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The Implementation of Scrum in Pharmaceutical Data Analytics and Statistical Programming

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ABSTRACT

Scrum is a popular agile project management framework that is useful for addressing complex environments, such as Pharmaceutical Data Analytics and Statistical Programming. By using Scrum, teams can control risk, minimize investments, and improve predictability. Scrum teams focus on value and learning, rather than relying on opinions, which increases the chances of a good outcome and a high return on investment. In comparison to the traditional waterfall approach, which is commonly used in our industry, Scrum allows teams to constantly adjust and adapt to changes, leading to more efficient and effective project delivery.

In this paper, we discuss Scrum's usefulness in complex environments and the benefits and learnings that we have experienced while implementing Scrum across our Data Analytics and Statistical Programming team.

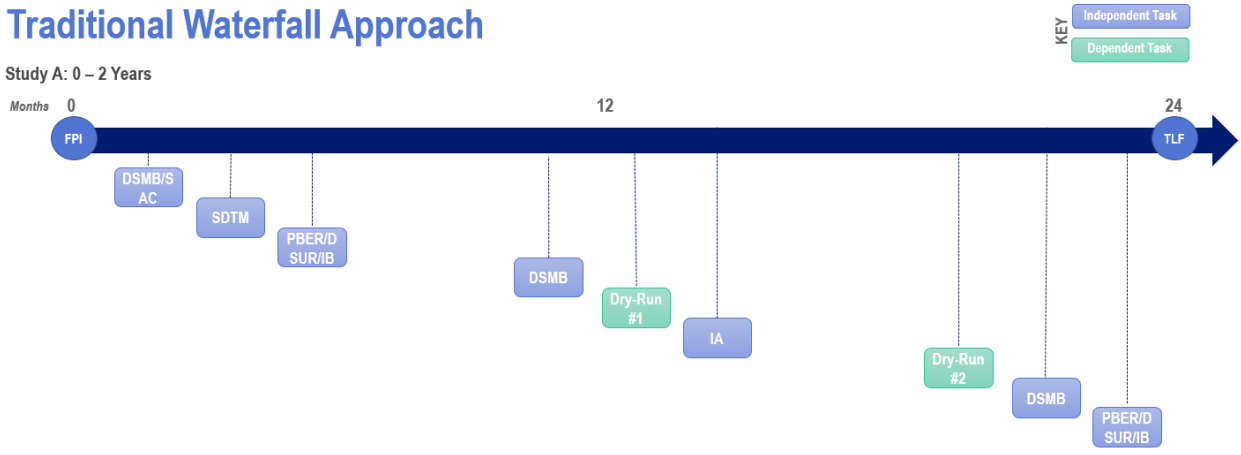
INTRODUCTION

Pharmaceutical organizations are constantly evolving, with increasing pressure to bring medicines to patients faster. Data Analytics and Statistical Programming teams play a vital role in these organizations, responsible for managing and analyzing data that support clinical research and drug development. To ensure successful outcomes and reduce time to market, it is essential for these teams to work efficiently, collaboratively, and rapidly adapt to changing regulatory requirements. Adopting the Scrum framework can help teams meet stakeholder demands by providing a flexible and iterative approach to project delivery.

SCRUM VS WATERFALL

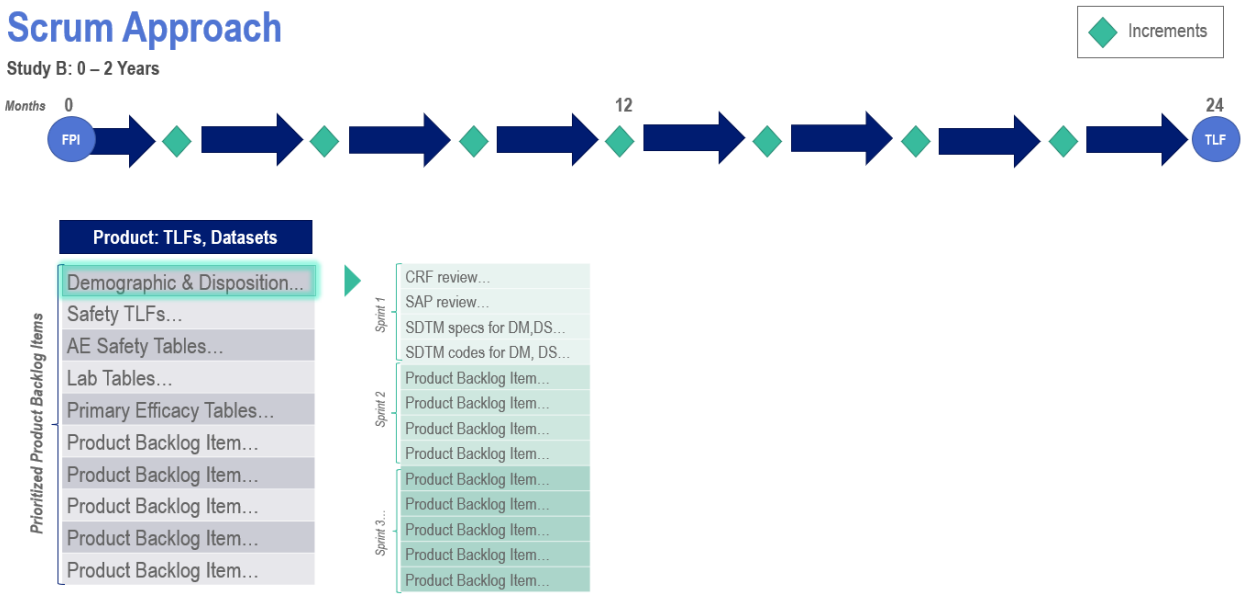
Although Scrum has gained immense popularity across various industries, it remains rather novel in the pharmaceutical industry. Traditionally, statistical programming teams have used a waterfall approach to manage their projects. This approach is a sequential method that follows a linear, step-by-step process to accomplish goals and objectives. This approach typically does not give way to unforeseen changes and events, which often occur in our industry. As a result, project teams find themselves confronting issues when it is too late - often causing delays in deliverables.

The graphic presented below demonstrates the traditional waterfall approach and its sequential nature.



In contrast, Scrum is an iterative and incremental project management approach that emphasizes flexibility, transparency, collaboration, and continuous improvement. This approach helps reduce time and energy by enabling teams to constantly inspect, align, and adapt their work. By leveraging the Scrum framework, teams can break their work into short cycles, so that they have an opportunity to course correct before reaching their end goal.

The graphic presented below demonstrates the Scrum approach and its iterative nature.



The key differences between the two approaches are:

1. Iterative vs Sequential: The Scrum framework breaks down a project into small, manageable increments called Sprints, which typically span 2-4 weeks. During these Sprints, teams focus on delivering value in increments towards the final product, while actively engaging stakeholders. This approach allows teams to garner valuable feedback on a regular cadence and course correct as needed. In contrast, the waterfall approach follows a sequential process where teams focus on one phase of the project at a time, before moving on to the next phase. Meetings with stakeholders typically take place during the project's development phase and once it is complete.
2. Flexibility vs Rigidity: Scrum emphasizes flexibility and adaptability to changing requirements and priorities. The Product Backlog, which is a list of prioritized work that needs to be done to complete the project, is continuously refined and reprioritized by the Scrum team. This enables teams to collaborate to deliver the highest value items based on business priority. In contrast, the waterfall approach follows a rigid plan that is typically set at the beginning of a project and is difficult to change once the work commences.
3. Collaboration vs Silos: Scrum emphasizes team collaboration and ownership. Teams are encouraged to maintain consistent communication and empowered to work together to solve roadblocks and deliver value. Progress is regularly shared through Daily Scrum meetings, where teams inspect their progress towards their Sprint Goal. In contrast, the waterfall approach often operates in silos. Team members tend to operate independently on their tasks and communicate only at certain milestones.
4. Continuous Improvement vs Final Product: Scrum emphasizes continuous improvement and learning. Teams hold Sprint Retrospectives at the end of each Sprint, where teams reflect on their performance and identify opportunities for improvement. These opportunities are then implemented in the following Sprint. In contrast, with the waterfall approach, feedback is typically shared at the end of a project.

BENEFITS OF SCRUM

Implementing Scrum across Data Analytics and Statistical Programming teams can bring several business benefits, including:

- Control Risks: The Scrum framework is designed to address complex and rapidly changing environments. As such, Scrum teams are constantly monitoring risks, roadblocks, and needs for reprioritization through Daily Scrum and Sprint Review meetings. These frequent inspections enable teams to rapidly adapt their approach to minimize negative impacts.
- Improve Predictability: Working in consistent Sprints improves team's ability to plan and make decisions. By leveraging a clear and transparent Product Backlog, teams can prioritize work based on value and estimate delivery times with greater accuracy.
- Increase chances of a good outcome and ROI: Scrum teams concentrate on value gained by doing and learning. Scrum enables teams to adjust and adapt to changes quickly, resulting in a more efficient and effective project delivery, and in teams making future decisions based on learnings rather than opinions.

IMPLEMENTING SCRUM

Now that we have discussed the differences and benefits in leveraging Scrum, we can begin to share our experience in implementing Scrum across our Data Analytics and Statistical Programming team.

In the Spring of 2022, our department set on a mission to innovate our approach to project delivery to become more proactive, agile, forward-looking teams, that are seen as strategic technical partners. To aid in the realization of our intended outcomes and vision, we began leveraging Scrum.

We first piloted the framework with a few teams, with little to no training on the framework. Like with any change, team members were resistant to this new project management approach. Admittedly, we were asking our teams to completely reinvent their ways of working, which was undeniably a big ask. After weeks of piloting, we identified the need to provide additional support to our teams to further enhance their knowledge of the framework and this new way of working.

BASELINE SURVEY

To measure and track the progress of our Scrum implementation over time and measure the impact on our teams, we conducted a department wide survey. We designed the survey to better understand the general awareness of Scrum and identify areas for improvement. Below were some of our key findings:

- 70% of respondents were open and willing to incorporate Scrum into their day-to-day activities, but only 50% saw the value in doing so.
- Overall, respondents reported Scrum high in team cohesiveness and efficiency.
- However, many respondents reported Scrum low in improving quality of their work, giving them greater control over their work, and fitting well with the way they like to work.

Ultimately, the results suggested that there was work to be done to improve perception of the value and benefits associated with Scrum.

SUPPORTING OUR TEAMS

To improve overall perception of the value of innovating our project delivery approach and to ensure a successful implementation of Scrum with our statistical programming team, we decided to provide additional support and training. We brought in a team of experts that had experience in implementing the framework across other organizations. These experts focused on value rather than following a strict methodology and helped tailor Scrum to fit our needs.

Together, we began offering several diverse types of support and training to our team, including:

- Guidance Document: We developed a guidance document to provide an overview of the Scrum framework and how it should be implemented within our department. The document serves as a

reference guide to ensure consistency in the application of the framework across different Scrum teams. This living document continues to evolve as we develop greater insights and learnings from our implementation.

- Templates: We developed templates for key Scrum artifacts and ceremonies, such as the Product Backlog and Sprint Planning. These templates provide a reference for team members that are new to the framework and help ensure consistency across different Scrum teams.
- Scrum Course: We enrolled our team members in a two-day Professional Scrum course where they learned about the framework and its ability to improve project delivery. This helped lay a strong foundation around Scrum and gave team members the opportunity to become Scrum certified.
- 1:1 Coaching Sessions: Our team of experts provided individual coaching sessions to team members to help them understand the framework and how to apply it to their work. This provided personalized support and allowed team members to get their questions answered in a more focused setting.
- Office Hours: We held bi-monthly, non-mandatory, office hours where team members could drop in to ask questions, get additional guidance on implementing the framework, and share learnings. This also provided the opportunity for team members to address any specific challenges they were facing.
- Micro-Training Sessions: Short, 1-hour, non-mandatory micro-training sessions were held bi-weekly to focus on specific aspects of the Scrum framework, such as Product Backlog Refinement or the Definition of Done. These focused trainings provided team members with the additional knowledge needed to apply the framework in their day-to-day work.
- Community of Practice (COP): We established communities of practice for Scrum Masters and Product Owners designed to bring together team members to discuss challenges, share successes / learnings, and provide opportunities for peer coaching.

This additional support and training have been an essential part of our successful implementation of Scrum. By providing a variety of different resources, team members have increased their knowledge and familiarity with the framework. Additionally, the various and consistent touchpoints have allowed us to quickly adapt and overcome challenges to ensure that the framework was implemented effectively.

ADAPTING OUR WAYS OF WORKING

As part of our implementation strategy, we made several key adaptations to our ways of working. These adaptations included:

- Clear Roles and Responsibilities: Scrum defines three specific accountabilities within the Scrum Team: The Scrum Master, Product Owner, and Developers. As such, it was important to clarify who would lead each role within our department. We set out expectations for Therapeutic Area (TA) Heads to play the role of the Scrum Master, as they are responsible for working with multiple Product Leads and managing strategic priorities and resources. Molecule Leads play the role of the Product Owner, as they are expected to create a comprehensive plan for the Product/Technology level programming with input from the Study Lead and TA Head. Finally, the Developer role is led by Study Leads and Study Programmers as they are responsible for creating value during each Sprint.
- Product Backlog Development: Developing a Product Backlog that works for the flow of statistical programming groups was key. We worked with our teams to help them think of the complete study

deliverables as one product and then developing a prioritized list of items required to deliver the product.

A sample Product Backlog can be represented as:

Product Goal: TLF outputs for concomitant medications
Product Backlog Items
SDTM Specifications (DM, CM)
Develop SDTM Specifications
Review SDTM Specifications
ADaM Specifications
Develop ADaM specifications [dataset = ADCM]
Review ADaM specifications [dataset = ADCM]
SDTM Datasets (DM, CM)
Develop SDTM Datasets
Review SDTM Datasets
TLF Shells
Update and finalize TLF shells to match Jazz standards [Source =ADCM]
Create Candid TOC and upload assignments to Candid [Source =ADCM]
ADaM Programming
Develop ADaM datasets [dataset = ADCM]
Review ADaM datasets [dataset = ADCM]
TLF Annotation
Annotate TLF shells [Source =ADCM]
Review annotated TLF shells [Source =ADCM]
Statistician Review
Table Programming
Table 9.1.7.1-Production-[U]
Table 9.1.7.1-Validation-[U]
Table 9.1.7.2-Production- [R: Table 9.1.7.1]
Table 9.1.7.2-Validation- [R: Table 9.1.7.1]
Statistician Review
Listing Programming
Listing 10.2.4.4-Production-[U]
Listing 10.2.4.4-Validation-[U]
Figure Programming
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- Consistent Team Members: We worked to ensure that each Scrum team had consistent team members throughout the duration of a project, with minimal changes to the team composition. This

helped build a sense of collaboration and continuity within the teams.

- Regular Sprint Schedule: We established a regular schedule of 2-week long Sprints. This provided a consistent and predictable rhythm to our work and helped us plan and prioritize work more effectively, while also allowing for continuous improvement and identification of risks through regular inspection.

  Please refer to the table below for an example schedule of Scrum events.

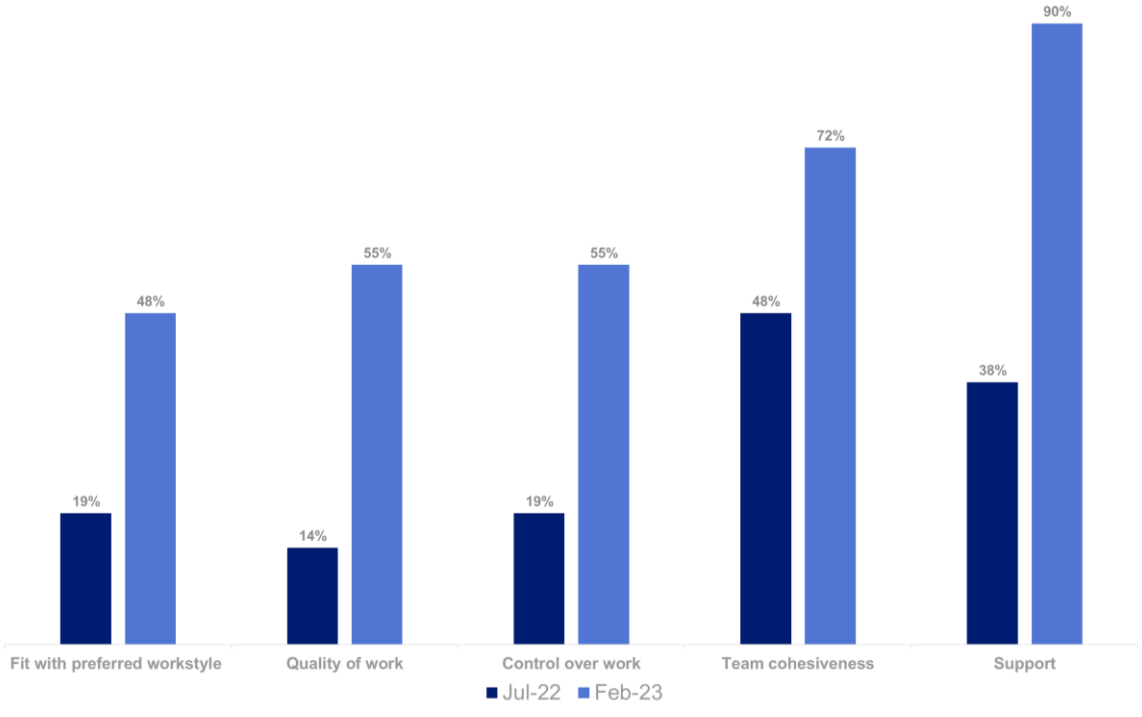
	Monday	**Tuesday**	**Wednesday**	**Thursday**	**Friday**
WEEK 1	Sprint Planning	Daily Scrum	-Daily Scrum -Refinement *(Optional)*	Daily Scrum	Daily Scrum
WEEK 2	Daily Scrum	Daily Scrum	-Daily Scrum -Refinement *(Optional)*	Daily Scrum	-Daily Scrum *(Optional)* -Sprint Review -Sprint Retrospective

Adapting our ways of working was critical to the success of our teams. By defining clear roles and responsibilities, ensuring consistent team membership, and establishing a regular cadence for Sprints, we were able to build a sense of collaboration and continuity within our teams and to plan and prioritize our work more effectively.

RE-SURVEYING OUR DEPARTMENT

To understand the overall impact of the changes we had made and uncover any areas of opportunity for further improvement, we re-launched the survey that we had conducted 7 months prior.

Overall, the results of the survey were positive. We found that respondents were more open and willing to incorporate Scrum into their work, with more people seeing the value in using the framework (73% vs 50% in the original survey). Additionally, we found significant improvements in several key areas, including in how people feel Scrum improves quality of work, gives them greater control over their work, fits with the way they like to work, and team cohesiveness. Finally, 90% of respondents reported that they have the proper training and support to leverage Scrum in their day-to-day activities.



Re-surveying the department was important in understanding the impact of our implementation efforts. Further, these results helped identify areas of opportunity for continuous improvement.

KEY OUTCOMES

The implementation of Scrum across statistical programming teams has had several key outcomes, which have demonstrated the value of Scrum as a project delivery approach within our organization and helped build support for its continued use and expansion across other departments. Some of these outcomes include:

- Greater Transparency: The use of prioritized Product Backlogs has resulted in greater transparency and visibility into the work being done by each Scrum team. This has enabled stakeholders to understand the progress being made and the team's priorities.
- Increased Communication: The use of Daily Scrum meetings and regular Sprint Reviews have increased communication and collaboration within the teams. This has helped build a sense of shared ownership and responsibility for the value being created.
- Better Alignment with Business Objectives: The use of a Product Backlog and regular communication with stakeholders has helped ensure that the work being done by the Scrum team is aligned with business priorities and objectives.

CONCLUSION

Pharmaceutical Data Analytics and Statistical Programming is a complex environment that can benefit from implementing Scrum and agile ways of working. By using Scrum, teams can control risk, minimize investments, and improve predictability and team collaboration. To ensure successful implementation, leaders must be willing to reinvent their ways of working. Efforts that can lead to effective implementation include, change management and communication, training, tailored guidance development, and ongoing support.

ACKNOWLEDGMENTS

We would like to thank the Jazz Pharmaceuticals Data Analytics and Statistical Programming team for their openness and willingness to innovate our approach to project delivery.

RECOMMENDED READING

- *The Scrum Guide*

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the authors at:

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