



Migrating a large users base from multiple legacy systems to entimICE-AZ: issues and lessons learned

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Introduction



Introduction

- In late 2013 AstraZeneca (AZ) launched the Integrated Clinical Analysis and Reporting Environment (iCARE) project, with the aim to redesign the existing landscape
- Included in the project was the migration of active studies from a number of legacy systems to a modern Statistical Computing Environment (SCE)
- The product selected was entimICE®, by the German software vendor Entimo®, and the customized installation was dubbed entimICE-AZ
- Another component was a central archival location for historical and completed studies, the Clinical Trial Data Storage (CTDS)



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Planning



Planning

- I joined AZ at the beginning of 2016, when all the project components had already been designed and partially implemented
 - No personal involvement or first-hand experience in the previous phases
- Internal presentations I attended soon after joining mentioned that entimICE-AZ and CTDS would replace up to 17 existing systems/file storage areas
- The new SCE was installed in a Windows environment



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Implementation



Implementation

- It was decided to use the services of a third-party implementation partner
- The application was hosted externally to AZ, IT support was provided by the external partner and all queries had to go through their ticketing system
- This decision was based on cost considerations
- Three main versions have been released until today, with the last one in early 2021 bringing many fundamental changes, among them
 - entimICE was updated to version 4.4 and installed on AZ servers running Linux
 - IT support was moved in-house
 - Product support was provided directly by Entimo
 - Training material and business process documentation were completely revised
 - A new tool to collate outputs into bookmarked PDF files was developed internally



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Main Issues



Main Issues Training

- After a few train-the-trainer sessions, training was administered by internal staff, with no substantial experience of the system
- Training material was provided by the integration partner, but did not cover sufficiently new aspects later revealed as bottlenecks
- The move to Computer Based Training released some resources, but removed any interaction between trainers and trainees, ultimately lowering the standard of the training results
- Several actions were taken in response:
 - Training material was completely revised with entimICE-AZ 4.4
 - Weekly Help Clinic calls were established, lately regularly attended by an Entimo representative
 - An MS Teams chat and dedicated web pages were created for offline discussions and documentation storage and organisation
 - IT created a specific knowledge base, covering the more technical aspects like issues with remote access for non-AZ personnel and hung Citrix sessions



Main Issues Business Processes

- The documentation initially provided with the new system, apart from the generic entimICE user manual, consisted of three SOPs and two guidelines
- This proved quickly to be insufficient to keep process variability at bay
 - Users were left to decide how to adapt their existing ways of working to the new environment, with no clear directions on which were the new capabilities and limitations and how to exploit or avoid them
- Over time more and more documentation was developed, mostly of the 'how-to' type, with priority given to topics which were indicated as major pain points by the user base
- As mentioned earlier, a full rework of these documentation was performed as part of the release of entimICE-AZ 4.4



Main Issues Programming Environment

- The new system had all the characteristics needed for a modern GCP-compliant SCE, including an integrated audit trail and pre-defined, separate locations for development work and final runs (but not validation)
- In theory programs could be written and run in SAS, R and S-Plus, but only SAS was fully usable from the beginning
- A set of SAS macros to initialize the programming environment in a consistent way were made available only after several months
- A commercial tool designed to help with the production of outputs using SAS was available, together with a set of template programs to produce outputs heavily based on it, but the uptake was minimal
- A validated R environment has been released recently, but it is still missing a number of common packages which will make it usable



Main Issues System Support

- The choice to use a third-party vendor as implementation partner, linked to the lack of internal knowledge and several teething problems, created huge communication issues with the software vendor
 - A sort of Chinese whispers game ensued, where the original message was turned into something else along the way
- Sometimes long-standing support tickets were closed without the issue being resolved and the users being informed
- In several occasions the system remained unreachable for a few days at a time, seeding distrust about its reliability among the user base
 - Senior management requested the creation of a Business Continuity Plan (BCP) solution, which was released roughly at the same time as entimICE-AZ 4.4
- The situation changed radically with entimICE-AZ 4.4, when IT support was moved in-house, and an internal ticketing system was adopted instead of the external one used initially



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Current Situation



Current Situation

- Six years after global release, there are more than 1500 trained users, and almost all clinical projects have been migrated to entimICE-AZ
 - One legacy system is still active, but is planned to be decommissioned in early 2023
- The introduction of entimICE-AZ 4.4 proved to be a game changer
 - System reliability has increased enormously, and there was never the need to use the BCP solution due to entimICE-AZ performance
- I was part of a team who supported the successful migration to entimICE-AZ of the staff (and study data) of a small company
 - Due to the availability of updated training and process documentation, as well as experienced internal support, we observed fewer issues with the effectiveness of the training than in the past



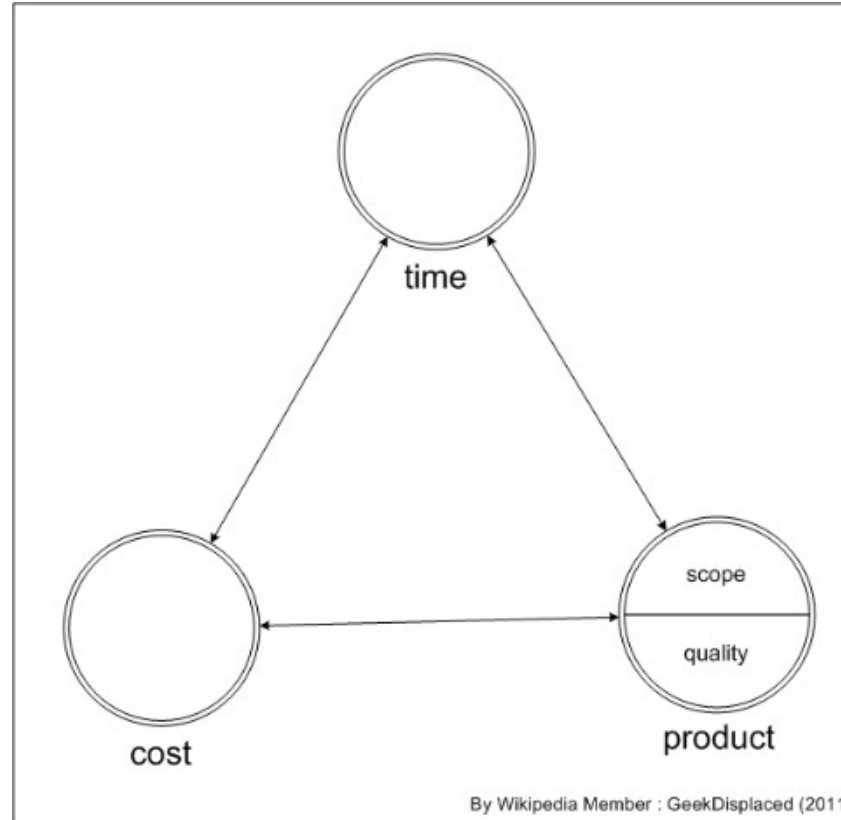
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Critical Aspects



Critical Aspects Introduction

- Every plan should be drawn keeping in mind the iron triangle principle: "Good, fast, cheap. Choose two."



- Some of the aspects I consider critical in similar occasions are illustrated in the following slides



Critical Aspects Training

- If no relevant experience is available within the company, proven external expertise should be brought in to help plan and support the migration
- Training material should highlight and discuss the basics of the new system, e.g., GUI, folder structures, naming conventions, navigation, system roles, etc., but also both similarities and differences, as well as the implications of the latter for common activities
 - In the case of entimICE, most users are still completely baffled by the role played by and how to use DataAccess/DataRead links
 - The consequences of SAS code being executed not 'as is' anymore, but sandwiched between `pre- and post-execution code, have led to some programs not running as expected in some situations, like

```
ods tags.rtf file='...';  
proc report;  
[...]  
run;  
ods rtf close;
```

- This discrepancy creates empty RTF files in entimICE



Critical Aspects Business Processes

- Process documentation should be developed together with the system architecture, then refined and finalized during the pilot phase
- Best practice detailing the recommended usage of the new system should be provided to the users from the very beginning, covering at least the basic day-to-day tasks
- While SOPs are fine to describe high level processes, devil is in the details so how-to's and user manuals are needed to direct the users
- These SCEs deal with Personal Data, so identification, analysis and documentation of integrations with other systems, both upstream and downstream, should be performed as early as meaningful
- This was a summary from my previous experience

NEW SOPs, WORK INSTRUCTIONS

- Business process re-engineering
- 100 controlled documents created/reviewed/revised
- 13 SOPs
- 20 Work instructions + 6 related documents
- 52 Forms, 7 Specifications, 2 Templates



Critical Aspects System Support

- Interacting directly with the system vendor, even if more expensive in some cases, allows a more effective and unfiltered interchange between the users and those with best knowledge of the system
- This reflects on the quality of the training, both in terms of trainers and material provided
- The vendor could suggest which details should receive special attention, like a standardised folder structure specifically designed to implement automation more easily
- Quality should be built into all processes from the beginning, including robust, thorough risk assessment and change management processes
- Data integrity, as well as traceability, must be maintained
- A pilot phase allows checking the actual viability and effectiveness of the choices made, allow internal staff to start gaining hands-on experience and possibly be able to apply minor changes before the global release



Critical Aspects System Support

- A clear distinctions should be drawn between active studies, which need to be fully migrated, and historical and completed ones, which can be archived 'as is'
 - Since migration involves in most cases a full remapping of all the study objects, reducing the scope might require less resources
- Proper levels of dedicated resources (Business, IT, etc.) need to be made available, not only for the design and implementation phases, but also for the long-term maintenance one
- Last but definitely not least, stakeholder expectations must be properly managed, especially in terms of budget and timelines



Critical Aspects Programming Environment

- Today users expect a modern SCE to support a number of programming languages, the most common ones being SAS, R and Python
- Due to the overhead due to the built-in regulatory compliance checks and balances, the internal editors might not be the best choice for intense code development
 - Secure ways to interface with tools like SAS Studio or R Studio should be investigated and provided at least to power users
- The adoption, maintenance and enforcement of non-proprietary clinical data standards is paramount to fully exploit the automation capabilities provided
- These standards should be paired to validated, reusable programs and macros, covering the creation of most SDTM domains, common ADaM ones and outputs common to all studies



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Conclusions



Conclusions

- The migration from a legacy system to a new is always a complex one, especially when the former lacks many of the capabilities of modern environment, and when the number of source systems increases, so does the complexity
- There are many aspects to be taken into consideration, some less obvious than others, but at least the most critical ones must be identified beforehand and properly addressed
- Not much has changed in 10 years, and the conclusions we drew then are still valid today

KEY CONCEPTS APPLIED AND LESSONS LEARNED

- It always takes more time, effort, and people than you originally think
- Allow for thought time and trial-and-error when trailblazing
- Dedicate people to the project instead of trying to work on daily activities in parallel
- Bring in expertise when needed
- Lay out the project ground rules early and enforce them
- Establish a common project-oriented mindset among team members
- Fully integrate vendor and other external project team members
- Recognize and address the challenges of a geographically dispersed team
- Manage and prepare people for change



Questions?



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