

Agile? WoW! How Agile Ways of Working can Drive Value for Conventional Clinical Trial Reporting

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ABSTRACT

Agile teams have been successfully implemented in many industries and primarily used for software development. As our industry continues to evolve its understanding of agile ways of working, it is becoming clear that there exists unrealized value, derived from adoption of agile methods by sponsor companies and CROs. This paper will explore alternative implementation approaches of agile principles on conventional clinical study reporting, comparing the merits and risks of various resourcing models, as well as provide insight into the current GSK approach in this area.

INTRODUCTION

The conventional clinical reporting model, which has been used for many years, involves generating SDTM, ADaM, tables, listings, and figures (TLFs) using SAS or R. This model relies on creating static outputs generated by code with numerous dependencies. However, should we be concerned about the sustainability of this approach, especially in the face of evolving regulatory demands and the rapid pace of digital technology.

There are indeed alternatives that could be explored. One such alternative is the adoption of Agile methodologies in clinical reporting. Agile principles, which have been successfully implemented in many industries, can offer significant value when applied to clinical study reporting. Agile teams can foster a culture of collaboration, transparency, continuous improvement, and customer focus which could help in reducing the time to generate outputs.

While the conventional clinical reporting model has been reasonably successful, exploring alternatives like Agile methodologies could offer significant benefits.

WHAT DOES AGILE MEAN?

PROBLEM STATEMENT

Clinical trials are extensive and complex, often spanning several years. This prolonged duration can result in programming teams becoming siloed, working on the same compound without much interaction with other teams. Such isolation can lead to several problems:

- **Limited Collaboration:** Teams working in silos miss out on cross-team collaboration, leading to limited knowledge sharing and innovation.
- **Resource Inflexibility:** Teams tend to hold on to their resources due to their specialized expertise, making it difficult to reallocate resources where needed.
- **Transparency Issues:** The lack of transparency in project plans makes it challenging to project and manage resourcing needs effectively.
- **Limited Performance Metrics:** Closer to waterfall delivery mechanisms reduce the understanding of team performance in terms of efficiency, effectiveness, and productivity.
- **Poor Stakeholder Management:** Programmers are under pressure to innovate and manage stakeholders effectively, which can lead to low productivity and reduced capacity to implement modern technologies.
- **Poor Change Management:** There is a low ability to project the impact of changes requested by stakeholders, leading to inefficiencies.

HOW CAN AGILE HELP?

The Agile manifesto outlines four values and twelve principles, although the focus of these when created were for software development, they can also be applied to clinical reporting as illustrated in the table below.

The Agile Manifesto¹ and the four values put emphasis on valuing:

- Individuals and interactions over process and tools
- Working software over comprehensive documentation
- Customer collaboration over contract negotiation
- Responding to change over following a plan

Principles of Agile...	...applied to Clinical Reporting
Customer satisfaction through early and continuous delivery	Reduction in late-in-the-game change requests No more Dry Runs
Welcome changing requirements, even late in development	When they come, easier to accommodate More accurately estimate the impact
Deliver working software frequently	Code base and documentation developed in sync
Collaboration between business stakeholders and developers	Statistics, Clinical, Asset Leads, Sponsor/Clients
Build projects around motivated individuals	Granular tasks enable targeting the right resources
Face-to-face conversation is the most efficient and effective method of communication	Frequent and regular communication, even hybrid
https://agilemanifesto.org/principles.html	
Working software is the primary measure of progress	Fully validated datasets, TFLs, data visualization platforms for each milestone
Sustainable development	Happy teams with infrequent and minimal stretch
Continuous attention to technical excellence and good design	Documentation (aCRF, cSDRG, ADRG, define.xmls) Testing, quality control, quality assurance, GPP
Simplicity – the art of maximizing the amount of work not done – is essential	e.g., minimal features of datasets to deliver interim analyses
Self-organizing teams	Leverage performance metrics from backlog Empowerment and not central planning
Regular reflection on how to become more effective	Retrospectives
https://agilemanifesto.org/principles.html	

Agile methodologies, characterized by iterative development, continuous feedback, and flexibility, can address many of the issues faced by clinical reporting programming teams, such as:

ENHANCED COLLABORATION

Agile promotes a culture of collaboration and communication. Regular stand-up meetings, sprint reviews, and retrospectives ensure that team members are constantly interacting with each other. This heightened level of communication can break down silos and foster a collaborative environment. Teams can share knowledge, discuss challenges, make decisions quickly and innovate collectively, leading to better solutions and improved efficiency.

FLEXIBILITY AND RESOURCE MANAGEMENT

Agile methodologies are inherently flexible. They encourage adaptive planning and continuous improvement, allowing teams to respond to changes and reallocate resources as necessary. By using techniques such as backlog grooming and sprint planning, teams can prioritize tasks and adjust workloads dynamically, ensuring that resources are used efficiently and effectively.

IMPROVED TRANSPARENCY

Agile emphasizes transparency through tools like Kanban boards, burndown charts, and sprint reviews. These tools provide a clear view of the project's progress, helping leaders make informed decisions about resource allocation and project timelines. Increased transparency also helps in identifying bottlenecks and addressing them promptly, leading to smoother project execution.

BETTER PERFORMANCE METRICS

Agile methodologies use metrics such as velocity, cycle time, and lead time to measure team performance. These metrics provide insights into the team's efficiency, effectiveness, and productivity. By tracking these metrics, leaders

can identify areas for improvement and implement changes to enhance performance and more effectively plan resource. Additionally, the iterative nature of agile allows for regular assessment and adjustment, ensuring continuous improvement.

EFFECTIVE STAKEHOLDER MANAGEMENT

Agile encourages frequent interaction with stakeholders through sprint reviews and demos. This regular engagement ensures that stakeholder expectations are managed effectively and their feedback is incorporated into the project in a timely way. Additionally, agile's iterative approach allows for early and continuous delivery of valuable outcomes, keeping stakeholders satisfied and reducing the risk of misaligned expectations on the critical path.

EFFICIENT CHANGE MANAGEMENT

One of the core principles of agile is embracing change. Agile methodologies are designed to accommodate changes and incorporate feedback quickly. By using techniques such as continuous integration and continuous delivery, teams can implement changes efficiently and minimize disruptions. This flexibility allows teams to respond to stakeholder requests promptly and ensure that the project remains aligned with business objectives.

IMPLEMENTATION APPROACHES

We believe that Agile principles and methodologies help address two organizational challenges:

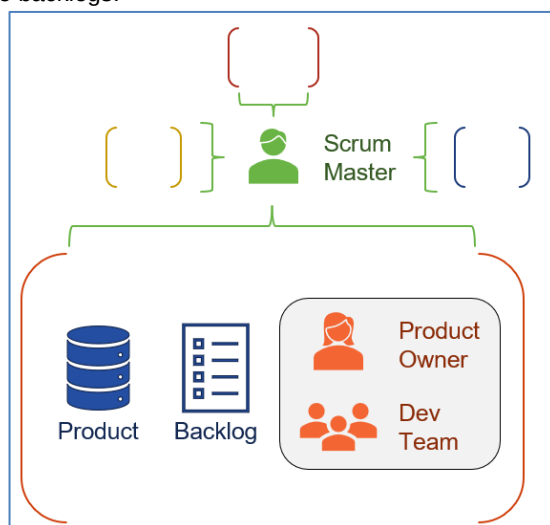
1. **Product Delivery:** Improvement of operational excellence
2. **Resource Management:** More effective decisions on resource allocation and improved personnel development

PRODUCT DELIVERY

When people think of the term 'agile', quite often it brings up other concepts such as scrum, kanban, sprinting, retrospectives, and demos. Perhaps there may be discussion of 'managing a backlog' or prioritization. All of these are relevant and, for the most part, all refer to seeking to achieve operational excellence on a delivery team.

In the world of clinical reporting, what does the 'product' mean? We argue that you can think of the set of deliverables from a conventional programming team as the product. Perhaps in your organization that means the SDTM database or the ADaM database. Perhaps it means SDTM, ADaM, and TFLs as a full package. For many years at GSK, this was referred to as the SAC package (statistical analysis complete) and included the ADaM database and all CSR (Clinical Study Report) post-text TFLs. In addition, we would recommend that all documentation supporting those deliverables are part of the 'product', such as reviewer's guides, define documents, and/or the annotated CRF (if SDTM is included).

Applying the typical model of software development, that product needs a Product Owner and a primary Business Owner – which, at GSK, we see as filled by the Study Lead Programmer and Study Lead Statistician, respectively. With the Product Owner identified, endowed with an army of developers, we now have a proper Product Team and a book of 'features' to develop to deliver the product – hence the ability to detail a task-based backlog for the Product Team to prioritize and deliver against. Add in a Scrum Master, and your team may look something like this, with the Scrum Master tending to multiple backlogs:



RESOURCE MANAGEMENT

Transforming the operational activities from conventional delivery to a task-based backlog managed by a product owner provides the opportunities to (i) make more effective decisions on resource allocation and (ii) enhance the development of team members. How do these results link back to the move towards agile ways of working? First, modern software firms tend to prefer flatter organizational structures with decentralized decision-making.² And, flatter organizational structures tend to be more agile.³ The flatter structure means less managers needed to support resource allocation decisions and development of team members. This means less people involved in discussions to reallocate resource across different development teams and more consistent development training across the organization.

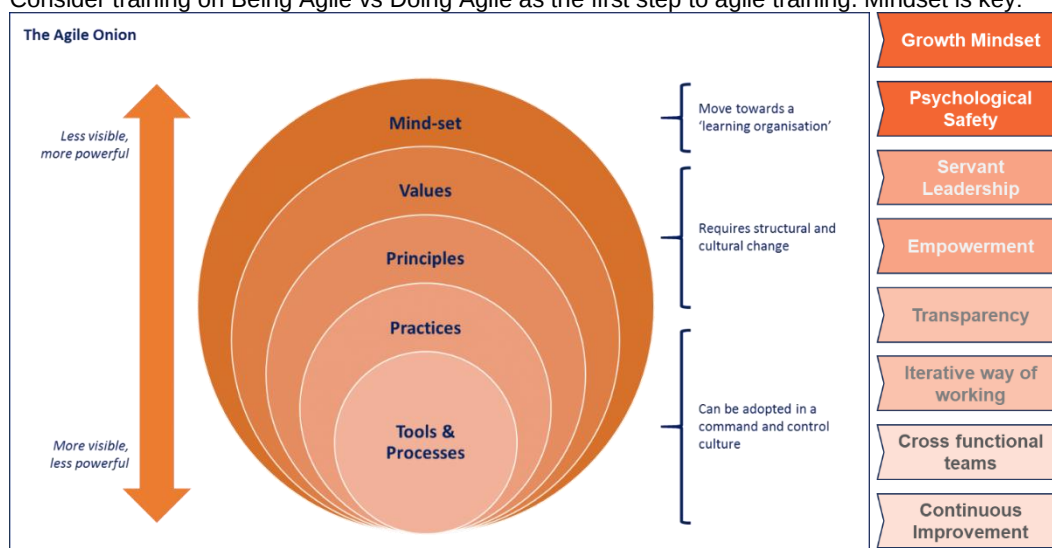
If you imagine a combined backlog of tasks across multiple studies or multiple projects, not only can the portfolio of tasks be globally prioritized, but it is also easier to identify where the resource need is the greatest. This enables an informed and data driven decision to move a developer from one squad to another for a single sprint to deliver the most valuable features for the business as a whole. Such a reallocation of resource is more challenging with traditional structures and management that 'hold on to' their team's resources.

If the organizational structure also includes an elements of a matrix structure, then management lines can focus development on the individual's career aspirations. In conventional structures, the career path may require an individual to be able to do everything – project management, budgeting, people management, technical excellence, stakeholder management, etc. A matrix structure can provide more opportunity and managers can focus on the individual career development.

IMPLEMENTATION STRATEGIES

To successfully implement agile methodologies in clinical reporting programming teams, leaders should consider the following strategies:

- **Training and Education:** Ensure that all team members are well-versed in agile principles and practices. Consider training on Being Agile vs Doing Agile as the first step to agile training. Mindset is key:



- **Agile Avengers:** Appoint agile coaches or champions within the team to guide and support the implementation process. These individuals can provide expertise, facilitate agile ceremonies, and help resolve any challenges that arise.
- **Tooling and Infrastructure:** Invest in the right tools and infrastructure to support agile practices. Tools like Jira, Trello, and Confluence can facilitate agile planning, tracking, and collaboration.
- **Incremental Adoption:** Adopt agile methodologies incrementally rather than all at once. Start with a pilot project and experimentation and gradually expand the implementation as the team becomes more comfortable with the new approach
- **Continuous Improvement:** Emphasize the importance of continuous improvement. Encourage teams to regularly reflect on their processes, identify areas for improvement, and implement changes to enhance efficiency and effectiveness.

BENEFITS OF AGILE TO ADDRESS THE PROBLEM STATEMENT?

- Foster a culture of collaboration, transparency, and continuous improvement to achieve a common goal
- Agile cross-functional teams, promote shared goals between pipeline groups and therapeutic areas to initiate regular and structured communication
- Agile workflow and tracking tools (JIRA) will promote visibility and transparency for all team members
- Iterative development techniques enables prioritizing tasks based on value and continuous improvement
- Continuous communication and feedback from stakeholders allows teams to adapt quickly and empower teams to make informed decisions and self-organize
- Implementation of JIRA will provide transparency of workload, enabling better prioritization and shift in resource more manageable
- Create supportive environment by promoting decision-making and ownership of tasks and projects
- Opportunities for new/enhanced roles e.g. Agile Leader, Scrum Master, Development
- Maintain accountability of Project Programmers, Study Lead Programmer roles for project & scientific level leadership for effective cross functional stakeholder management
- Short production cycles to deliver useable increments of product/s – gather feedback promptly to support the next iteration
- Opportunity to use collaboration tools to manage activities ensuring visibility and alignment across teams

CONCLUSION

Agile methodologies offer a promising solution to the challenges faced by large teams of programmers involved in clinical reporting. By fostering collaboration, enhancing flexibility, improving transparency, and embracing change, agile can help teams overcome silos, manage resources effectively, and deliver high-quality results. Implementing agile requires commitment, training, and the right tools, but the benefits and potential to increase efficiencies could outweigh the initial challenge to implement a change in HOW clinical reporting is modernised. With agile, clinical reporting programming teams could achieve greater efficiency, productivity, and innovation, ultimately leading to better outcomes for clinical trials.

Implementing agile methodologies could streamline clinical reporting delivery demonstrated by the table below.

From	To
1. Output focused	1. Outcome and Customer focused
2. Output based activities	2. Task based activities
3. Single owner of code	3. Collaborative coding
4. Waterfall (with dry runs)	4. Frequent Demo ceremonies
5. No data on performance except the deliverables	5. Automatic capture of performance metrics against estimates
6. Finger-in-the-air estimates of impact of changes	6. Historical knowledge to estimate impact of changes with accuracy
7. Informed guesses for resource/timing needs	7. Data driven projections for resource/timing needs
8. Prioritization by individual programmer	8. Sprint planning to enable strategic prioritization (e.g., by domain)
9. Difficulty resource planning above study	9. Scrum of scrums – enable portfolio and asset level planning
10. Difficulty to optimize talent profile based on current needs of the reporting activity	10. Enables specific types of personas to pop in and out as needed
11. Ring-fenced teams with little flexibility	11. Resource pods – SMEs, follow-the-sun, more efficient deployment
12. Difficult to document impact of individuals on the project	12. Individuals are now explicitly informed for performance reviews – they know what they've done

REFERENCES

¹ <https://agilemanifesto.org/>

² <https://softwaresim.com/blog/common-organizational-models-in-software-firms/>

³ <https://www.mckinsey.com/business-functions/people-and-organizational-performance/our-insights/the-five-trademarks-of-agile-organizations>

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