



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

Sheetal Patel / Michael Rimler

Interactive – create word cloud (e.g., menti.com)

What does
agile mean to
you?

Join at:
vevox.app

ID:
100-482-879



The Agile Manifesto

...emphasizes flexibility, collaboration, and customer satisfaction

Principles of Agile...

Customer satisfaction through early and continuous delivery

Welcome changing requirements, even late in development

Deliver working software frequently

Collaboration between business stakeholders and developers

Build projects around motivated individuals

Face-to-face conversation is the most efficient and effective method of communication

...applied to Clinical Reporting

Reduction in late-in-the-game change requests
No more Dry Runs

When they come, easier to accommodate
More accurately estimate the impact

Code base and documentation developed in sync

Statistics, Clinical, Asset Leads, Sponsor/Clients

Granular tasks enable targeting the right resources

Frequent and regular communication, even hybrid

<https://agilemanifesto.org/principles.html>

The Agile Manifesto

emphasizes flexibility, collaboration, and customer satisfaction

Principles of Agile...

Working software is the primary measure of progress

Sustainable development

Continuous attention to technical excellence and good design

Simplicity – the art of maximizing the amount of work not done – is essential

Self-organizing teams

Regular reflection on how to become more effective

...applied to Clinical Reporting

Fully validated datasets, TFLs, data visualization platforms for each milestone

Happy teams with infrequent and minimal stretch

Documentation (aCRF, cSDRG, ADRG, define.xmls)
Testing, quality control, quality assurance, GPP

e.g., minimal features of datasets to deliver interim analyses

Leverage performance metrics from backlog
Empowerment and not central planning

Retrospectives

<https://agilemanifesto.org/principles.html>

Unique Selling Proposition (USP)



*Better collaboration
among pipeline teams*



*Better use of
modern technology*

How might we... **transform** the way we work in clinical study reporting, strengthen our ability to use **new capabilities**, and deliver results at a **faster pace** - with a highly **engaged team**

*Ability to deliver key study
results within hours of
database lock*



*Greater job satisfaction for
programmers providing leadership and
technical career pathways*



Sounds good – but WHY is this important for us?

We have listened to our teams. Their feedback has helped us understand key WoW pain points they face.



Pipeline teams **working in silos** significantly **hindering effectiveness** and success of projects, limiting clear communication and **reduced collaboration**



Restricted flexibility in resource to meet peaks and troughs resulting in **decreased ability** to effectively respond to demands and workloads



Limited career paths for technical strengths with lack of clear **path for career advancement**



Low productivity and reduced capacity to implement modern technology resulting in below optimal capacity, **inefficient processes** and **lack of standardization**



Adopting Agile ways of working, our **industry competitors** are able to **deliver faster** with **highly motivated teams**



Plus, why not?

A large, flowing orange shape that starts as a thick, rounded form on the left and tapers into a thin, elegant line that curves across the top of the frame.

You have the why – now the how

GSK

How we are going to do this?

Project Orbit team will **partner** with our teams and leaders to embed **Agile** ways of working (WoW) across Clinical Programming (CP) - helping us deliver goal driven outcomes with defined value

Drive efficiency **with AGILE WoW** by embedding:

Collaborative Workflow & Tracking Tools

Better Workload Forecasting and
Transparency

New Enhanced Roles

Always Improving Mindset

Learning sources of value from Agile WoW through:

SDTM/ADaM experimentation

Center of Excellence experimentation

(e.g., DSUR reporting)

JiRA experimentation

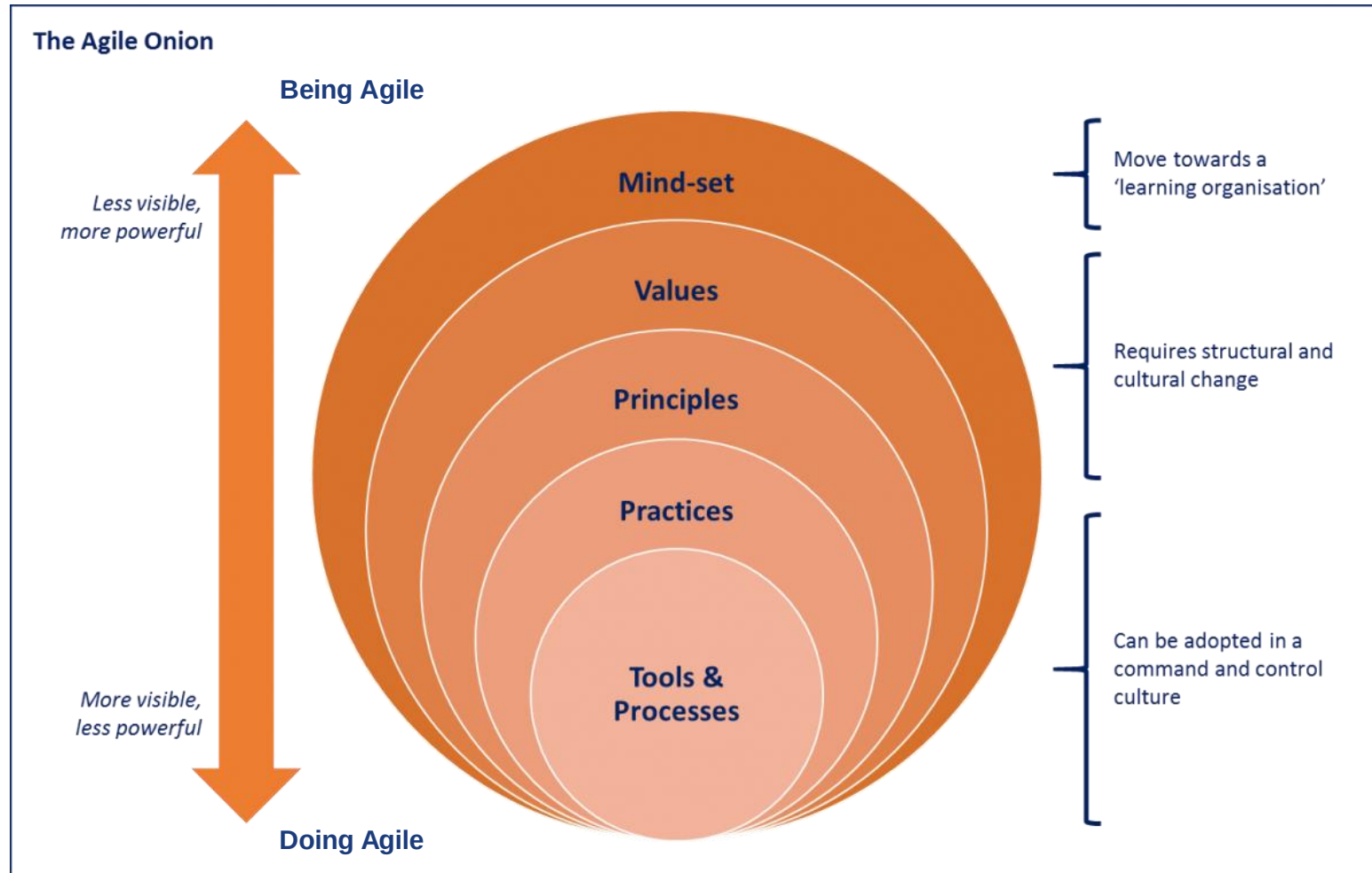
managing backlogs, quality control (QC) activities

Pilot reporting

scrum master, backlog design and management, ceremony design

Growth Mindset is part of Being & Doing Agile series

Empowering teams to flourish by developing leadership, culture and practices



Growth Mindset

Psychological
Safety

Servant
Leadership

Empowerment

Transparency

Iterative way of
working

Cross functional
teams

Continuous
Improvement

What questions might Agile WoW help answer?

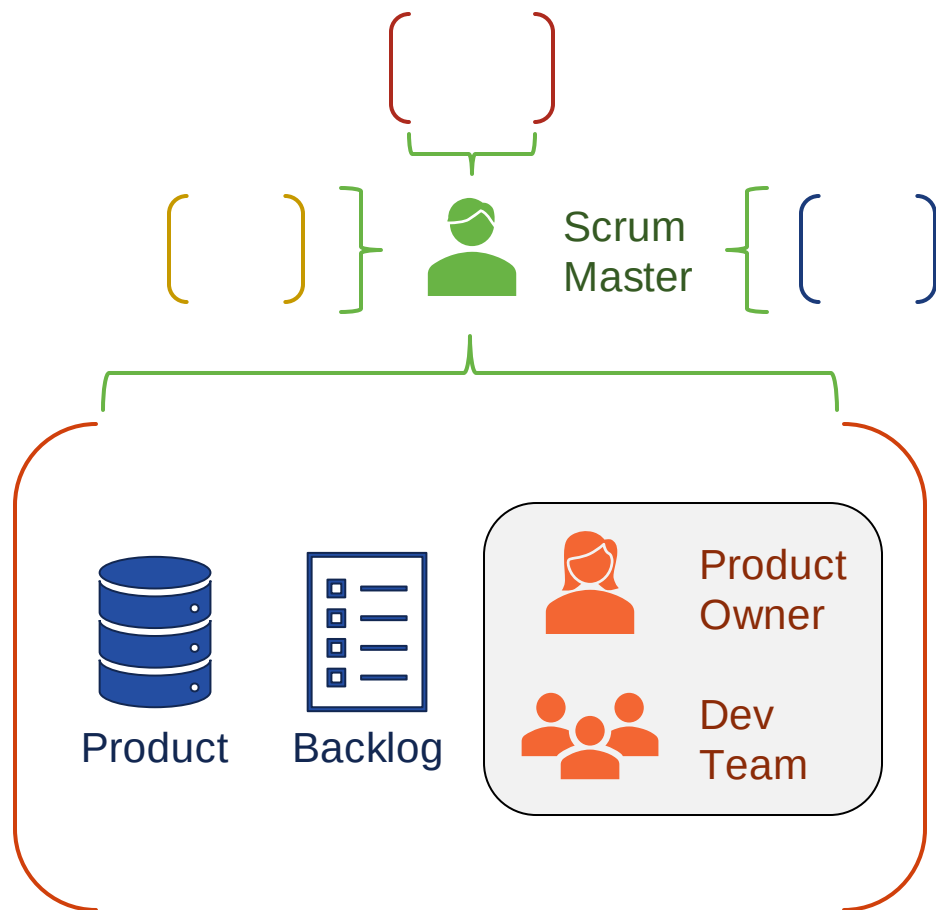
**How
might we
improve...**

... product delivery

... resource management



Product Delivery



Product

- ☐ Statistical Analysis Plan (+OPS)
- ☐ ADaM Package
- ☐ SDTM Package
- ☐ ISS/ISE
- ☐ Submission Data Package
- ☐ Interim/Primary/EOS

Backlog

- ✓ Build in quality testing/review (e.g., QC)
- ✓ Include documentation development
 - aCRF, ADRG, cSDRG, DEFINES
- ✓ Accommodate changing requirements

Resource Management

Modern Software Firms¹

Chain of Command ↓ flatter
Span of Control ↓ single manager
Centralization ↓ autonomy

Flatter organizational structures are more agile²

Organizational Structures

by Function by Product
or Matrix?

How does this help you manage risks related to...

- *resource allocation?*
- *product delivery?*
- *staff career development?*

... and who is accountable or managing these risks?

¹ <https://softwaresim.com/blog/common-organizational-models-in-software-firms/>

² <https://www.mckinsey.com/business-functions/people-and-organizational-performance/our-insights/the-five-trademarks-of-agile-organizations>

Imagine if...



Additional GSK Presentations on Agile for Clinical Data Reporting

- Agile Development Methodology for Delivery of the Clinical Data Pipeline, Ben Arancibia and Michael Rimler, 2021 PHUSE US Connect
- An Agile Approach to Onboarding, Ben White (GSK), 2023 PHUSE EU Connect
- The Implementation of Scrum Framework in Clinical Programming Teams, Polina Kornilova, GSK, 2024 PHUSE Single Day Event, Hertfordshire, United Kingdom

GSK