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Analysis and Reporting Toolset (A&RT): Lessons on how to develop a system with an external partner.

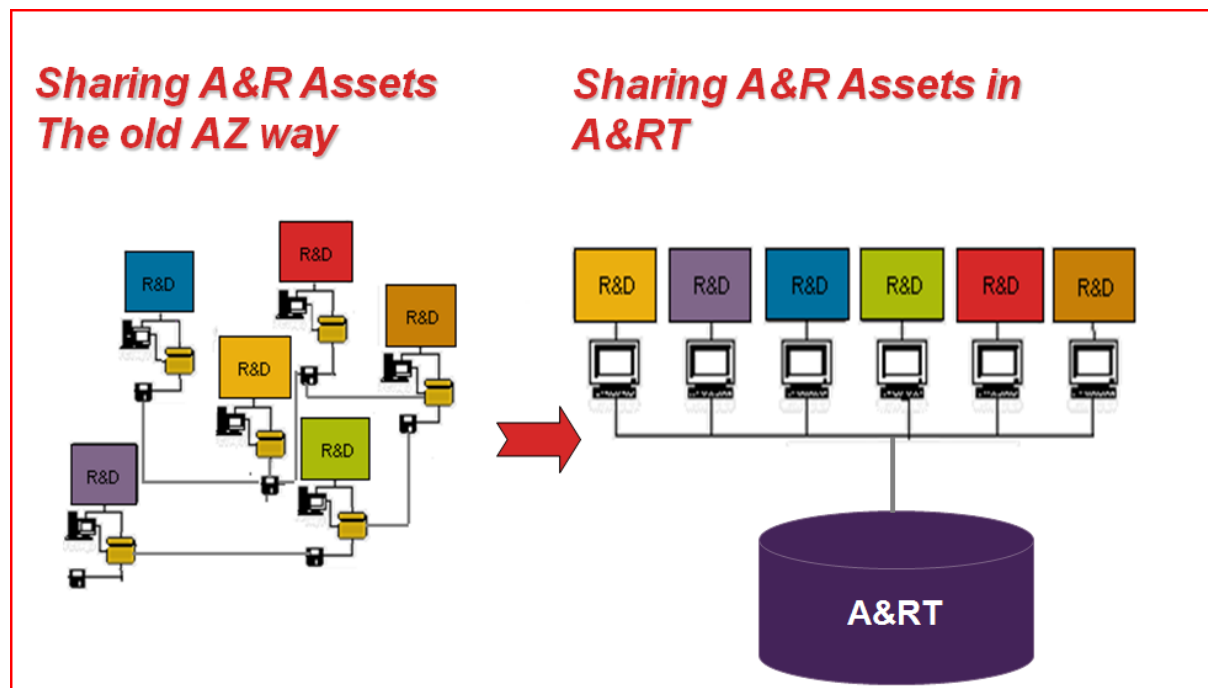
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Abstract

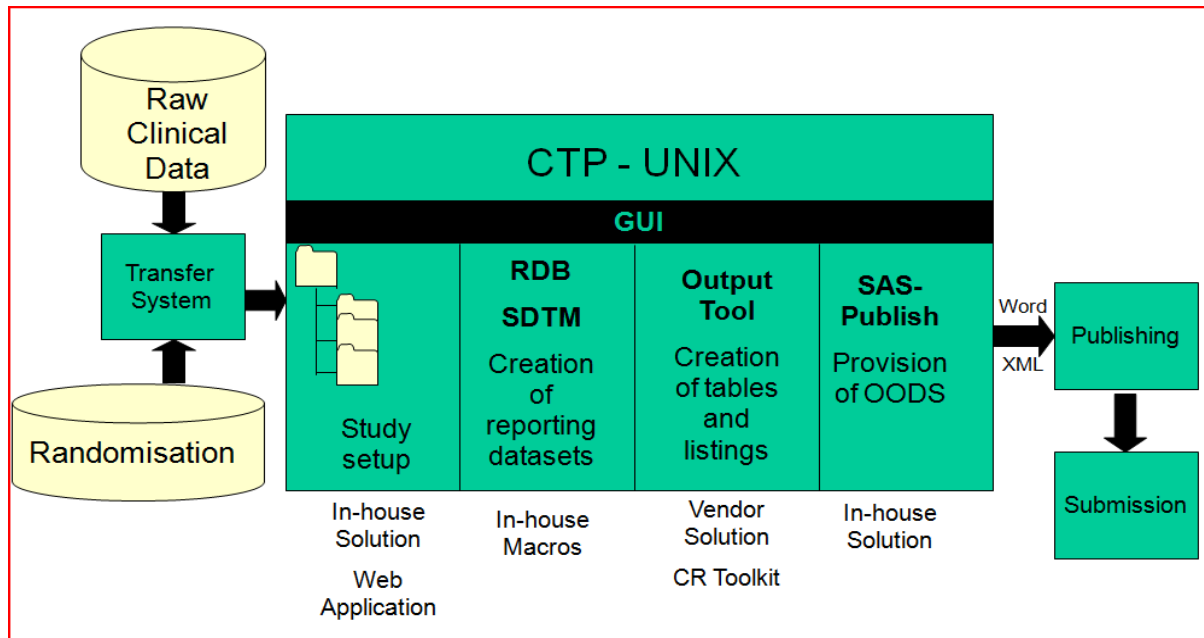
AstraZeneca needed a global analysis and reporting system. The business knew what it wanted but were inexperienced working in a collaboration with IS and an external IS development partner. The business application development programmers had traditional experience working closely with users to prototype SAS® AF and related systems. In the new world, documenting requirements then waiting for the IS development partner to deliver the solution to the business was often frustrating and confusing requiring a number of development iterations. In 2009, the first working version of the Analysis and Reporting Toolset (A&RT) was implemented. The project was a challenging and fascinating orchestration of activities performed by a multi-expert and cross functional team. This presentation is a guide to anyone in a business department planning a similar project and provides information on lessons learned from the experience at AstraZeneca

Introduction

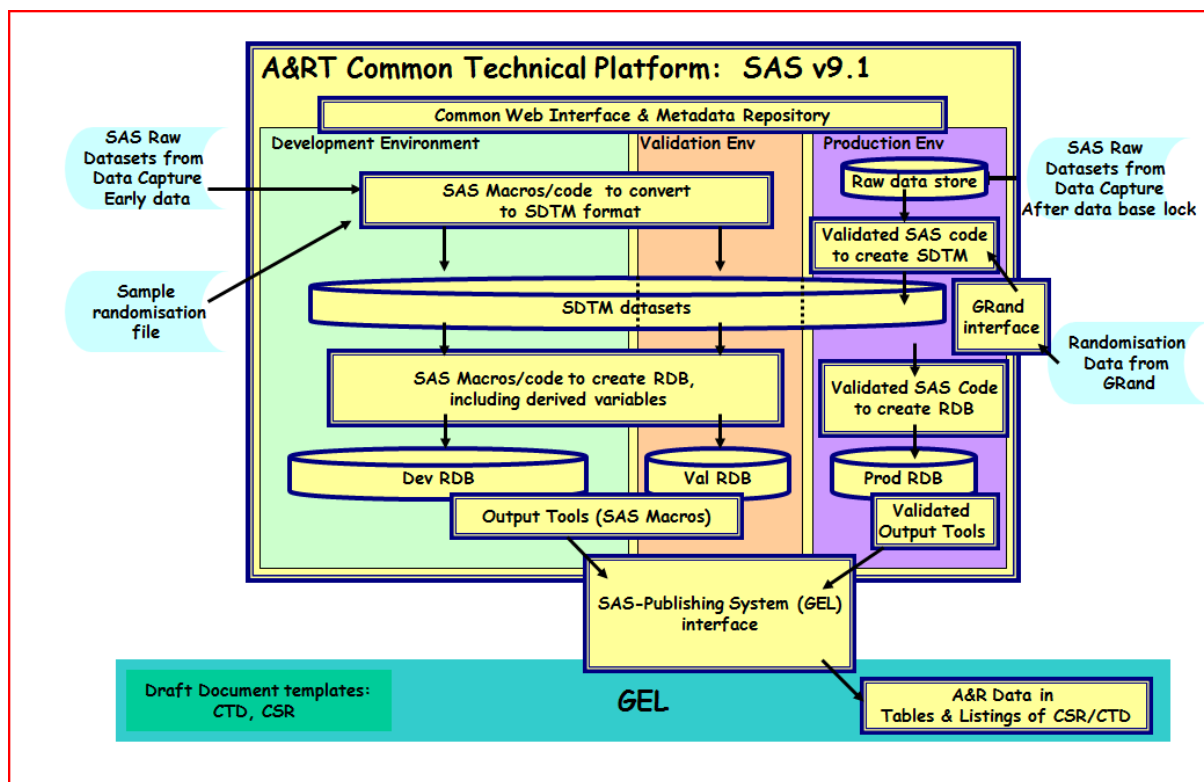
Up until recently AstraZeneca has operated the study analysis and reporting process exploiting a disparate and non-standard set of technical environments. The A&RT (Analysis and Reporting Transformation) project decided in early 2006 to develop a standard analysis and reporting environment based on a set of integrated applications.



The business team formed to define the requirements for this system had already developed a high level set of user requirements. We knew the system should be based upon a powerful UNIX Common Technical Platform and we had specified there must be a functional GUI interface that allowed statisticians and programmers to manage each stage of the A&R process in an easy way.



The business team also knew we needed to create a development, validation and production environment that allowed flexible programming and controlled, compliant production reporting.



Based upon this high level set of business user requirements a joint IS and business project team was formed to evaluate both off the shelf solutions like SAS® Drug Development and the possibility of developing an in-house solution. The team decided that we should progress with an in-house development model. Up until this point, the business clinical programming application development groups in each of our R&D sites had always taken regional responsibility for the development of SAS based systems. It was the business that had the SAS application development expertise in products like SAS® AF. The new strategy within AstraZeneca was to place this systems development and provision under the IS scope of responsibility. Once the decision had been made to develop an in-house solution IS therefore took on leadership of the system development project. The IS organisation had a preferred partner who would perform the business analysis and application development of the system. This was the beginning of a fascinating collaboration between IS, development partner and the clinical business team.

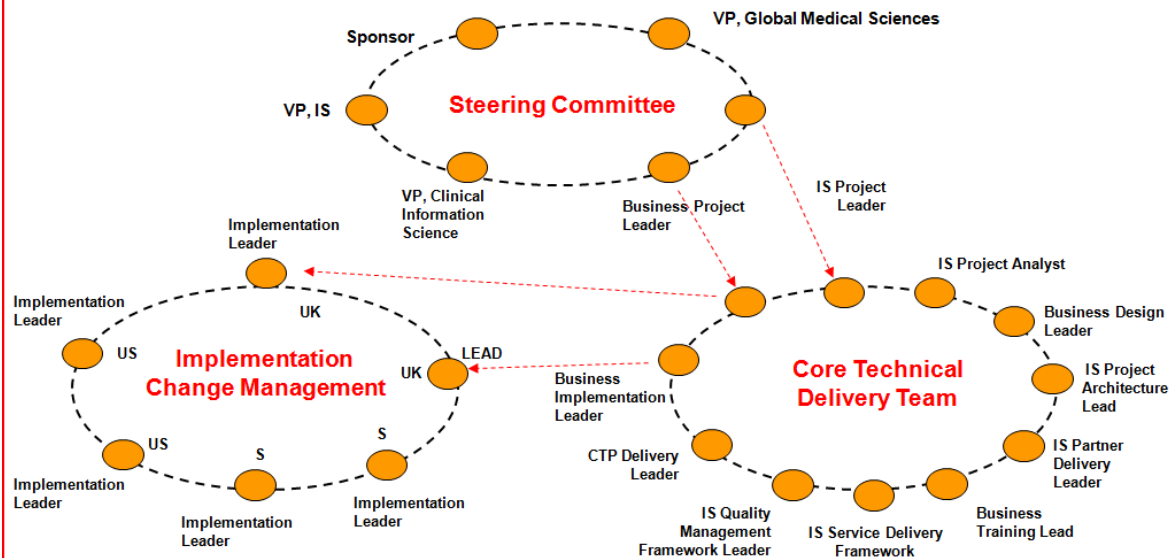
Project Initiation and organisation

The A&RT project was initiated via the formation of a steering committee comprising members from the main medical, clinical information science and IS departments. A senior leader in the clinical department was appointed as sponsor. Both an IS and business project leader sat on the steering group. These two people were tasked with the creation of a joint IS and business technical delivery team that would plan and manage the specification, development, testing and implementation of A&RT. This delivery team included the following core members

- AstraZeneca IS
 - Project leader
 - Project analyst
 - Architect
 - Quality manager
 - Project manager
- Business
 - Project leader
 - Business design leader
 - Training development leader
 - Implementation and business change management leader
- IS Development Partner
 - Delivery leader

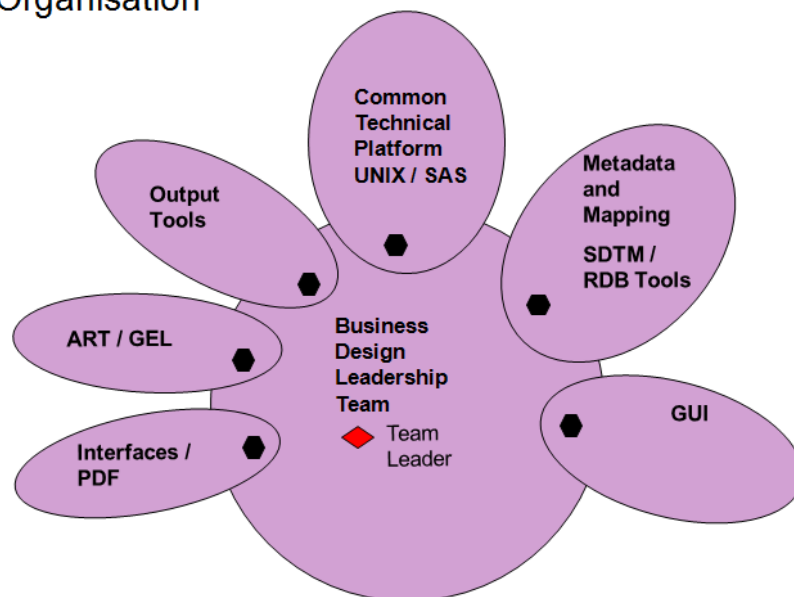
In addition to the technical delivery team, there was also an implementation and change management team formed to plan the business change management and prepare the clinical departments for the transformation of the analysis and reporting process to the new A&RT process. This implementation and change management team had implementation leader representatives from each of the main R&D regions.

A&RT Governance Structure



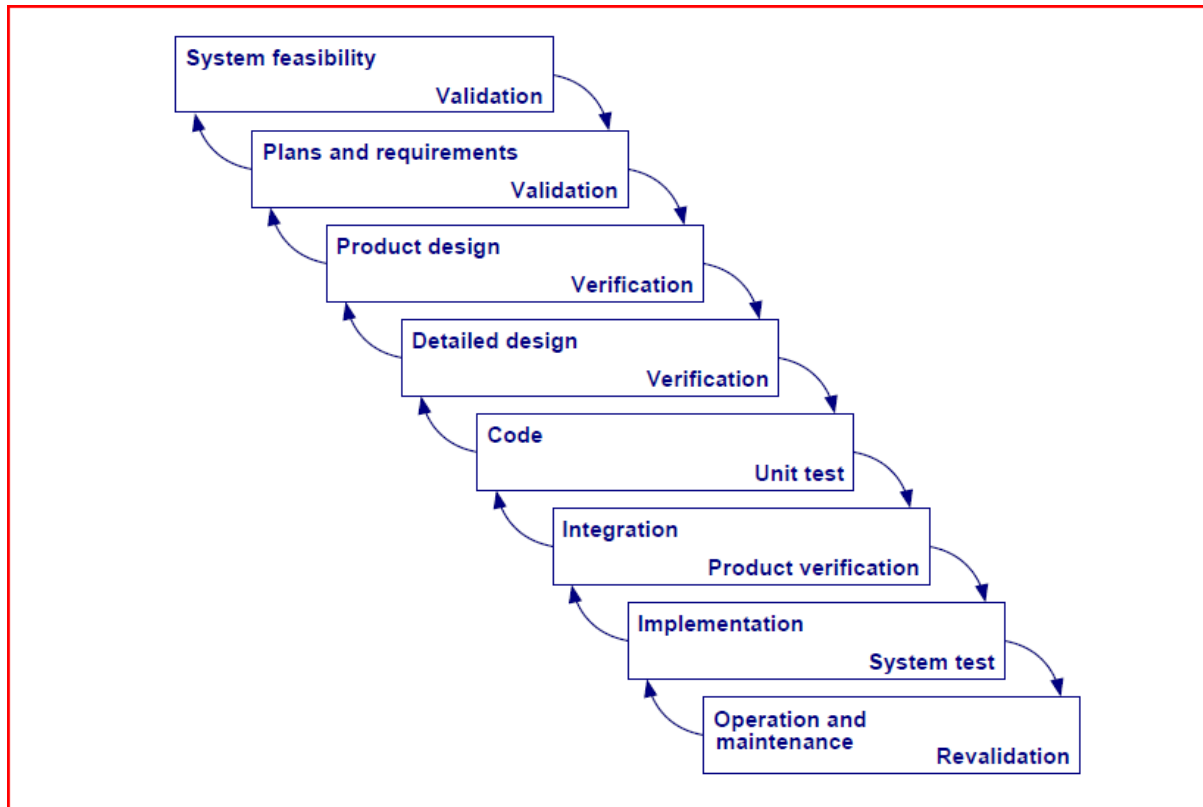
The main feature of the A&RT project that distinguished it from our previous collaborations with IS was the importance of business SAS application development experts. A business design leader led their own team of business experts who had individual responsibility for defining functional requirements and in some cases actual development of SAS tools.

A&RT Business Design and Delivery Organisation



Development Methodology

In accordance with the IS Quality Management Framework methodology in place at the time the technical delivery team followed a development methodology known as the waterfall methodology. This can also be known as the Classic Life Cycle Model (or) Linear Sequential Model. This model has the following activities.



This was an alien concept for the business application development experts who had always followed a far more flexible prototyping and iterative method of developing smaller SAS applications. With the A&RT project, business experts had to define the precise functional requirements of the system and describe these in detailed written documents. This was equivalent to the product design in the above diagram. These documents were then formally signed off before the IS development partner developed the detailed design or technical specifications. Once complete the detailed design was signed off and only then was the code development performed by the development partner. Once coding was complete there was a formal plan of integration, system and user acceptance testing (integration and implementation in the above diagram).

Get the business analysis right

With the A&RT project, the reality was not as easy as the waterfall theory suggested. An absolutely critical component in the waterfall development methodology is the business analysis. This has to be performed by analysts who understand the business requirements and the technical process for developing the solution: they have to tease out the user's every last requirement detail. If anything is missed,

misunderstood or incompletely thought through, there could be significant consequences later on. Once functional or product design documentation is formally signed off, a change control process has to be followed to go back and update anything. This is time intensive and can impact development timelines. The business functional specification was scheduled to take about 1 month. This was achieved in 3 months as the complexity and dependencies within the system had been underestimated. Upon sign-off, these functional specifications went to the IS development partner who developed the detailed technical specifications the coders would actually work from and these specs came back for final AZ approval before coding could begin. From the first technical specification returned, it was obvious the business had significantly underestimated the detail and clarity needed in the functional specifications. The business design experts were still living in their old application development world where problems, gaps or misunderstandings could be corrected at the next iteration. The business design team experts, IS business analysts and IS development partner entered into several more months of specification document change.

It had taken 9 months from the start of the functional design to the point that the technical specifications were used to start actual development coding. In hindsight, this method of specifying the detailed functionality of a system did not work effectively. Even after 9 months, what was thought to be a complete and detailed functional specification was not the case. In this case, the waterfall system development methodology did not work effectively.

Get the planning right. What can go wrong often will go wrong!

As mentioned, by the time code development started we were already late according to the original plan agreed by the steering group. We had significantly underestimated the complexity and time needed to perform a full business analysis. As a consequence, we became locked into an iterative change control process of updating functional and technical specifications. The plan was for the IS development partner to deliver working parts of the system for our review soon after code development started. This became impractical for several reasons.

- The AstraZeneca hardware infrastructure was not ready to run the applications built by the development partner. Their development area was not the same as AstraZeneca's.
- Many of the GUI screen and database functions did not work when loaded into the AstraZeneca environment. Simple things like differences in the version of Internet Explorer caused delay.
- The development partner had been contracted to build the GUI interface software and the Oracle database that controlled the functionality of the system. It was only when this part of the system was integrated with the SAS servers within AstraZeneca that the full functionality of the system could be seen and any issues identified.

The review was therefore halted to allow these issues to be resolved. The first time the business really saw the system working was when round 1 of integration and system testing was formally executed. This formal system testing was performed by

IS and appeared to go reasonably well. When we received the first draft of the system, we realized that while the development partner had followed the specifications, following the waterfall methodology had led to misinterpretation of the complex nature of the data that would be involved. This was not the fault of the development partner and was not something the business could reasonably have been expected to do differently at the time. The underlying problem was the waterfall methodology. We found this to be unsuitable for the development of the complex system we were trying to build in the time given. From this point on, we decided to take a different approach with the development partner.

Getting it right: Collaborate, prototype and get the right experts

To resolve the issues described, the technical delivery team implemented a rapid iterative development process and formed a close team of business and development partner experts. Through a series of Web meetings and informal business testing days, we were able to build a joint understanding of the full requirement and the technical constraints within the system build. We also implemented a shared system development environment that allowed the external development partner to develop the system directly in the environment the AstraZeneca business experts could evaluate. This direct collaboration between the actual developers and the business experts meant the external developers started to build up the domain knowledge needed to understand the business specifications which was the necessary break through to complete the build. We still had the formal document change control process to drive but we avoided the flaws that were inherent in the waterfall approach.

Another important development was the recruitment of IS domain experts into the developer team. This included people, for example, who were members of the SAS and Oracle Centres of Excellence in the development partner organisation.

Don't forget load testing

The first full production version of the system was delivered to the business in early 2009 but issues were soon detected that had gone unnoticed during the formal system and user acceptance testing. These issues were soon identified as being load related. In our haste to deliver our system, we had not performed adequate testing to show what works for 5 studies and 10 users will work for 100 studies and 200 users. At this stage, we realised how critical formal load testing was to the final success of the tool.

Implementation

The project delivered the A&RT system into full production use in 2009. Functionally the system does what it was designed to do. From this perspective the collaborative development approach was a success. There are still challenges as we work to fully deliver the system performance users expect. This is the subject of ongoing system enhancements based on load testing performed late in the project.

Conclusion and lessons for the future

The initial adoption of a waterfall methodology for the development of the A&RT system and the inherent reliance on strict and detailed business analysis is not a step we would repeat in a project of this type. Clinical systems have to work with clinical data from a large variety of sources, study designs, drug development stages and data quality. Any system that manages this has to have complex rules and compliance procedures built in. There is a fundamental requirement for the developers to understand the mind of the person providing the functional specification. Only an iterative prototyping, or agile, system development methodology can effectively deliver such a system. In summary these are the main points recommended to anyone embarking on a similar exercise in future.

1. Before embarking on a complex system build consider the possibility that a vendor 'off the shelf' supplied solution might be a more cost effective long term plan. When performing cost comparisons the vendor supplied solution may look expensive, but if all the extended in-house resources and maintenance costs are included then the in-house build may be less attractive. Instead of building a new system from the ground up it may be an advantageous model to work with the IS partner to configure and implement a vendor system to meet the users requirements.
2. If you are developing a new system whether internally or with an external development partner then resist the desire by IS to follow a waterfall approach. Fortunately, this is not as popular with IS organisations as it was a few years ago. Insist on the business experts who defined the requirements being part of a prototype review team. Follow the agile software development methodology based on iterative and incremental development, where requirements and solutions evolve through collaboration between cross-functional teams. This methodology also promotes adaptive planning, evolutionary development and encourages rapid and flexible response to change
3. Form a joint business and IS development team that will work closely together, often in one to one collaborations. Do this by Web meetings and teleconferences if the developers are at a distance from the business design experts.
4. Ensure the IS developers have access to experts in their own organisation, e.g. SAS application experts, Oracle experts and system performance experts.
5. Plan for a number of prototype iterations to be performed with the business experts before the formal functional and technical system specifications are finalised. The business has to recognise resource will be required for an extended period to do this.
6. Even with this agile methodology in place, plan for more iterations of system and user acceptance testing than you might be asked to plan for. Project planners

necessarily have an eye on budgets and timelines but recognise that more time may be needed in reality to ensure robust testing.

7. The requirements must include non-functional requirements that describe the expected user and data load on the system along with the expected performance. Always include load testing in the plan based on these non-functional requirements. Do not economise on this testing. This seems obvious but it's something easy to ignore if you are working to budget and time constraints.

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