

The Tortoise versus the Hare – And the Winner is...

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ABSTRACT

This paper focuses on the successful enterprise-level implementation of a complex technology (system and service) outsourcing project in 2015, within a collaborative Pharma/CRO (Clinical Research Organisation) partnership, and reasons why the delivery approach worked.

The authors of this paper played key roles in this project, and will feed back their perspectives on the team's delivery method, and why this is a more important consideration than the technology itself.

INTRODUCTION

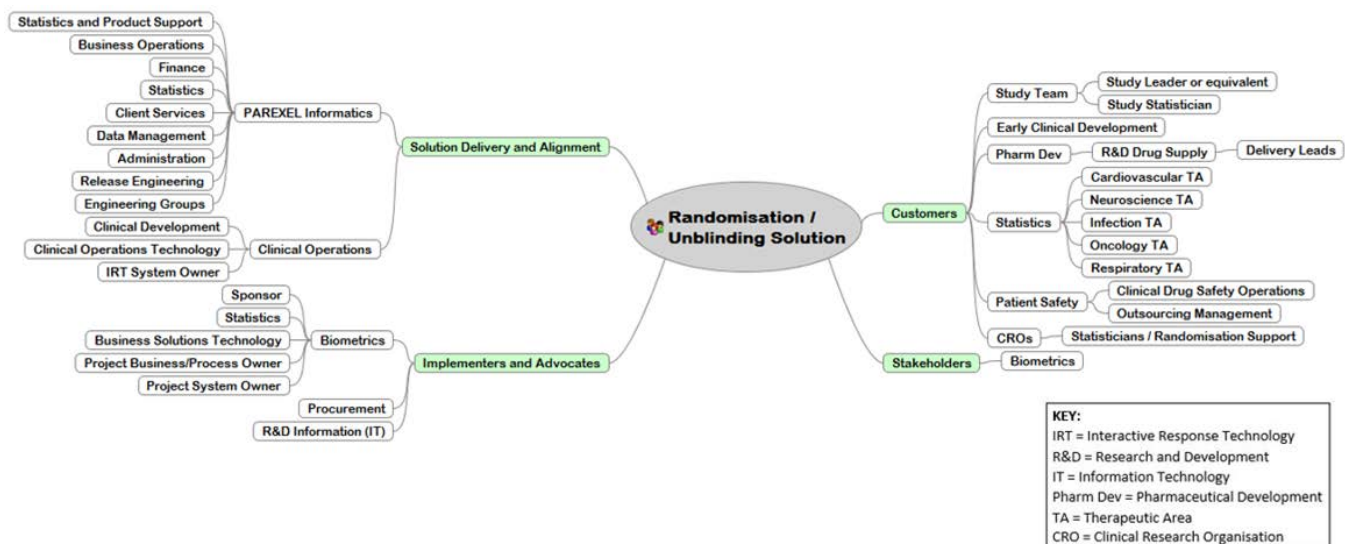
In a legacy environment, updating a fully integrated, tier-1 enterprise application (from in-house to external) is a considerable undertaking. The underpinning for this project's success was a process model application, using comparison to Aesop's Fable of 'The Tortoise and the Hare'. By taking a considered and methodical approach, 'inspecting and adapting' throughout, this set the foundation for speed and efficiency gains downstream; towards agility in delivering a major milestone – gaining regulatory approval in the shortest time with the lowest expenditure.

BACKGROUND

A sponsor may outsource tasks such as the generation of randomisation schedules (randomisation design and scheme) and provision of unblinding services to a partner company, in order to allow their biostatisticians to focus on core tasks; thereby removing the need for the sponsor to expend resource on maintaining and improving existing tools. This outsourcing may require a new process and/or system to be implemented, both within and between companies.

The aim of this project was to implement a new, scalable and high quality randomisation/unblinding technology solution (system and service) for AstraZeneca, by PAREXEL Informatics, within a truly collaborative framework for partnership. Due to the complex and comprehensive nature of this project, it required numerous concurrent joint AstraZeneca/PAREXEL Informatics workstreams, to take into account all interdependencies between the AstraZeneca/PAREXEL Informatics' functions affected, their roles and responsibilities and the stakeholders/customers impacted.

The breadth of scope and impact is shown in the project map below:



SCOPE AND HIGHLIGHTS

This paper will discuss aspects of this project's implementation phase in detail.

Working in a Partnership between Companies

AstraZeneca and PAREXEL Informatics had an existing and established relationship, with PAREXEL Informatics being the default Interactive Response Technology (IRT) provider for AstraZeneca. This was further expanded, creating a more open and trusting partnership within the project delivery model. This meant AstraZeneca and PAREXEL Informatics working on any challenges together, so sharing the burden and finding a solution as 'one team'. Joint working led to avoidance of duplication of effort, so reducing redundancy, for more effective collaboration. One key benefit of effective collaboration was ensuring optimal and fully transparent pricing strategies. We also connected with our peers at an inter-company level, which created an opportunity for our team members to benefit from feedback, as part of their 'on-the-job' development. This led to PAREXEL Informatics feeling empowered to provide solutions for the process, and learn more about AstraZeneca teamwork.

Stakeholder/Customer Management

Achieving alignment to what was a change in AstraZeneca's strategic focus required a dedicated effort to secure continued 'buy-in' via customer interview, analysis of their feedback, ongoing support and highlighting improvements in the new randomisation/unblinding solution. Too often, the users of a new system/process are treated as passive recipients of change. Our focus was to solve the problems and needs of the people who were going to use this new technology solution. Part of this effort involved an assessment of current and future states, as well as a detailed gap analysis. For example, ensuring user friendly access for Patient Safety unblinding in the new randomisation/unblinding solution required an understanding of their work, as well as understanding of the need of their role. Hence, strong change management capabilities were important. 'Lessons learnt' included bringing in peripheral teams earlier, to optimise the opportunity for Subject Matter Expert (SME) input (for example, to ensure the most efficient business process flow). Despite the regular stakeholder interactions, there were still challenges in place around ownership of some process components because it was a major change. This highlighted the importance of including customer representatives as stakeholders in the solution being developed, as a means to facilitate 'buy-in' from their peers.

Resource/Project Management

The core project delivery team (joint AstraZeneca/PAREXEL Informatics) was relatively small in size, to allow availability of expertise from both AstraZeneca and PAREXEL Informatics when it mattered. Having this shared perspective supported these relatively smaller multi-disciplinary teams working together, and improved their decision making.

'Lessons learnt': As a result of having a small, core team, one disadvantage that was encountered was the relatively larger impact on individuals' availability for BAU (Business As Usual) within their own individual function. This highlighted the importance to consider 'ring-fencing' dedicated resource, if possible.

Implementation Road Map

The business process journey was a challenging one, with numerous moving parts, including multiple concurrent workstreams. Each of these parts needed to transition in a coordinated way to the new technology solution for randomisation/unblinding, all while ensuring that the services continue to function during the transition (via the existing randomisation/unblinding technology solution in AstraZeneca). Linking up of functions also meant not working in discrete 'silos', but at a 'bigger picture' level. This allowed joint agreement between AstraZeneca and PAREXEL Informatics on this project's implementation strategy. It also facilitated better cross-functional risk analysis – for example, if the file format of the randomisation scheme for the AstraZeneca drug supply group does not meet their requirements, this can delay treatment packaging and therefore dispensation to patients. Or in order to prevent inadvertent unblinding, ensure that the appropriate colleague or group receives the unblinding notification (this reports the actual treatment assigned to patient).

'Lessons learnt': Despite best efforts, post-implementation feedback highlighted some gaps in requirements due to differing interpretation of the specification/process – for example, in the receiving of alerts triggered by critical transactions (defined in the process map), recipients had been defined to receive these. But later, they deemed that the alerts were not appropriate for that group. This highlighted the importance of validating tacit approvals of a process map by all groups, ensuring that the requirements and impact are discussed in detail. Piloting all aspects with discussions around real-life scenarios would help mitigate.

Process Model

Consider the following analogy:

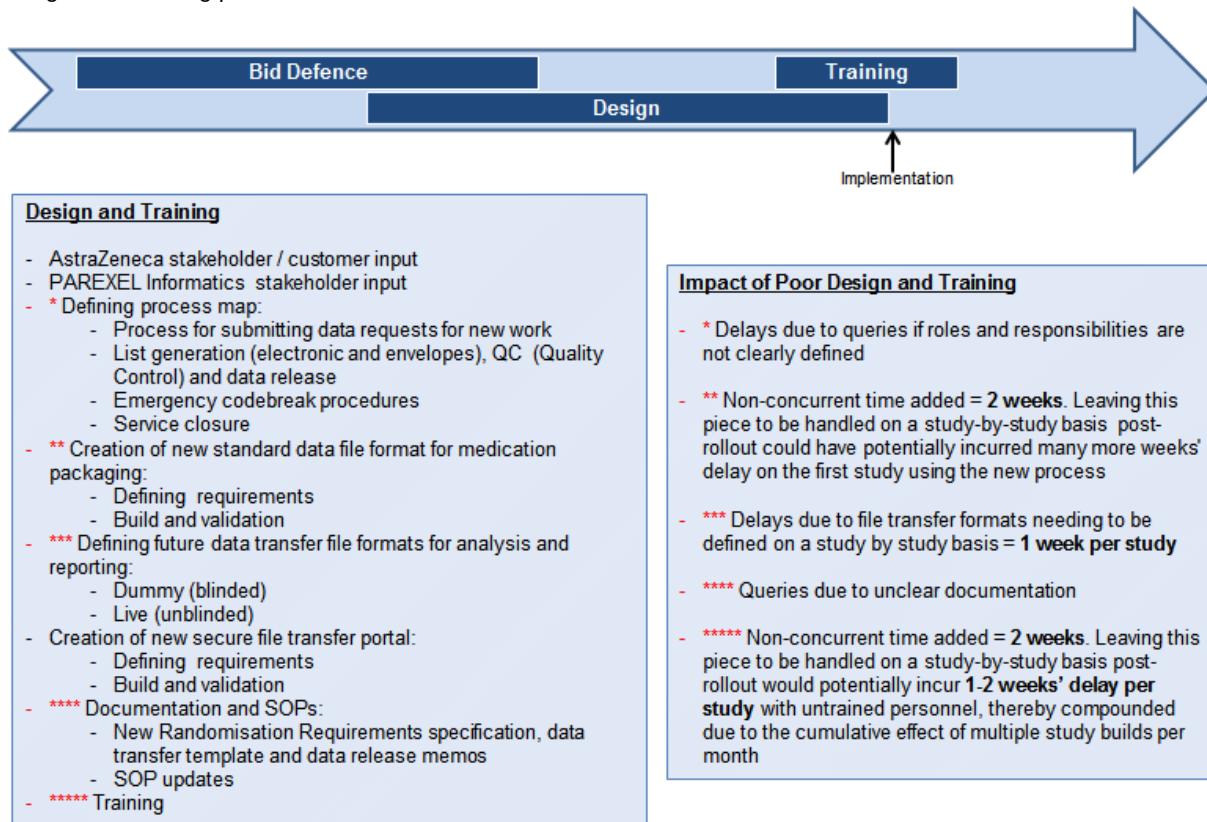
A tortoise and a hare enter a race. During the race, the tortoise stops for regular breaks to chat to his turtle colleagues to get feedback on his running technique, and to ask the race stewards if his map is still current, making adjustment to his course as needed. Meanwhile, the hare races on alone, and soon crosses what he ***thinks*** is the finishing line, only to realise that the race had changed course several times, but he had not stopped to ask or take notice. He is so far off route that by the time he back-tracks and corrects his mistakes, the tortoise is celebrating reaching the finishing line.

Now consider the implementation of a new process model:

For this randomisation/unblinding solution, the model required ongoing iterations around the re-design of process maps. The process required agreement across multiple teams, and even organisations (AstraZeneca and PAREXEL Informatics). This was a continuous process and there were several cycles. The core team met almost weekly to review the process maps and to incorporate stakeholder feedback. As a result, updates were made to the process maps after every meeting. We avoided the tendency to overestimate short-term gains in order to deliver sooner and reduce costs. Instead, we focussed on taking the time to implement major changes in workflow and process re-design.

Both the Design and Training phases were originally implemented with some overlap, to save time. However, with the 'inspecting and adapting' of the process maps, this led to an estimated extra two weeks being spent on the 'Design and Training' phase overall. An example of where this additional time was spent was on the theoretical process flow work. This included more robust testing of the scenarios for data transfer 'piloting' in drug supply. If the two extra weeks had not been factored in upfront, this could have had a much bigger downstream impact if that time had been required at study-level instead; especially as several studies per month are being set up in this randomisation/unblinding solution.

Design and Training phase:



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So far, the data indicates that there have been no delays associated with the provision of medication packaging files, and as such the two additional weeks spent upfront during this project's implementation phase was time well spent.

'Lessons learnt': For the component of defining future data transfer file formats for analysis and reporting, studies requiring 'masked' transfers have resulted in additional discussions on a study-by-study basis. This again highlights the importance of validating tacit approvals of documentation by all groups, ensuring that the definition and implications are discussed in detail.

This project's relationship model of trust between AstraZeneca and PAREXEL Informatics meant that 'pre-race' preparation could commence even prior to contract signing. This was reflected by the 'Design and Training' phase starting before the 'Bid Defence' (selection and confirmation of PAREXEL Informatics, as this randomization/unblinding solution service provider) period ending. The effect of this was open sharing of information between AstraZeneca and PAREXEL Informatics, prior to and throughout the design stage.

CONCLUSION

Our aim was to achieve process standardisation (in randomisation and unblinding), across clinical trial phases; streamlining efficiency and consistency to improve productivity in the long run. In all of this, ongoing commitment and flexibility were the drivers for success.

Since 'Go-live', we are seeing the initial indicators of benefits realisation, via positive feedback and meeting KPIs (Key Performance Indicators) in the first two quarters of 'roll-out' and use. Also, it has provided the opportunity to implement more sophisticated randomisation designs. Therefore, we can gauge so far that the investment is starting to pay off. This is a result of key execution of the following:

- Through the strong stakeholder/customer management, being able to implement the changes in the business enabled by that system and process (as the new technology solution for randomisation/unblinding)
- A 'right first time' approach of minimising downstream impact of delay and re-work
- Being facilitated by a truly open and trusting partnership between AstraZeneca and PAREXEL Informatics
- Visible endorsement and sponsorship from AstraZeneca's senior leadership

Putting patients first and not allowing current constraints and legacies to be 'obstacles' are critical to success. It is important to maintain a holistic approach of integrated, cross-functional working, and not focus solely on the technology itself. Hence, by aligning to the PhUSE theme of 'Fast Track to Approval: Speed and Efficiency', implementing a new technology solution (system and service) via a methodical and considered approach leads to speed and efficiency downstream. For this project, this is quality randomisation/unblinding delivery, for the ultimate aim of faster regulatory approvals. This can be further realised by being responsive to change, i.e. working in an agile and flexible way throughout.

Be an 'agile tortoise'!

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Your comments and questions are valued and encouraged.

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