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# The Implementation of Scrum in Pharmaceutical Data Analytics and Statistical Programming

**Paper Number PD08**



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Jagan Achi is the Executive Director and Head of Integrated Data Analytics Statistical Programming at Jazz Pharmaceuticals. With 16 years of experience in the industry, Jagan Achi has proven skills in leading teams, utilizing advanced analytics and navigating regulatory requirements. He is a subject matter expert in data analytics and statistical programming, with a track record of successful NDA/BLA submissions. Jagan Achi and his team at Jazz Pharmaceuticals leverage state-of-the-art analytics to support the development of new therapies for patents of unmet medical needs.



## Eliana D'Angelo

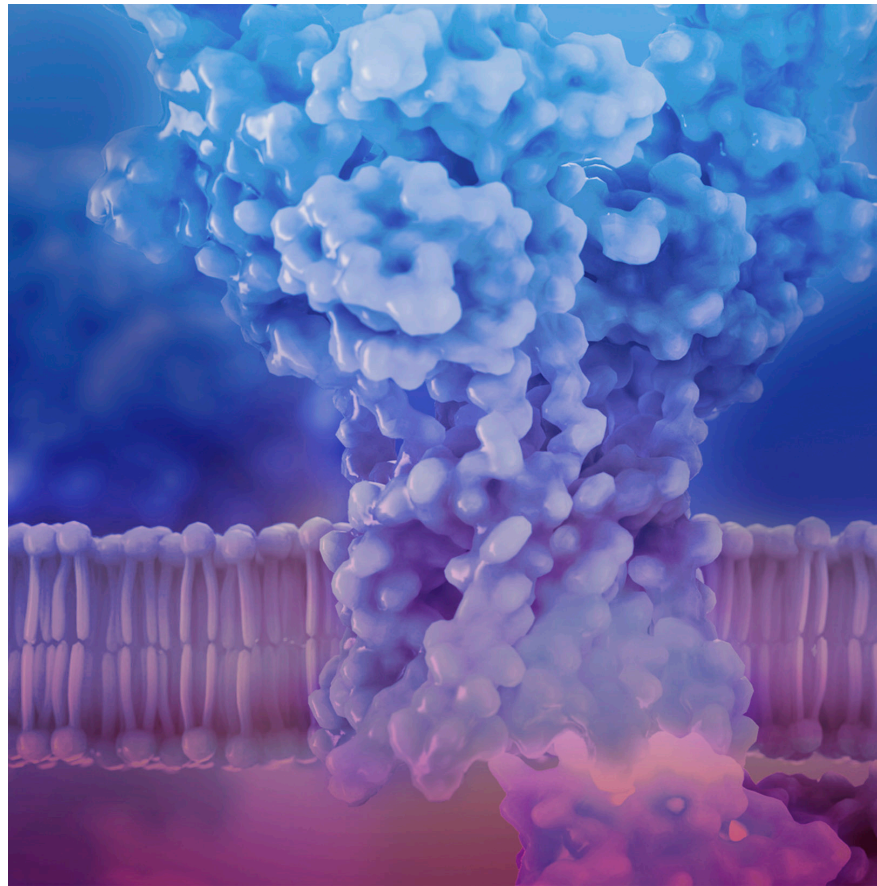
### Scimitar Inc.

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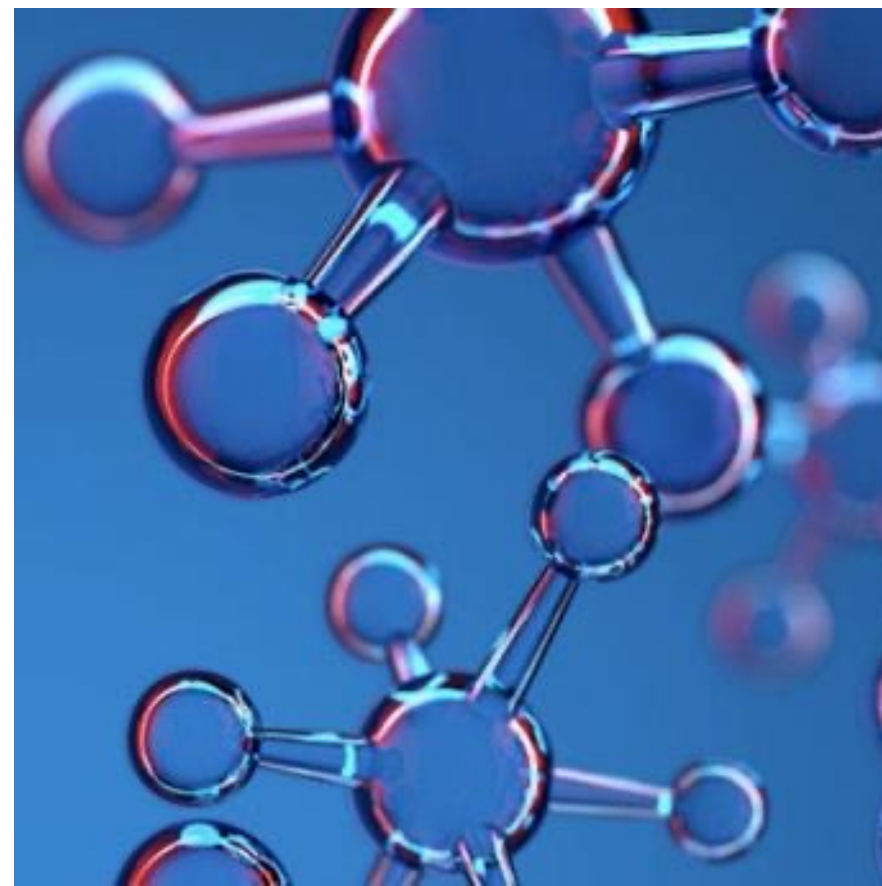
Eliana is a dynamic business management consultant and strategist known for her passion in guiding clients through intricate challenges and discovering groundbreaking business opportunities. Currently serving as an Engagement Manager at Scimitar, Inc., a global life sciences consulting firm, Eliana brings a wealth of expertise to the table. With an unwavering commitment to excellence, she thrives in transforming obstacles into triumphs and remains at the forefront of driving innovative solutions for her clients.



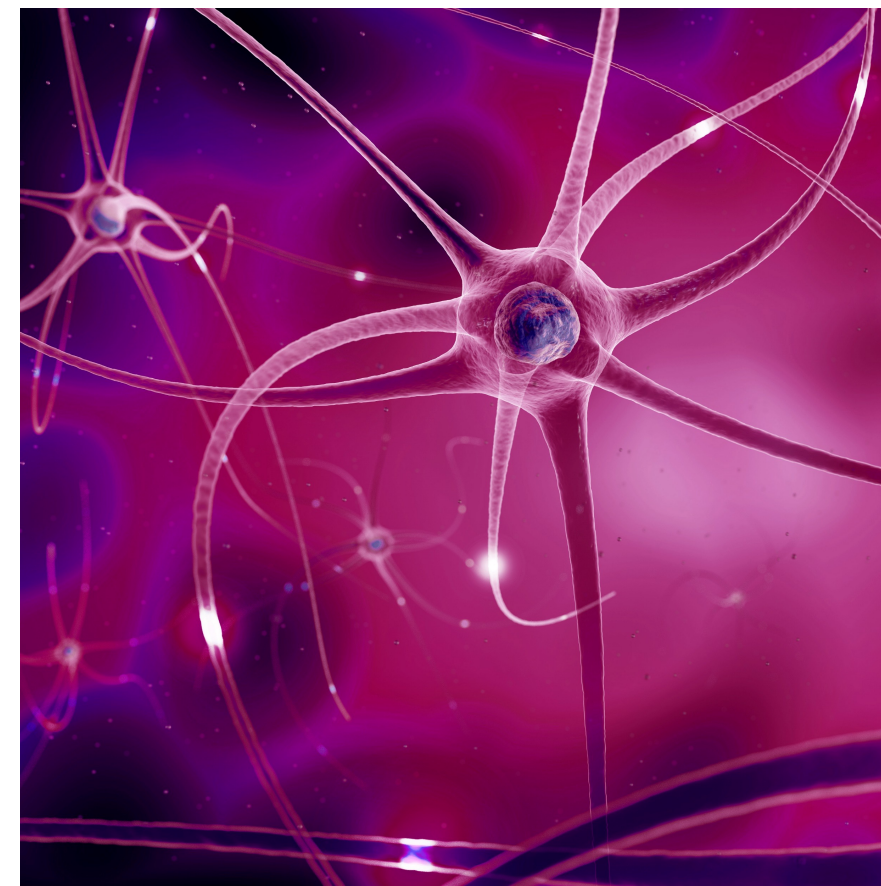
# Agenda



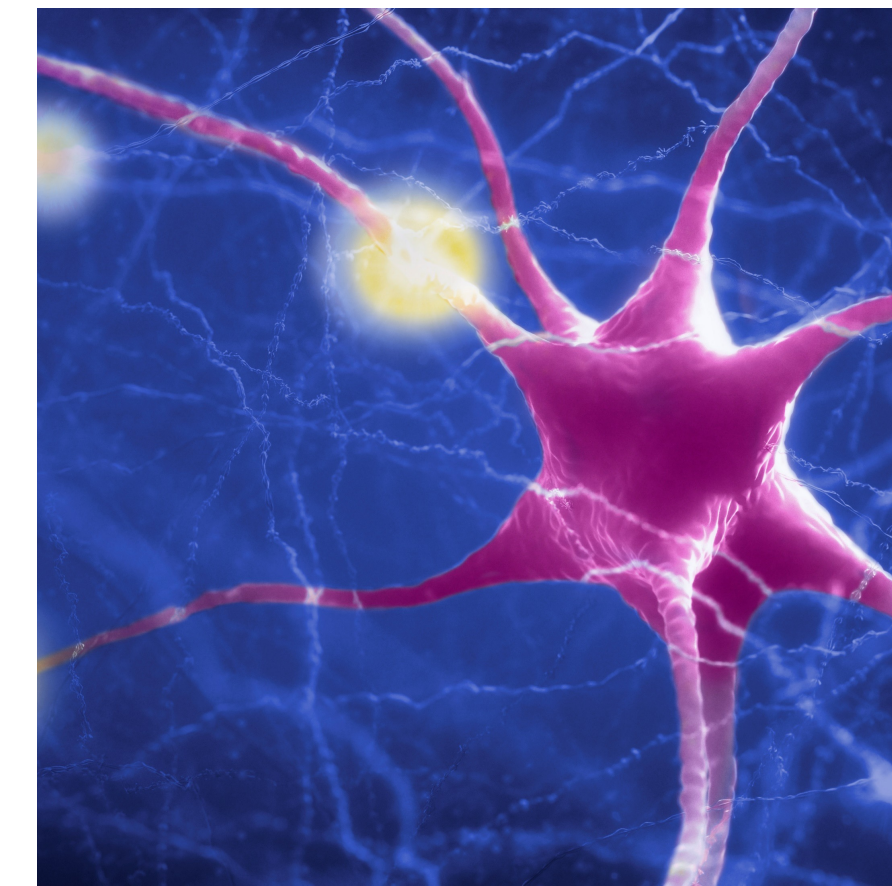
Introduction



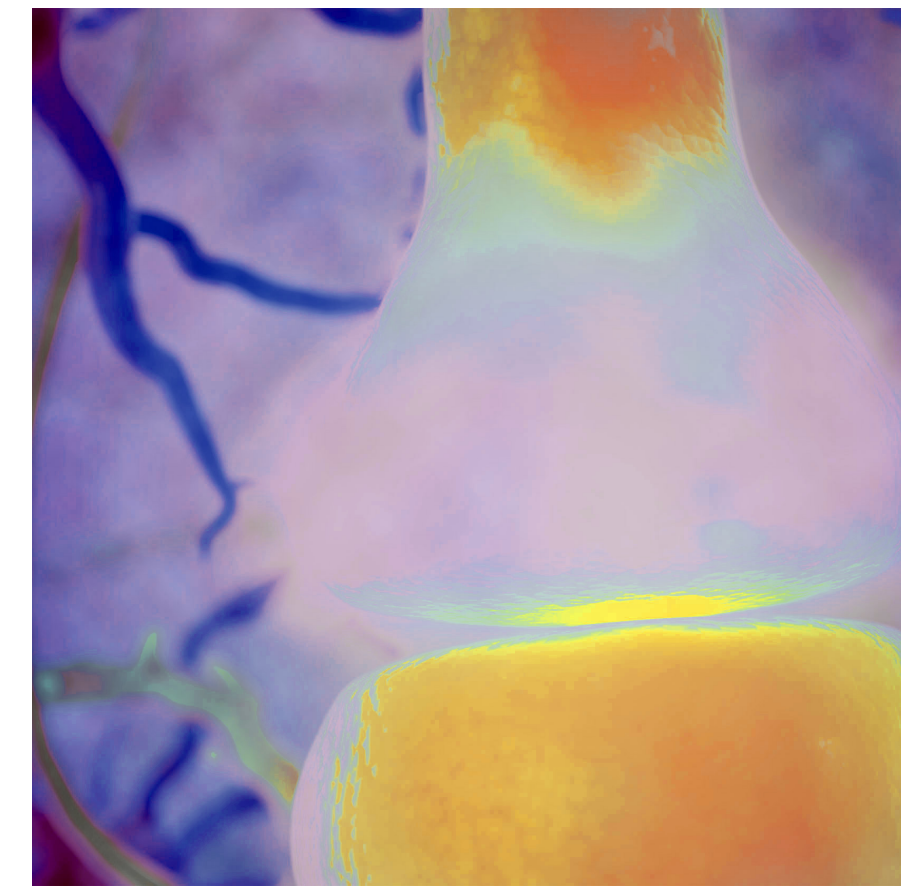
Scrum vs Waterfall



Implementing Scrum



Key  
Outcomes

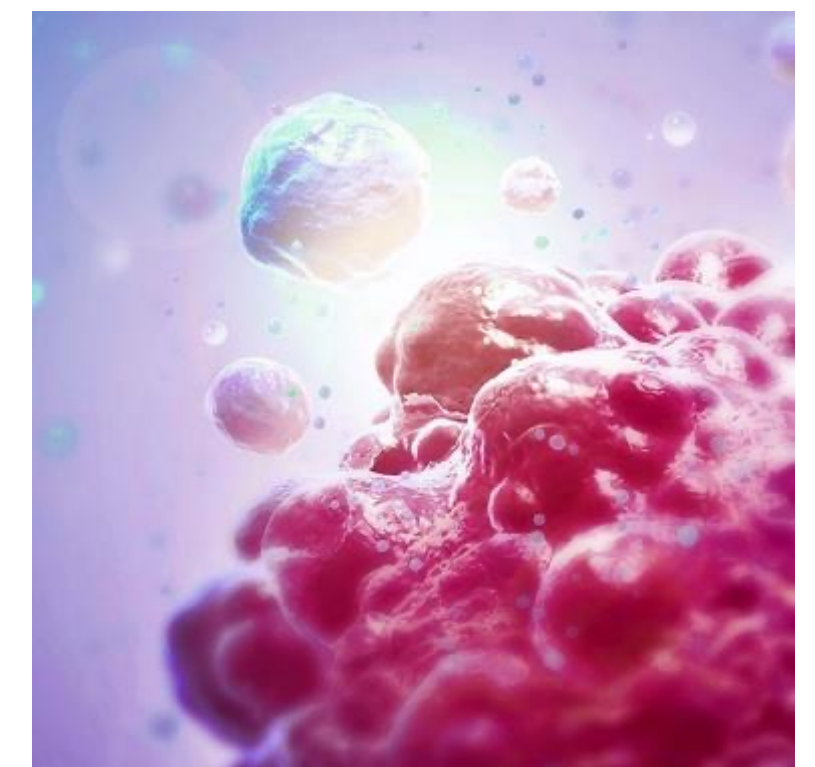
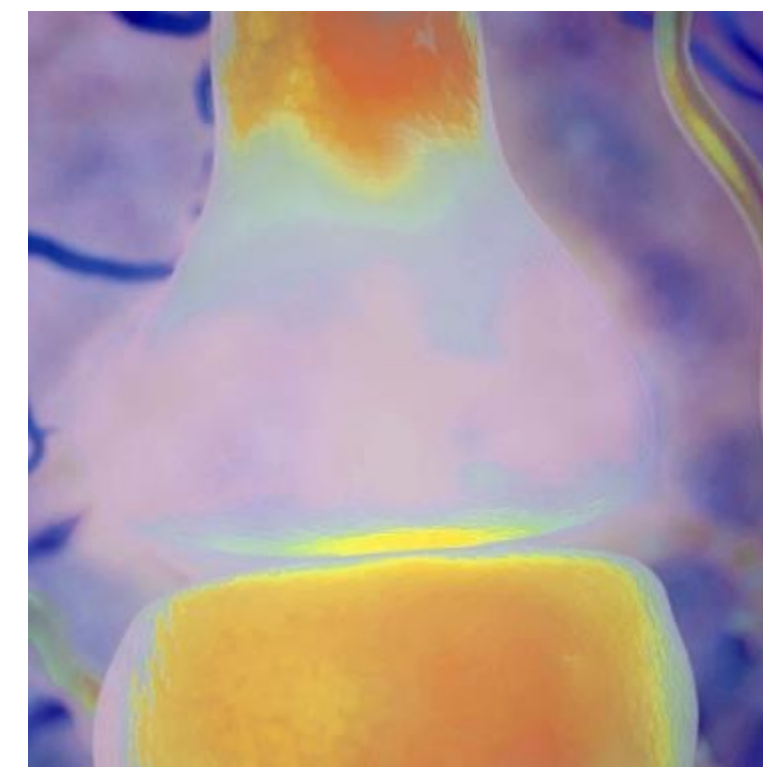


Conclusion



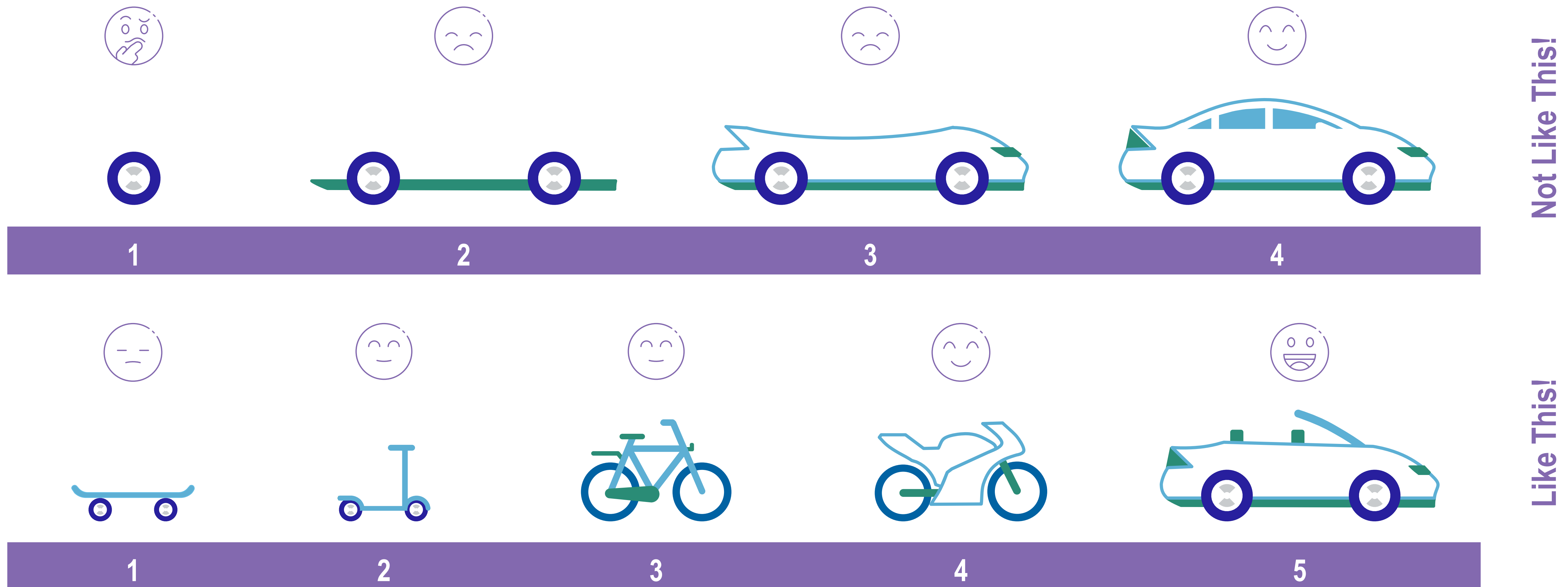
Scrum is an agile project management framework that is useful for addressing complex environments.

In comparison to the traditional waterfall approach, Scrum allows teams to constantly adjust and adapt to changes, leading to more efficient and effective project delivery.





# Adopting the Scrum framework can help teams meet stakeholder demands by providing a flexible and iterative approach to project delivery





# Why Scrum?

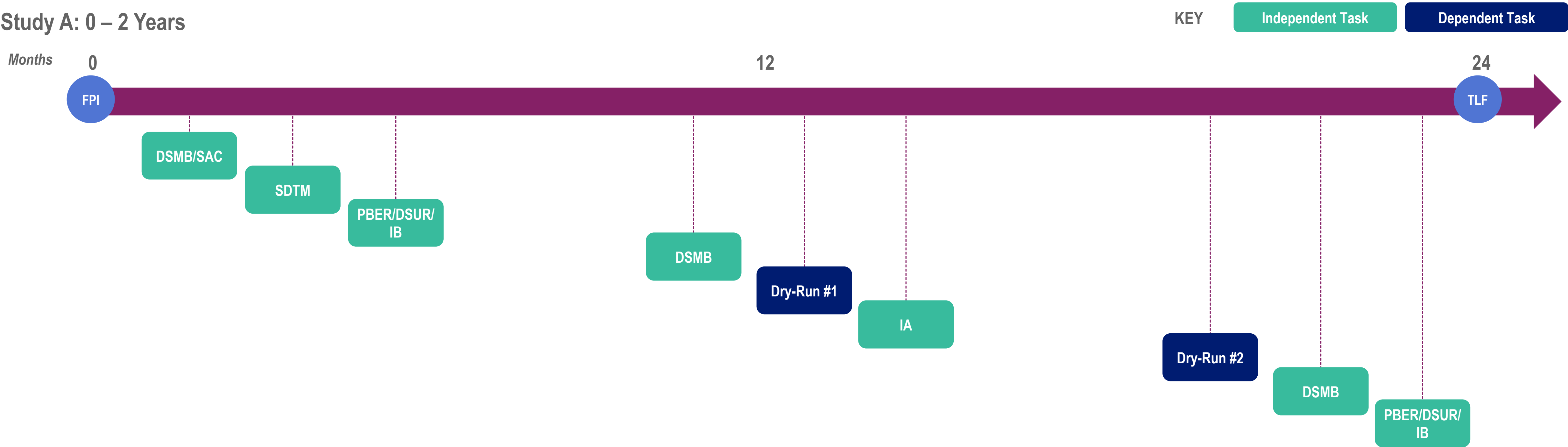
**Pharmaceutical organizations are constantly evolving, with increasing pressure to bring medicines to patients faster.**

To ensure successful outcomes and reduce time to market, it is essential for teams to work efficiently, collaboratively, and rapidly adapt to changing requirements.





# Traditionally, statistical programming teams have used a waterfall approach to manage projects

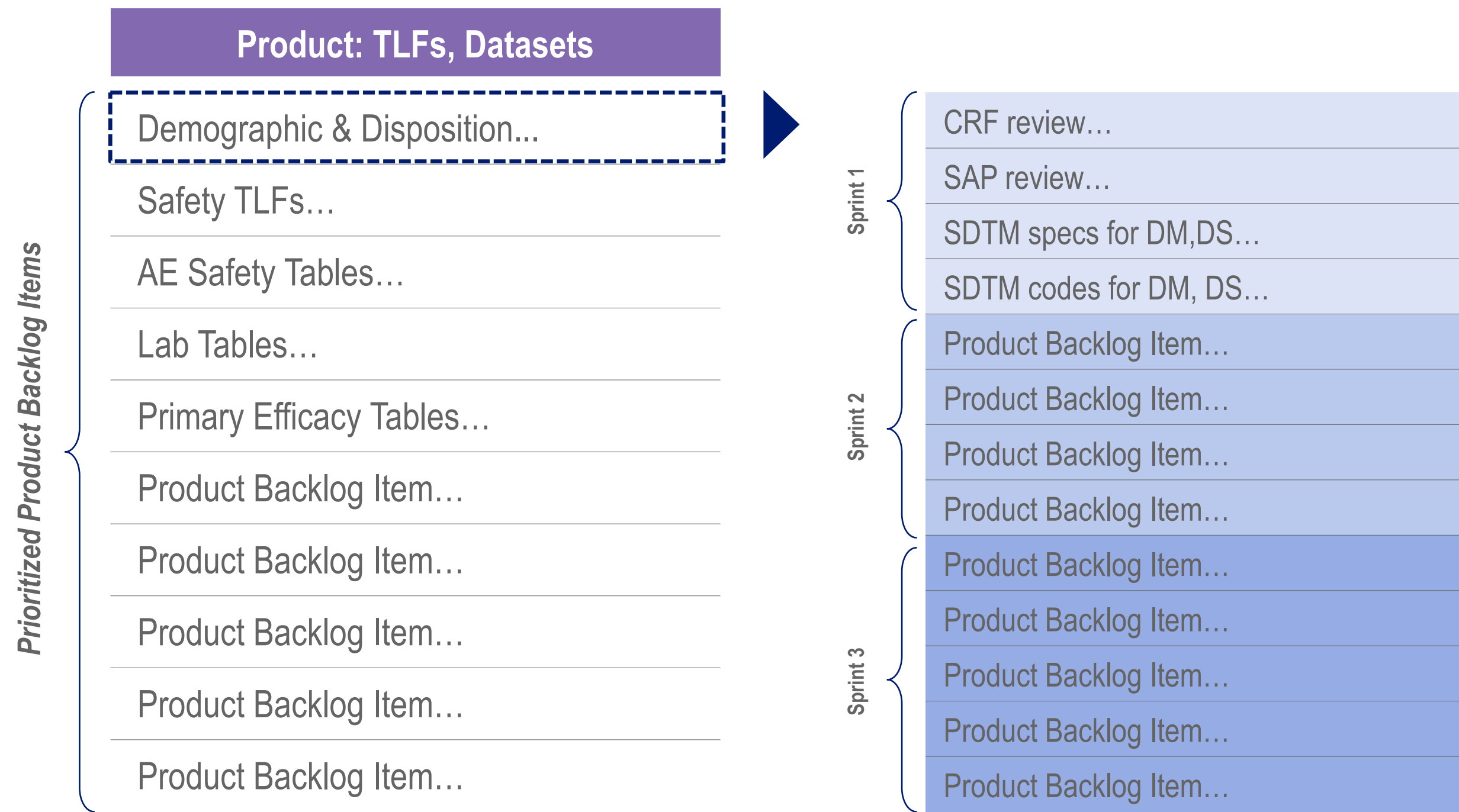


The waterfall approach typically does not lend itself to unforeseen changes and events, which frequently occur in our industry. As a result, project teams can find themselves confronting issues when it is too late - often leading to delays in deliverables.



# Scrum is an iterative and incremental approach that emphasizes flexibility, transparency, collaboration, and continuous improvement

Study B: 0 – 2 Years



This approach helps reduce time and energy by enabling teams to constantly inspect, align, and adapt their work. By leveraging the framework, teams can break their work into short cycles, so that they have an opportunity to course correct before reaching their end goal.



# Scrum vs Waterfall

SCRUM	VS.	WATERFALL
Iterative		Sequential
Flexible		Planned
Collaborative		Siloed
Continuous Improvement		Final Product

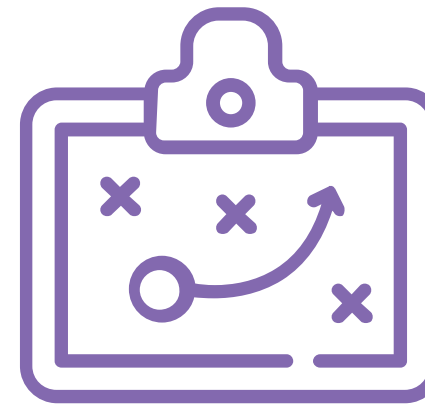


# In the Spring of 2022, our department set out on a mission to innovate our approach to project delivery



## Strategic Technical Partner

- Improved stakeholder relationships
- Solve complex problems / projects across all of R&D
- Challenge the status quo and traditional ways of working



## Proactive Management

- Anticipate impediments/ manage risks
- Greater accessibility to pertinent information
- Accelerated approach (submission ready)

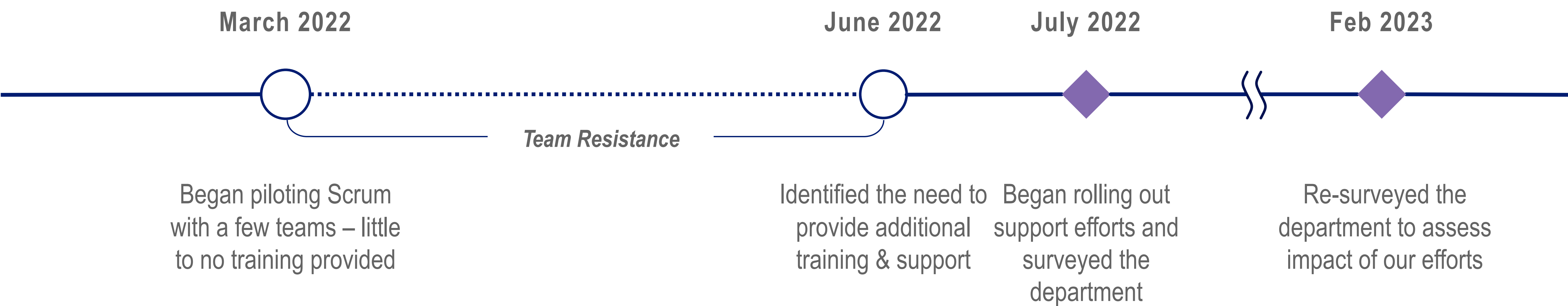


## Forward-Looking Team

- Curious, ever learning, inspiring, and motivated
- Prioritize employee growth and development
- Drive industry trends and processes/ways of working

# To aid in the realization of our intended outcomes and vision, we began leveraging Scrum

## A look at our journey...





# 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

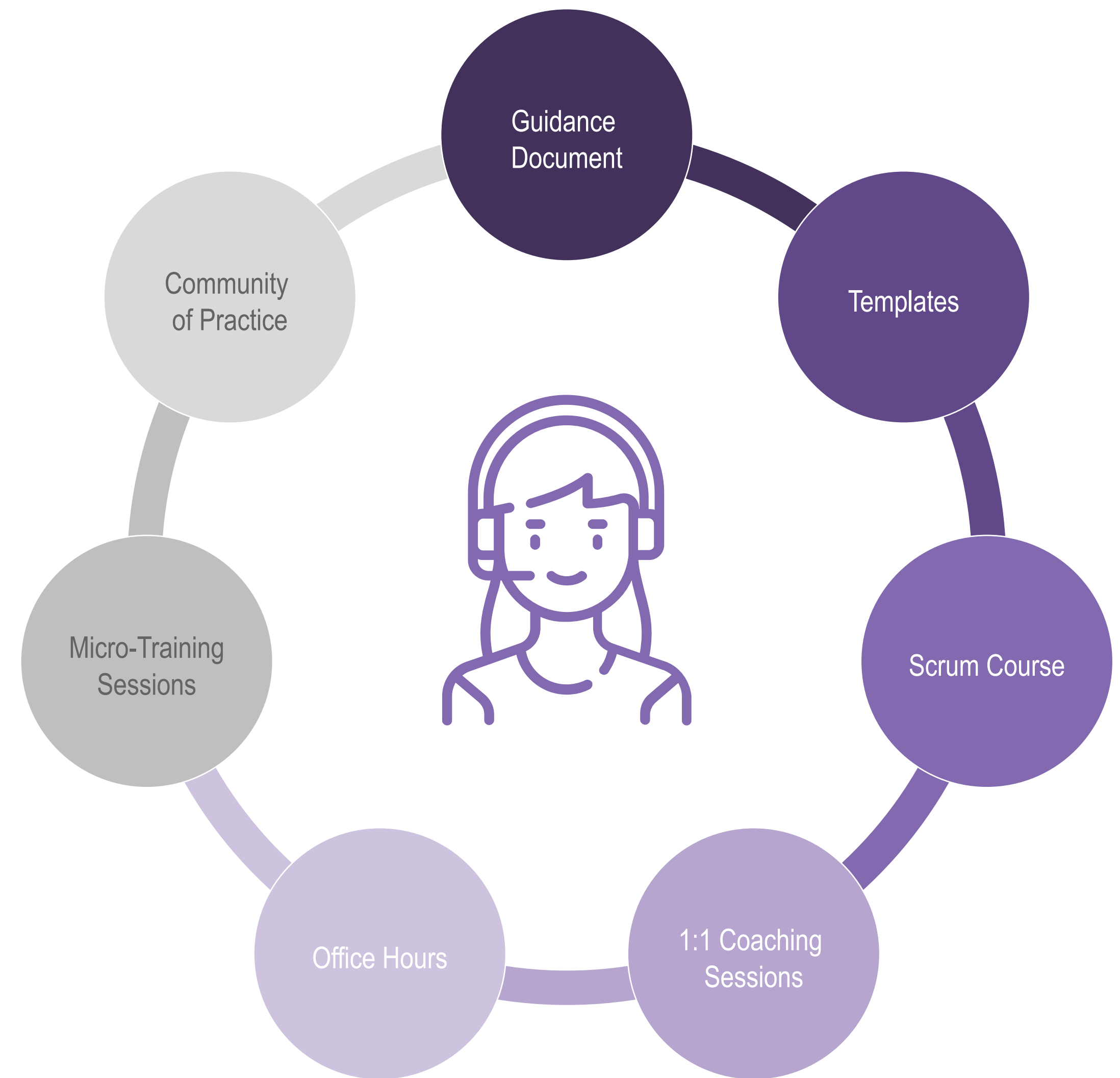
## Below were some of our key findings:

- 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
- Respondents reported Scrum high in team cohesiveness and efficiency
- 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

We brought in a team of experts, focused on value rather than following a strict methodology, that helped tailor Scrum to fit our needs



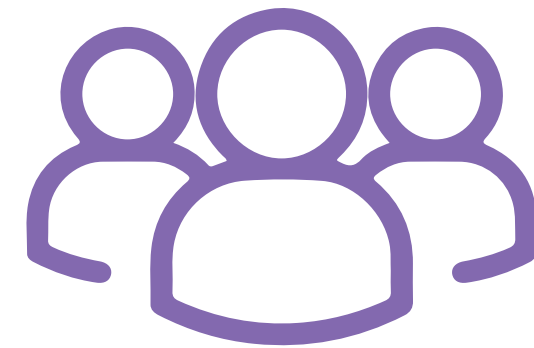
The various and consistent touchpoints allowed us to quickly adapt and overcome challenges to ensure that the framework was implemented effectively



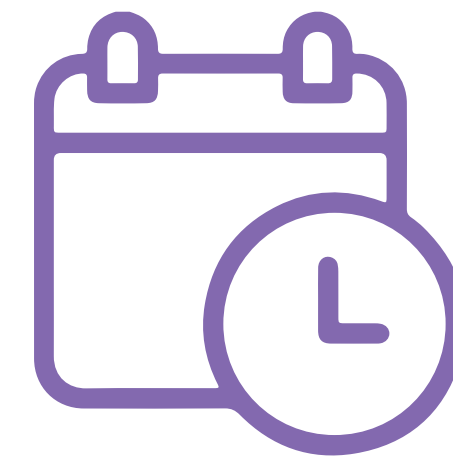
# As part of our implementation strategy, we made several key adaptations to our ways of working



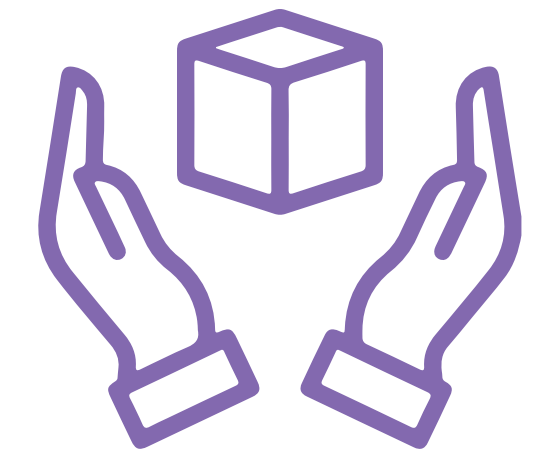
Clear Roles and  
Responsibilities



Consistent Team Members



Regular  
Sprint Schedule



Product Backlog Development

# We worked with our teams to help them think of the complete study deliverables as one product and then developed a prioritized list of items required to deliver the product

**SAMPLE:** 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

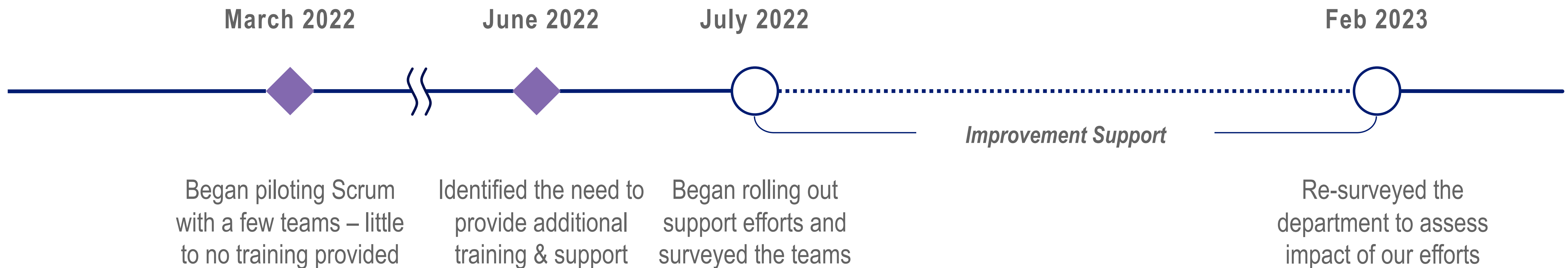
- Listing 10.2.4.4-Production-[U]
- Listing 10.2.4.4-Validation-[U]

## Figure Programming

- ...
- ...



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 February Survey were positive

**We found that respondents were generally 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:



## **Workstyle**

48% reported that Scrum fit well with the way they like to work.



## **Quality of Work**

55% reported that Scrum improved the quality of their work.



## **Control Over Work**

55% reported that Scrum gives them greater control over their work.



## **Team Cohesiveness**

72% reported that using Scrum improves team cohesiveness.

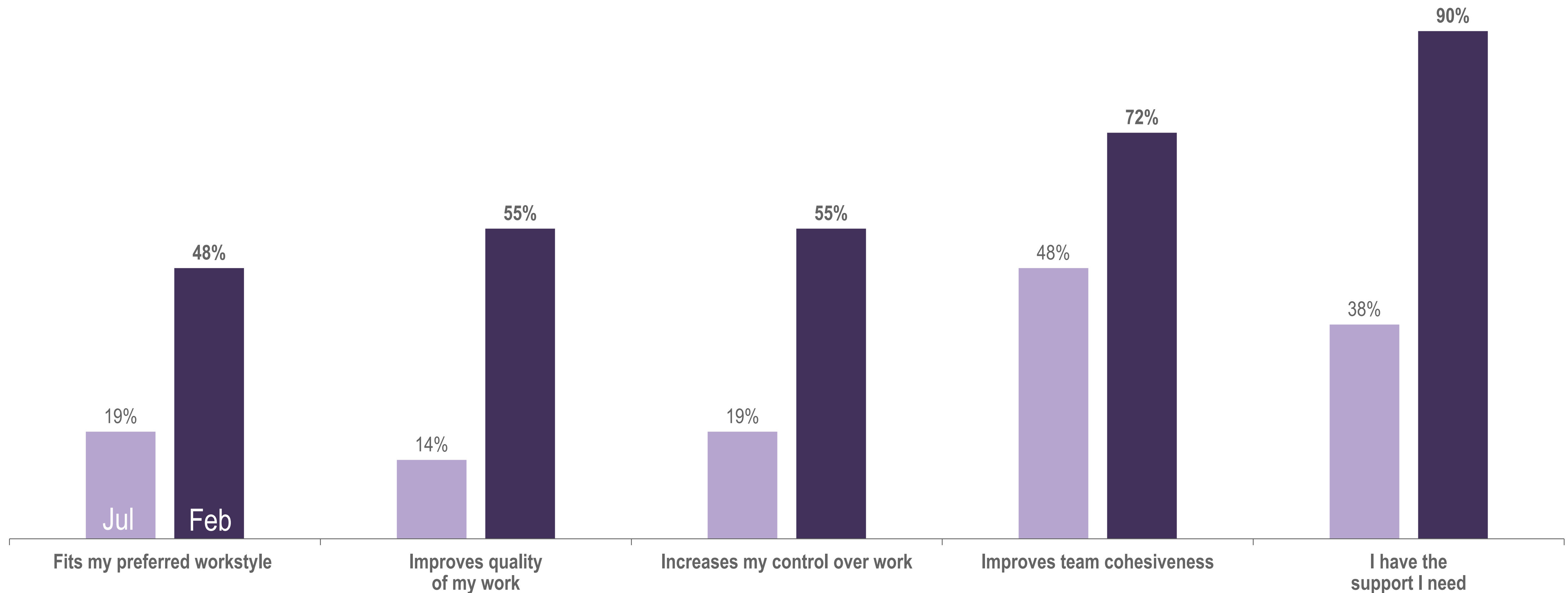


## **Support**

90% 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.



# Several key outcomes have demonstrated the value of Scrum as a project delivery approach within our organization



Greater Transparency



Increased Communication



Better Alignment with  
Business Objectives

These outcomes have helped build support for continued use of the Scrum Framework and expansion into other departments.

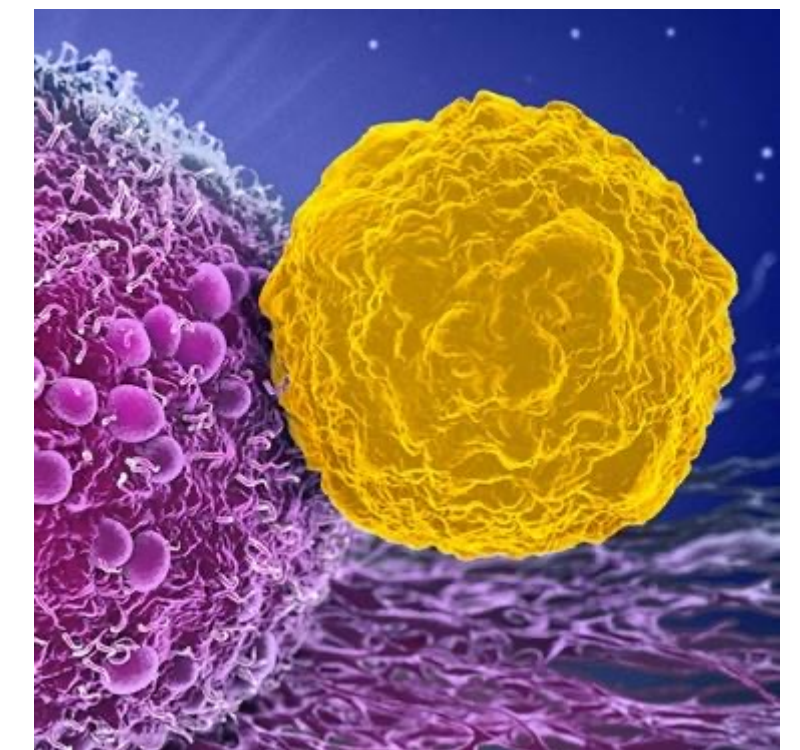
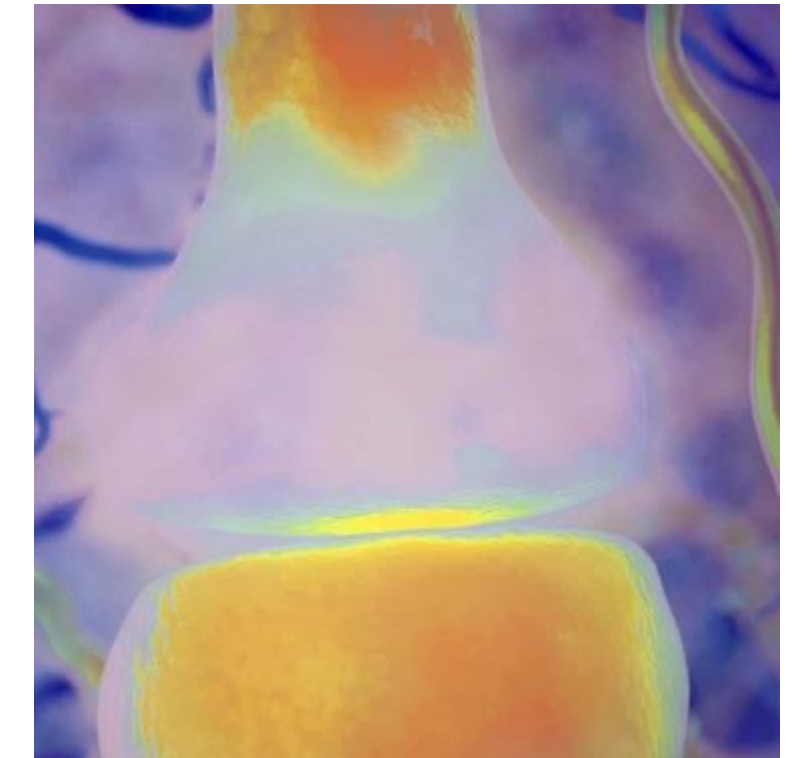


# Pharmaceutical Data Analytics and Statistical Programming is a complex environment that can benefit from implementing Scrum

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:

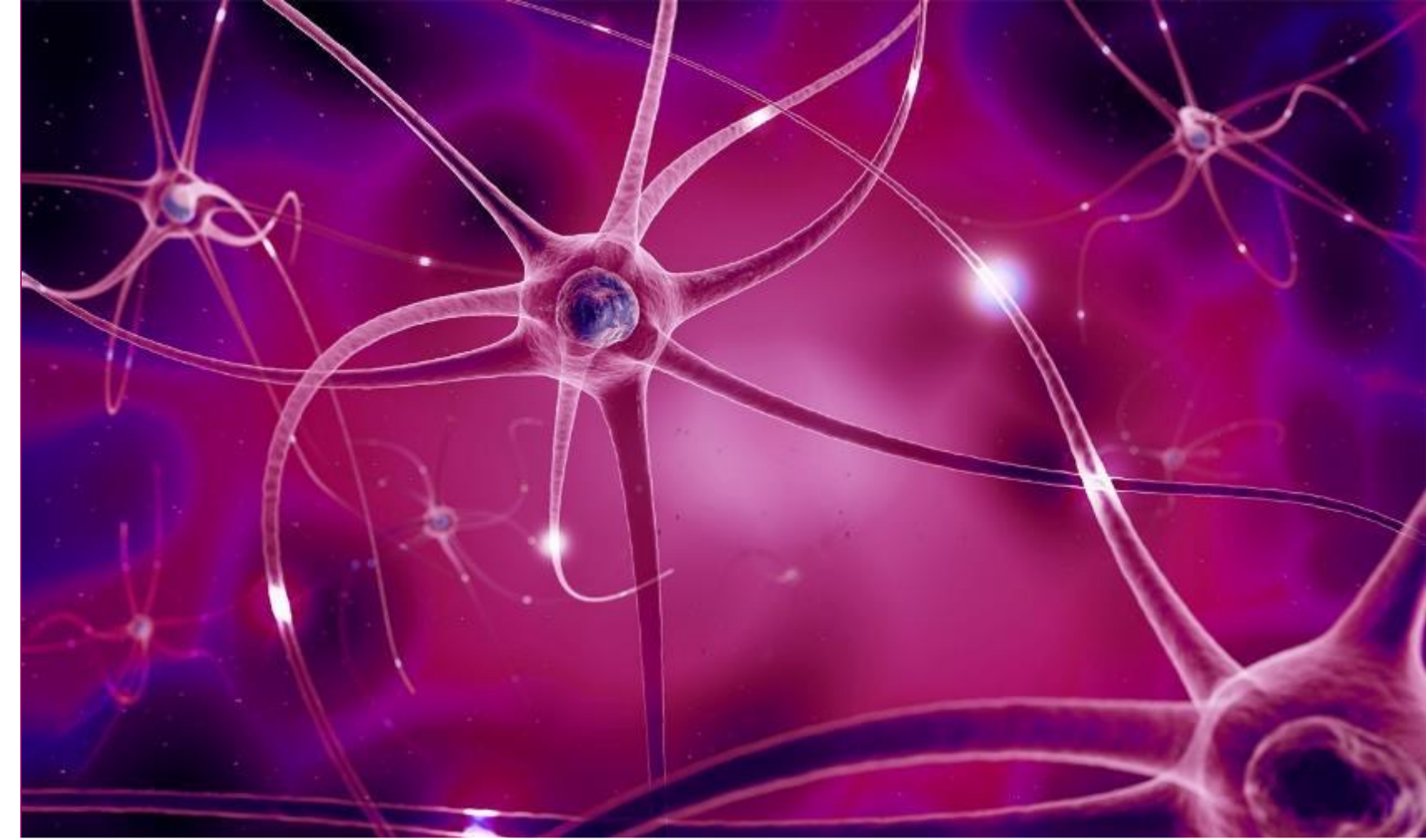
- Change management and communication
- Training
- Tailored guidance development
- Ongoing support





# That's a wrap....

- Scrum vs Waterfall
- Implementing Scrum
- Positive Outcomes
- Is Scrum for your organization?





# Thank You



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