



*How Agile can you be -
Looking at statistical
programming as a software
development process*



Oliver Wirtz, Bayer AG



When the clock strikes 'lock,' it's time to pray to the data gods!





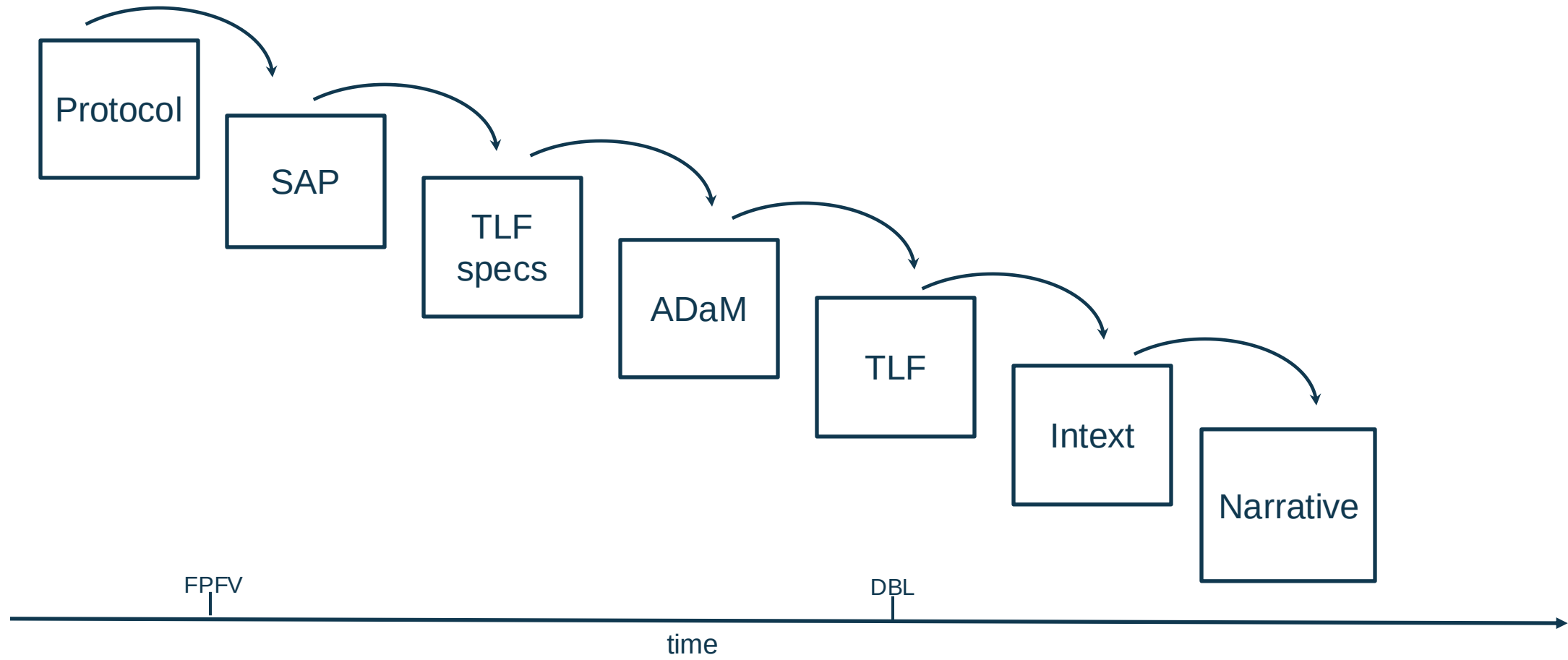
Agenda

- // Re-visiting the clinical trial analysis process
- // Analogies with software development
 - // DevOps to enhance collaboration
 - // Agile tools to help organizing work
- // Bringing Agile into the organization



Clinical Trials Analysis (process view)

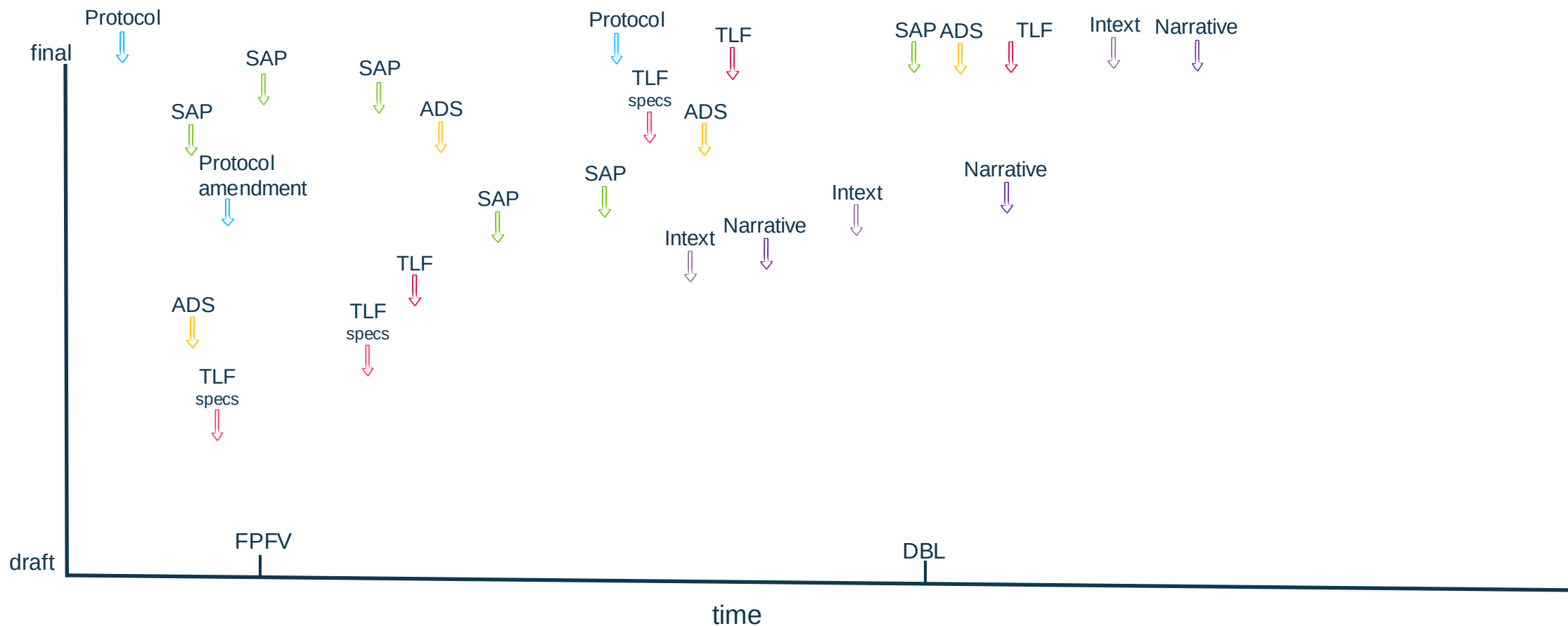
sequential availability of pre-defined deliverables





Final availability is something like this

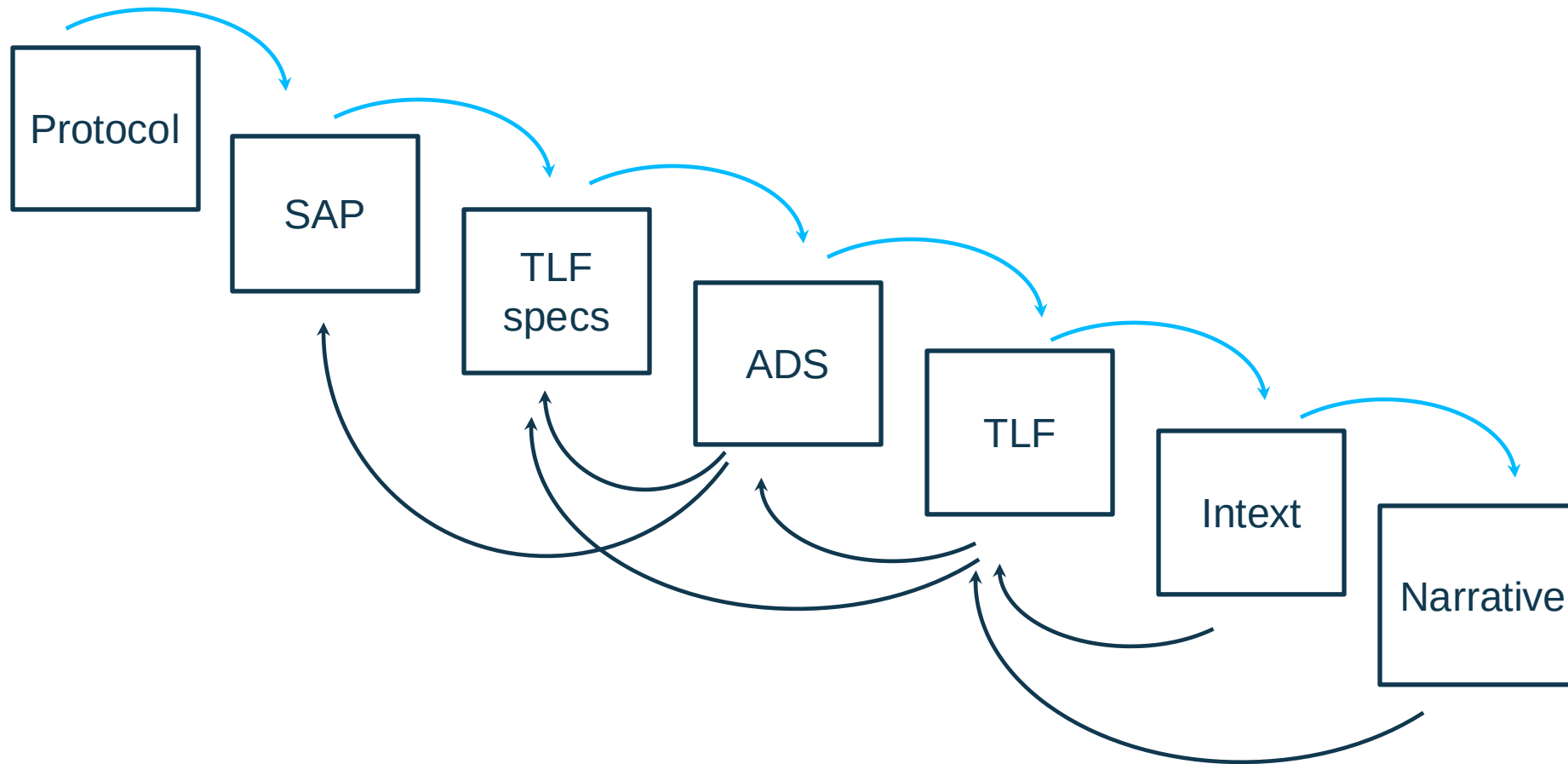
...in fact, there is a lot happening between FPFV and DBL





We are idealizing the course of trial analysis

waterfall/sequential vs. iterative-incremental

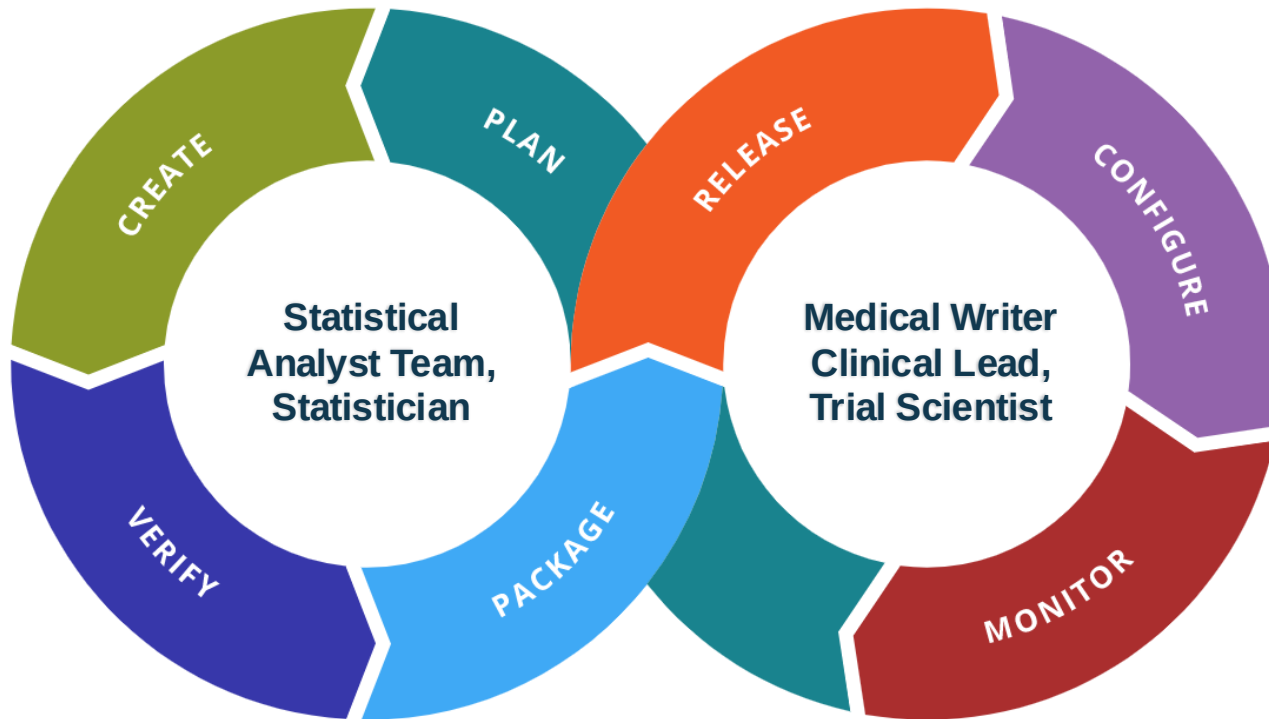




Revisit pharmaceutical programming process

Change of mindset to actively encourage collaboration and agile behaviour(s)

- // Recognize statistical programming work as an ongoing interaction between development- and operations team – organize this interaction using DevOps/Agile tools



Adapted from <https://www.cabotsolutions.com/public/DevOpsCycle.png>



When projects go well...

...it's because

- // Everybody on the team knows their role
 - // The team has established an efficient communication style, off record, as needed
 - // The team can react fast to changes
 - // The team is self-organizing and works cross-functional
 - // The team front loads tasks
 - // The team provides regular updates to stakeholders
 - // The team pro-actively tries out new/alternative ways to solve issues and is innovative
 - // ...and many more
-
- // Core principles of Agile: Adaptability, Collaboration, and Incremental Delivery.



Iterative-incremental workflow

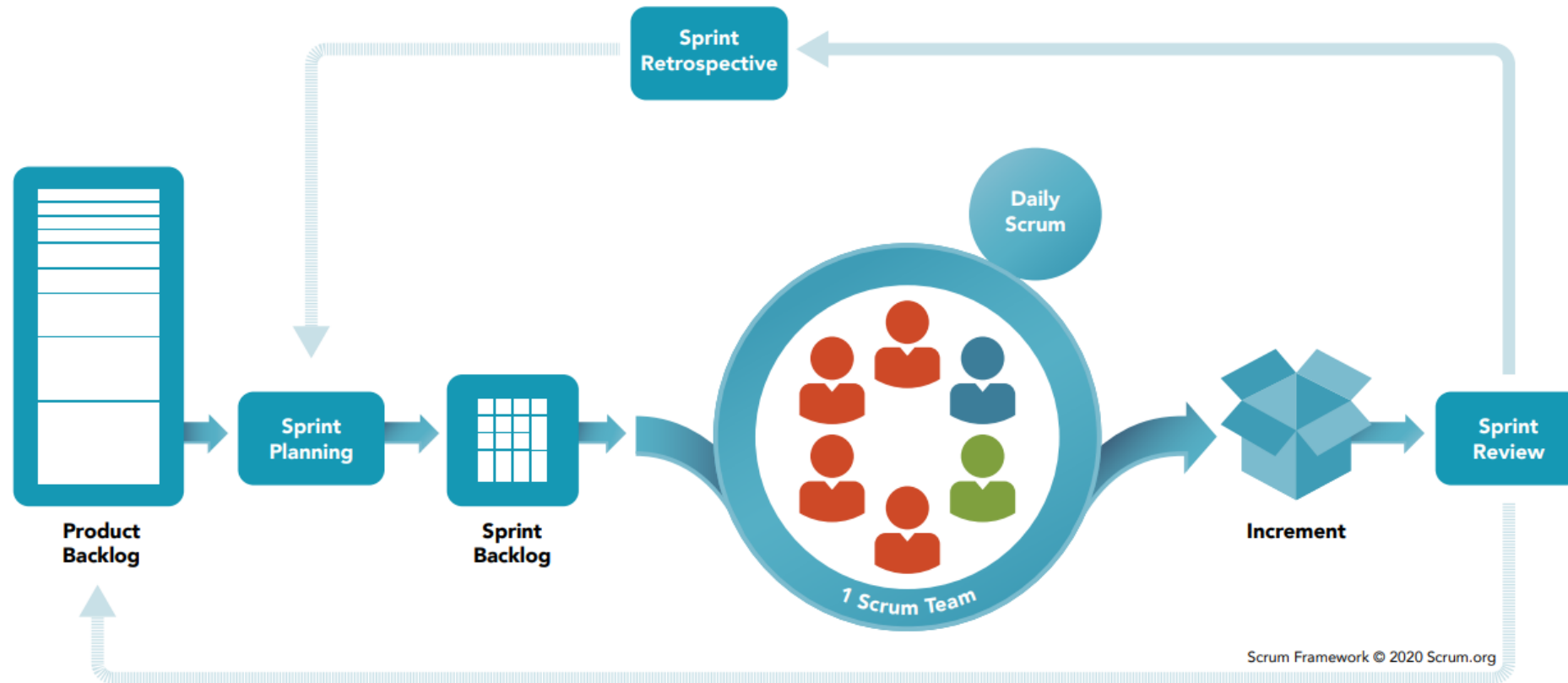
...complete what's possible to complete – all the time

- // Break down overall workload into work items/tasks
- // Discuss in team which items can be started and completed with the available information
- // Divide overall time until final deliverable into time-boxed intervals (sprints) of e.g. 2 weeks
- // Commit to a number of work items that can be completed during the time interval
- // (discuss prioritization, if needed)
- // After the sprint, track and share the outcome with the team
- // Accepted outcomes are seen as completed
- // Changes and comments are addressed and reviewed in next sprint
- // Repeat!



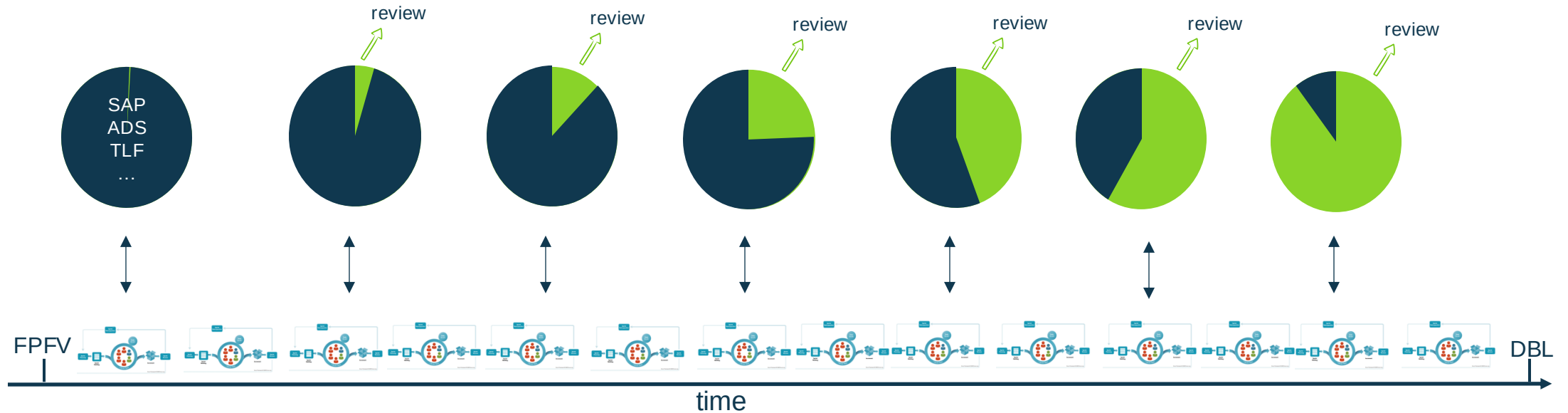
Scrum framework

an iterative-incremental workflow



Iterative-incremental workflow

...complete what's possible to complete – all the time





Summary

- // Embrace change as integral part of the clinical trial process
- // Extend the scope to interaction with stakeholders outside statistical programming
- // Change of mindset to actively encourage agile behavior(s)
 - // Leverage existing practices and tools to transition effectively.
 - // Identify already existing agile working behaviors
 - // Utilize agile tools for better collaboration and incremental delivery
 - // Actively include stakeholders in sprint review
- // Be aware that agile may have different flavors depending on type of trial



Any questions?



Contact the author:

oliver.wirtz@bayer.com