Can RPA transform the drug development process?

CLIENT: **ICON plc** REGION: **Global** INDUSTRY: **Pharmaceutical & Medical Devices** UIPATH.COM

ICON plc is one of the world's largest Contract Research Organisations (CRO) handling every aspect of the drug and device development process for pharmaceutical and medical device clients – from site management and patient recruitment to regulatory submission and post market surveillance.

PROCESS TYPE:
Drug development

As declining ROI puts new drug development at risk, ICON turns to UiPath to help it deploy RPA to transform its clinical trial processes.

According to Deloitte, the mean projected return on new drug research and development investments by a dozen large pharmaceutical firms fell to 1.9% in 2018– from 10.1% in 2010[1].This rate of decline will see drug development making a loss by 2020 placing new drugs and therapies at risk. ICON, one of the world's largest Contract Research Organisations (CRO), believes that Robotic Process Automation (RPA) is a key tool in supporting efforts to reverse this trend.

ICON handles every aspect of the drug and device development process for pharmaceutical and medical device clients – from managing clinical trials and patient recruitment to regulatory submission and post market surveillance. Like other organisations in the pharmaceuticals sector, the company has been introducing digital automation into the drug development process for several years to increase efficiency and reduce time and costs. However, it was concerned that traditional automation techniques were still not enough to eliminate the risk that the process could become unsustainable.

As RPA has matured, ICON implemented UiPath technology to help transform the drug development process so that important new breakthroughs continue to be achieved.

When discussing clinical trials, the company has said: “We believe that twenty years into automating clinical trial processes, the industry is on the cusp of another transformation that promises to have a profound effect on study timelines and costs. The benefit of the next wave of automation, made possible through RPA, cognitive analytics, and AI, will … be magnified when these innovations are adopted across studies and research programs.”[2]

Tom O’Leary, the Chief Information Officer (CIO) at ICON plc. emphasises the point: “The cost of developing a new drug is around $2 billion so anything that can improve the process and speed Return on Investment is essential to our industry. We started working with UiPath because we saw that RPA can eliminate the need for manually transferring data from clinical sites to trial master files, reducing errors and delays and reducing data loss by detecting anomalies more quickly and reliably than manual review.”

“I estimate that so far our saving from RPA has been in the single digit thousands of hours but there’s definitely the potential for it to take a chunk out of the average $2 billion development costs for a new drug,” he continues.

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— Tom O’Leary
Chief Information Officer (CIO),
ICON plc

How RPA benefits drug development

In its white paper *'Digital Disruption in Biopharma'*[3], ICON identifies a number of areas where RPA brings major benefits within clinical trials, including:

- Capturing routine clinical data, such as patient vital signs
- Collecting operational data, such as drug administration dose and time
- Testing data to flag safety issues, such as an out-of-range lab result
- Assessing potential data entry errors, such as duplicated or missing data points
- Detecting potential protocol deviations, such as the emergence of a non-random variation trend
- Forwarding clean data to the Electronic Trial Master File (ETMF) and alerting trial monitors to anomalies

It was this final area – updating the ETMF - that ICON first automated within clinical trials. The ETMF holds all the supporting documentation – such as staff qualifications, insurance documents, policies and procedures – to show the company has all the correct approvals to conduct the trial within a specific location. It must be up-date, accurate and complete as it is an essential part of regulatory submissions. Delays or errors in the ETMF add cost and time to gaining approval for the drug or device.

Improving the quality of the ETMF

The majority of documentation is received by email and has to be extracted and input into the appropriate areas of the ETMF. Previously, this was all conducted manually. A team received the documents, checked them to make sure there was no missing or incorrect information, logged in to the system, and updated the relevant fields. The company realised that it was much quicker and more effective to train a robot to execute the task.

"When we automated the first document type within the ETMF, we found that the robot helped us free three members of staff who could be re-assigned to the vital quality element at the end of the submissions process. To fully grasp the potential for automation, you need to know that there can easily be over 500 different document types in a single trial, and we are running over 200 trials worldwide simultaneously," explains Colin Orr, Head of the RPA Centre of Excellence at ICON plc.

"That's a huge amount of human effort. There's a huge potential for error and a lot of time. Robots can take care of a lot this automatically."

The company discovered that robots work twice as fast as humans when updating the ETMF and the result has been to reduce the cycle time for processing documents by 45%.

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Delivering error-free data management

Tom O'Leary states: "Our deliverable is data. Whether to our clients or the regulatory authority, what we provide is data. We have four pillars of data in clinical trials: operational data, safety data, clinical data and documentation. It all has to be gathered and processed correctly and everyone involved has to be confident that the data is correct and can be relied upon when submitted."

The company established its RPA Centre of Excellence in early 2019. The centre differed from most in two key ways. First, it included a validation professional as compliance is one of the most important areas within the Life Sciences sector. Secondly, it selected processes for automation not just on being rules-based and repetitive. Processes were selected where they had to be completed perfectly every time.

Colin says: "We always ask 'how important is it that the process needs to be completely accurate?'. If there's an error from manual input, is that going to be an issue from a regulatory or audit perspective? That's a key consideration as we know that a robot will do exactly the same thing every time."

An excellent example of this is the management of clinical data. During a clinical trial, a wide range of data is collected on every patient. As the trial progresses, regular checks are made on each patient and the results recorded in a Case Report Form (CRF) in the study Electronic Data Collection (EDC) system.

It is incredibly important that this information is 100% accurate at all times so it is frozen and locked as soon after a patient completes the trial as possible. The goal for any CRO is to freeze and lock all the patient data effectively the closer you get to the end of the trial to speed up final submission.

Like updating the ETMF, managing clinical data for ICON had been a mostly manual activity and a massive one.

Colin explains: "Imagine going over pages and pages of CRFs to see what information had changed and what fields in the EDC had to be updated. In two months, a clinical trial can collect up to 60,000 CRFs. The task is long, boring and repetitive leading, understandably, to human error."

"A robot can now complete the task in under 30 hours. That's compared to more than a week for a human. But we have hundreds of trials and need the clinical data updated quickly so we're talking teams of people that can be replaced by a few robots. More importantly, the data is 100% accurate as a robot doesn't make mistakes."

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By the numbers

1,000's

RPA has already saved 'single digit' thousands of hours, but only the tip of the automation iceberg

500

Automating just one document type in the Electronic Trial Master File (ETMF) frees three FTEs. There are over 500 document types per trial

45%

Robots update ETMF twice as fast as humans leading to a 45% reduction in cycle times for document processing

60k

Robots update 60,000 Clinical Report Forms (CRF) in 30 hours, compared to over a week for a human

100%

Robots ensure 100% accurate processing of clinical data

RPA drives improved compliance by delivering full auditability of robot activities

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Lower risk, improving compliance

This ability for the robot to do the same thing time and again has become a major benefit when it comes to compliance.

"It's really important that we know it's doing the same thing and we have all the evidence to show exactly what the robot has done. Every execution of the process is logged, and we can track the robot's activity unambiguously. This, again, helps us to streamline the submission process," says Colin.

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Automation is the future of work, so if you haven't automated in your company yet, you will. If you aren't the person that brings automation to your company, someone else will, so why not be that person? The upside to this market is huge because we can remove man hours from your workforce and allow you to reallocate that workforce to doing things that are more valuable to your company.

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UiPath is the RPA leader

UiPath is leading the "automation first" era—championing one robot for every person, delivering free and open training and collaboration, and enabling robots to learn new skills through AI and machine learning. Led by a commitment to bring digital-era skills to more than a million people, the company's Robotic Process Automation (RPA) enterprise platform has automated millions of repetitive tasks for organizations around the world—improving productivity, customer experience, and employee job satisfaction.

With thousands of customers and more than 200,000 community users, UiPath is one of the fastest-growing enterprise software company in history. Gartner's 2019 Magic Quadrant for RPA software recognized UiPath as an industry leader based on ability to execute and completeness of vision.[4] UiPath was also named the leading RPA technology by both Forrester Research and Everest Group, and honored as Leader and Star Performer in Everest's 2018 RPA Peak Matrix—the only vendor to receive both distinctions two years in a row.[5]

References

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