manage product and data lifecycles. Utilising a combination of fully integrated Application Lifecycle Management tools and individual technology tools to help manage agile processes within our regulated environment has enabled rapid compliance within delivered solutions.

Central to the approach in utilising automation technologies such as RPA, AI and ML is identifying when and where we can get the most benefit and ensuring those technologies are fit for the business intended use. Successful adoption of automation relies on business stakeholders' buy-in and awareness of the associated benefits and limitations. To gain the maximum impact from any automation requires that business stakeholders are driven by the need to automate and enabled to make decisions quickly for optimal delivery.

Much of this organisational/management effort builds trust, both in the underlying technology and the capability to deliver to a high level of quality. Quality is about much more than bugs or errors – it is a measure of how well a solution matches the need of the business, which incorporates fitness to requirements, robustness, security, performance, sustainability, compliance, and of course, errors.

Engaging with key stakeholders early and often ensures that risk is minimised, identified and governed in an appropriate way, and in the context of the patient associated with the use of the AI/ML augmented automation.

Putting quality at the forefront, combined with risk and stakeholder management, ensures that we deliver fit-for-use business enabling automation in a repeatable and consistent way.

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Ronan Fox is Senior Vice President of IT R&D at ICON. Ronan's role encompasses the complete software product life cycle – product management, design, test, validation and delivery. He directs and defines product roadmaps and agile approaches to maximise efficiency and effectiveness. Ronan drives intellectual property identification and protection for clinical and financial enterprise systems. To ensure products meet stakeholders' needs, Ronan creates strategies and operating models to ensure connectivity between IT and customers for robust, sustainable and scalable products.