



Why Be Different? Shouldn't Everyone Be Using Agile to Deliver Their Clinical Trials?

2025 PHUSE US Connect / ET08

What is Agile?

Agile Manifesto

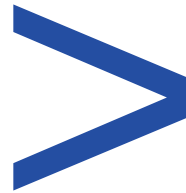
Value

Individuals and interactions

Working software

Customer collaboration

Responding to change



Over

Processes and tools

Comprehensive documentation

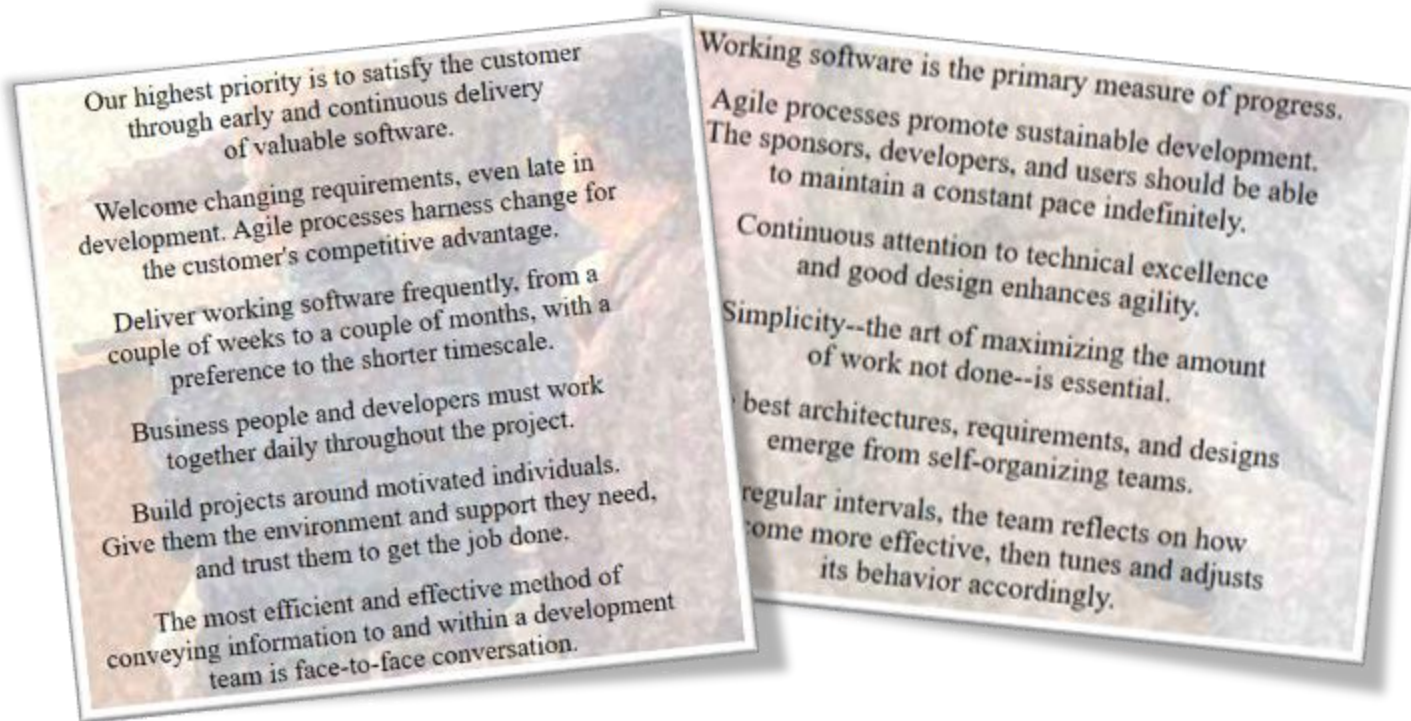
Contract negotiation

Following a plan

<https://agilemanifesto.org/>

What is Agile

Principles of Agile



Emphasizes...



flexibility



collaboration



customer satisfaction

<https://agilemanifesto.org/>

Why do we do what we do?

- Help patients
- Help people
- Develop medicines/vaccines
- Love the science
- Love to program
- Love data

Who are our customers?

- Asset Owners
- Medical Writing
- Regulatory (internal)
- Safety
- Statistics
- Health Authorities

- Sponsors (CRO)
- Patients

What do we produce?

- SDTM
 - Define, aCRF, cSDRG
- ADaM
 - Define, ADRG
- ARDs
- TFLs
- Interactive Displays
- Patient Profiles

How do we know what customers want?

- Protocol
- Analysis Plan
- Programming Specifications
- Data Standards (e.g., CDISC)
- Reporting Standards
- Safety Review Plan

- Dry Runs
- Customer interaction??

Principles of Agile applied to Clinical Reporting

- ★ Drive value to customers: Statistics, Clinical, Asset Leads, Sponsor/Clients
- ★ Definition of Done: Fully validated deliverables at release
- ★ Frequent and regular communication on team
- ★ Retrospectives – improve team from within
- Empowerment and not central planning
- Strategic targeting for the right resources for the task
- ★ No more Dry Runs
- Code base and documentation developed in sync
- Happy teams with infrequent and minimal stretch
- More accurately estimate the impact of late-in-the-game change requests
- Leverage performance metrics from backlog

LI07: 2024 PHUSE EU Connect, Sheetal Patel and Michael Rimler

**Agile is more
than a project
management
toolbox**

**Deliver value to the customer
when they need it**

Agile applied to Clinical Reporting

Implementation at GSK

Pilots/ Experiments

- Introduced Scrum Master role
- Defined Study Lead Programmer as Product Owner (PO)
- Explored use of backlog (features and tasks)

Wave 1

- Multiple squads
- New to all: SMs, POs, and Programmers
- Multiple POs in a squad – prioritization key

Future waves

- Foster incremental learning
- Ensure knowledge sharing
- Ask “What did we get wrong – how do we adjust”

Business continuity

**Migrate people,
not projects**

Target for full adoption

“Flexibility without volatility”

Agile applied to Clinical Reporting

Benefits

Combined backlog above study/project

Strategic prioritization of work

More efficient resource allocation –
prioritizing needs of the group

Data driven estimation of change requests

Earlier identification of risks to delivery
timelines

Challenges

SLP (PO) vs Scrum Master identity crisis

Breaking down the backlog into tasks –
smaller than the dataset/display

Jira – does it do more work?

Will get many adoption:

→ more meetings?!?!?

→ Sprint duration, frequency of standups

MINDSET

Agile applied to Clinical Reporting

Three additional takeaways

*How do we **differ** from software development (textbook agile)?*

- We know what features are required - pre-determined specifications
- Fixed timelines – little room for negotiation
- 100% accuracy is required
 - Quality control tasks needed, not just 'testing'

*Breaking down the backlog – the **display driven** approach*

- Driving value to the customer early and incrementally
- Maximizing the work not done
- What does this mean in practice?

***Estimation** of effort – pros and cons*

- Empowerment or increased monitoring and micro-managing?
- Prediction and data-driven assessment of change requests

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



- Agile? WoW! How Agile Ways of Working can Drive Value for Conventional Clinical Trial Reporting, Sheetal Patel and Michael Rimler, 2024 PHUSE EU Connect

Open Discussion

...and Q&A 😎

What other considerations do you think
are important when applying
agile principles and *ways-of-working*
to conventional clinical reporting
processes?

GSK