ROBOTIC PROCESS AUTOMATION IN PHARMA: THREE CASE STUDIES

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Abstract
With population getting older in the developing countries, the cost associated with Research & Development (R&D) for the government, organizations and NGOs is growing significantly from year to year. Most of the cost in R&D are spent by organizations and hence the need to halt or to stop the double digit expense growths. Automating with software robots the R&D field in Life Sciences can shift the paradigm to a patient-centric and outcome-based model that can change this industry radically, by providing in the end cheaper healthcare.
The regulatory processes in this industry are very complex and organizations follow tens and hundreds of steps until their clinical trials can hit the market. While the regulations can vary from country to country and there is no sign that the minimum level required for documentation may decrease, how the process is handled internally can change radically due to the new technologies available, like Robotic Process Automation.

Keywords
Robotic Process Automation, RPA, Machine Learning

JEL Classification
M15, M16, M19

Introduction

In this paper we will go through two cases studies resulted from implementing RPA in two leading pharma organizations. As already explained and detailed in other papers (Anagnoste, 2007;), RPA is a software solution that can be used to automate repetitive work. These leads always in (1) cost reduction, (2) quality increased for the desired outcome and (3) faster processing. From here to cognitive automation (ie. machine learning, RPA and Chatbots, Intelligent OCR it's a matter of months or maybe a few years) (Anagnoste, 2017)
Specifically, for the pharma organizations from this case study the main challenges facing were high data volumes, high error rates (which can have a big impact on the company's image), long hours spent on rework, clicks and checks through different legacy systems and, ultimately, high turnover due to repetitive work.

Literature review

In order to comply with the numerous government regulatory requirements pertinent to clinical trial, every organization must maintain and store specific documentation and content regarding the clinical trials. The information is stored in a in the Trial Master file, also known as TMF, which nowadays is an electronic storage, hence becoming electronic TMF

or eTMF. The eTMF can also comprise strategies, methods and tools used through the whole lifecycle of the clinical trial. These systems must have a (1) Digital content archiving, (2) security and access control, (3) change controls, (4) audit trails and system validation.
One of the main components of the eTMF process is the Green Light Form (GLF). Prior to a clinical test going live a set of more than 20 documents have to be issued and signed by different parties as a demonstrations that various checks, steps, activities, and approvals have been carried out according to the state regulation, so that the company can receive the green light on starting the drug test and recruiting the first patience(s).
Summarizing, the GLF is a checklist of these documents. The GLF checklist itself is a document that needs to be completed and signed prior to site initiation. Currently the completed GLF document is printed, signed ("wet" signature), rescanned / uploaded and saved to the eTMF.
The processes are complex and not 100% standardized, with many variances and use of multiple systems from study to study, making it an ideal candidate for automation. In Table no 1 I summarized the process complexities, consequences and the automation opportunities:

Table no. 1. Process complexities, consequences and automation opportunities

#	Complexity	Consequences	Automation opportunities and benefits
1.	Not structured approach though multi-countries.	Each time a variation between countries arises more checks and different documents are required	- Process redesign - Document management - Audit trail generation - Multiple systems integration - Less errors - Better compliance - Time saved
2.	Broad volumes of information (*ie. clinical trials can generate more than several hundred documents*)	A lot of work and constant monitoring from the project team	
3.	Regulations becomes more and more complex	The study teams face more and more regulation through increased compliance checks in varieties and volumes	
4.	Interacting with multiple applications and databases in developing the studies	Hard to track and communicate the study progress at any point in time	

Source: Author's research

In this case study our team automate it 10 out of the 15 steps in the GLF process including document tracking and completion, feedback collection and final document posting, as seen in Figure 1:

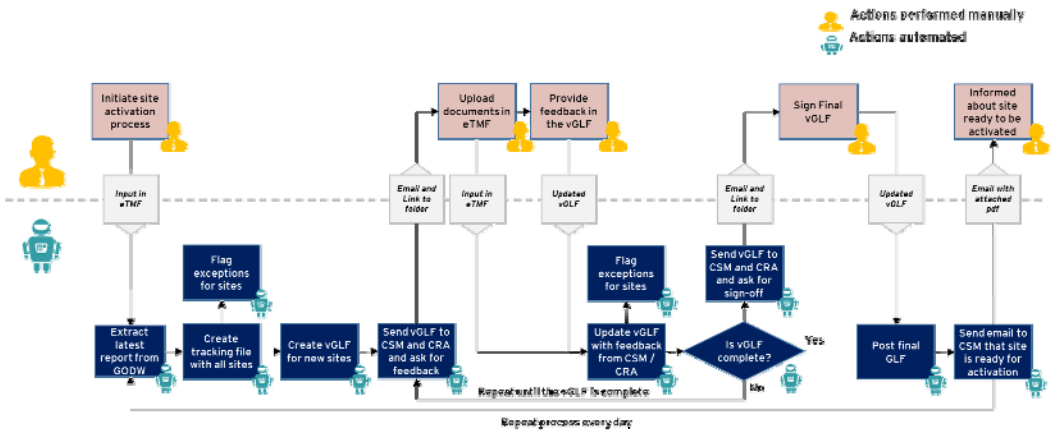

Fig. no. 1. Global life sciences in an organization

Source: Author's results after automating a process in pharma

During the process automation the engagement team role was to improve compliance and to provide a secure way of centralize documentation. As a result, a process redesign was necessary so after a carefully process decomposition and a business cases provided at the end.

The results in this case were pretty impressive which can be summarized by better compliance at reduced costs:

- Increased support for study's document management team
- Increased compliance in eTMF and GLF process
- Improved new process
- Better metrics tracking

On a second case study performed to another large pharmaceutical company, the client needed to increase compliance by automating *"check, chase, escalate*" steps for required documents in the eTMF. As a result, after we deployed the robots requested by the client the following happened:

- Consistency throughout all study escalation procedures
- Easily adaptable robot to new business changes which allows the business to adapt to new regulations and compliance requirements
- Diagnostics for continuous process improvements

In the R&D activities in Life Science there are multiple areas that can be the perfect clients for automation. Beside the area of document management, here are the additional areas:

1. Pre-emptive warning of due documents – check the due dates of each document and inform the project team accordingly. Penalties and huge image damages can be avoid.
2. Consolidate status reports – with all rules based on predefined criteria
3. A chatbott – that can interact with the project team increasing both efficiency and quality
4. Website documents activation – by initiating the activation procedures
5. Document retrieval – by retrieving specific documents in due time from different sources (*ie. systems*). A robot can have his own username and password, but ensuring also an audit trail.
6. Document upload – sending all documents to be uploaded to the robot and letting it to do the correct upload in eTMF
7. Document archiving – verifying the status of each document one by one and archiving them accordingly
8. Patience tracking – input patience information between systems

In the third case study a leading global pharma company asked our firm to conduct a RPA Pilot in Switzerland in order to automatize the Pricing process in the Finance and Controlling department. Our team used UiPath, a recognized leader for research companies (Gartner, 2017) and developed a robot in 6 weeks automating all the manual work in this process. The main systems/applications with whom the robot interacted are the following:

- Internet Explorer
- Microsoft Sharepoint
- SAP
- Microsoft Excel
- Microsoft Outlook

Updating prices to tens and hundreds of products and services is boring, time consuming and prone to error. On top of these the attrition rate in the Finance & Controlling department has suffered also, people leaving mainly due to ample repetitive work.

A Process Diagram and User stories were developed by the development team, but also they proposed a new process design (*ie. process reengineering*). The client accepted all the proposed changes because those were reflected in qualitative savings, such as:

a) Increase in accuracy – the error rate to prices fell to 0%, which released the employees from this stress
b) Consistency of the process outcome – due to the fact that many people had different methods of updating the prices now a single and uniform method is applied across the organization
c) Staff retention – allowing people to focus on things that really matter with high-value added made the attrition rate to decrease to 0% in the following months after the implementation
d) Reliability – the robot got very fast the reputation of being trustworthy or performing consistently well
e) Independence – while each key geographic location had to wait the updates from the headquarters now can do it independently

The automated process reduced the processing time for each pricing list from 25 minutes to only 6 minutes, a reduction of 76% in terms of time, as reflected in the *Figure 2* below:

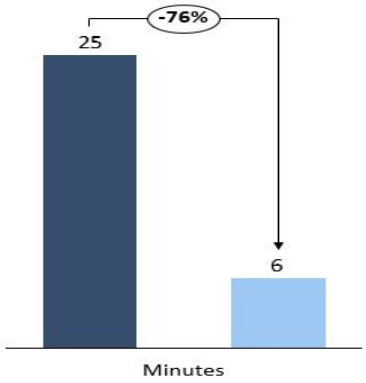

Fig. no. 2. Pricing updates duration in minutes (before and after the automation)
Source: Author's calculation

Given the several pricing lists the automation resulted in more than a million EUR in savings, while the process itself was 100% automated – with no human intervention at all.

As a result the client requested additional process to automate, while developing also a Center of Excellence (CoE).
The CoE is an alternative to contracting external consultants in performing future work. In the RPA case this work means future automations and maintenance services. Before enrolling into developing a CoE an organization must first ensure the following pre-requisites:

- Has already implemented successfully a Pilot
- Has developed all the procedures and means to attract, train and coordinate a future team of RPA developers
- Has put in place the right infrastructure on which the RPA team will work

In the *Figure 3* one can observe the path to Center of Excellence:

Fig. no. 3. RPA path evolution
Source: Author's developed framework regarding a Center of Excellence

Its main purpose is serving the internal clients in the organization by helping with (1) Process assessment, (2) Process prioritization, (3) Development and Maintenance, (4) Operation support, (5) technical Support and (6) Training. The aforementioned services make the CoE scope.
After the implementation a CoE will have also a crucial role in creating the (1) Recruitment guidelines, (2) Assessing the candidates' skills, (3) Training the team and the business partners, (4) Creating methodology on working with robots and (4) Coaching the team.
As a result, in *Figure 4* we can see the stages in setting up a CoE:

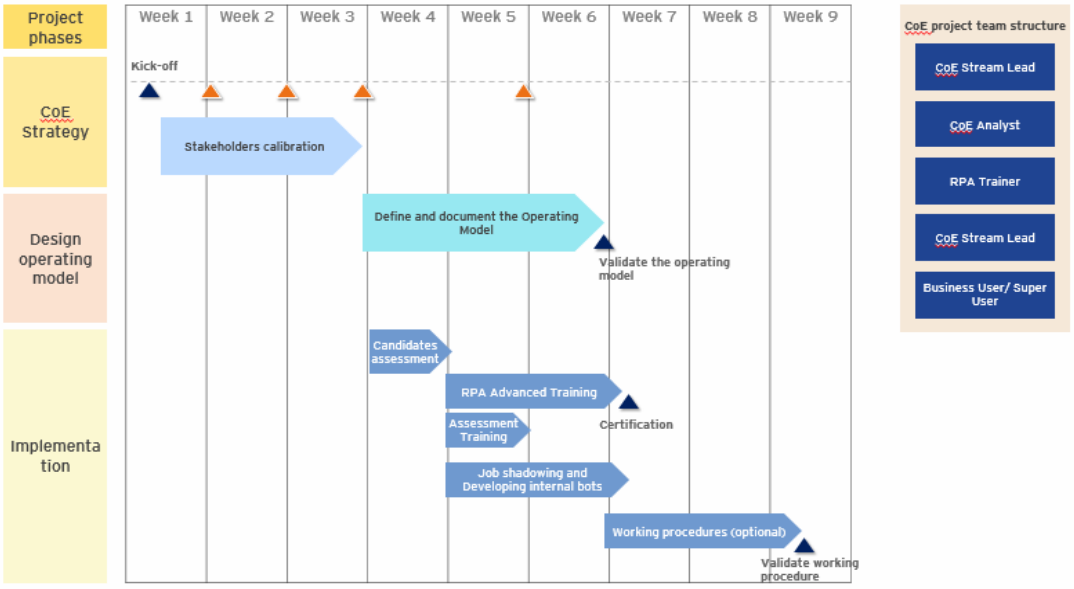

Fig. no. 4. Typical phases for setting up a CoE
Source: Author's project map to implement a Center of Excellence

Conclusions

The cases studies presented in this paper should lay ground for:

1. Future automation in the pharma industry, as already seen in other fields (Feranzzi, 2015)
2. Reduce costs for doing research, which can be translated further in lower costs for services and products to the final client. Only in USA the medical services are expected to increase with 5.5% per year between 2017 and 2018 according to Center for Medicare & Medicaid Services (CMS, 2017)
3. Begins a new working collaboration model: robots and humans (Chui&all, 2012)
4. Allows the employees to focus on task that require complex problem solving, critical thinking, creativity and people management (World Economic Forum, 2012)
5. Reduces the costs associated with attrition and job satisfaction
6. Puts in perspective the next phase after implementing a Pilot, and that is, developing a Center of Excellence
7. Presents also a success story for a little Romanian software company with 10 employees in 2013 to more than 700 employees and 10 worldwide offices. Like always the leadership at top applied the right strategy (Bratianu & Anagnoste, 2011)

2018 and going further will require more and more jobs where humans work side by side with robots, from which the organizations, governments and individuals alike will highly benefit.

The future is already here and will shape everything: cultures, behaviors, and way of doing business yet laying the ground for what is already know as Intelligent Automation.

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