

Exploring the Efficacy of Agile at FDA

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How is FDA using Agile?

With innovative, outside-of-the-box thinking, the Office of Computational Science (OCS) has led the way implementing the Agile Mindset on multiple in engagements – many of which are not the “traditional software development” efforts that Agile is usually applied to. Does Agile work beyond software development? You bet it does! And the results have been incredible and infectious. These include using Scum to build an entire suite of Data Quality reports, produce specialized Statistical Programs based on end-user needs, and iteratively create documentation such as Process Guides and SOPs. Even non-IT, Service-Oriented projects use principles including Kanban boards and Work In Progress (WIP) limits to enable deeper visibility into the work across resources, amplify the flow of work across teams, and foster a culture of continuous learning at the FDA. From vision to execution, innovative implementation of Agile principles has been the secret sauce to accelerate value to the mission!



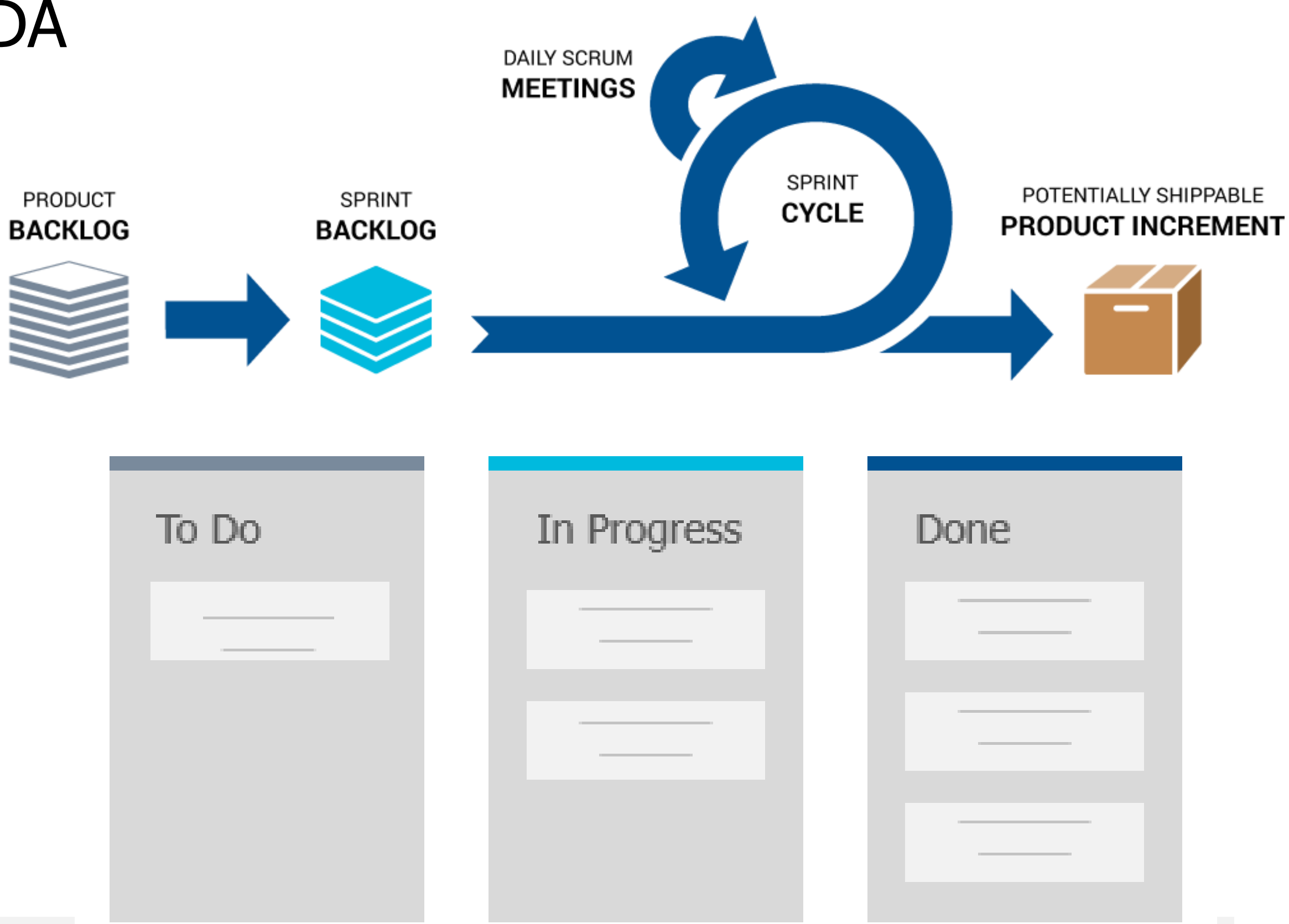
What is Agile?

Agile is an approach and a mindset that focuses on value delivery, outcomes over output, and continuous improvement. The requirements, solutions, and plans are flexible and evolve over time. Agile teams are self-organizing, cross-functional, and work collaboratively with end-users.

Methodologies used at FDA

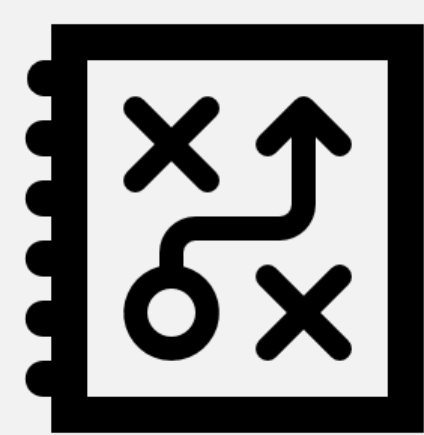
Scrum

- Set roles and responsibilities
- Required to commit to specific amount of work
- New items cannot be added to ongoing iterations
- Collaborate to complete a task



Kanban

- No set roles, flexibility with responsibilities
- Commitment to work is optional
- New items can be added whenever additional capacity is available
- Strive to achieve goals



Ability to Pivot

Provides agile teams the flexibility to reprioritize work in an ever-changing environment to ensure value-added delivery.

- **Statistical Programming Support** implemented a bug management Kanban board to alternate between developing features and addressing **technical debt**
- **Data Management** developed **6 tools** to improve processes including automatically identifying data **within 1 hour** of arrival to FDA and moving data now takes **seconds** regardless of size



Project Visibility

Offers a holistic view of project goals that is visible to team members and stakeholders alike.

- **Service Desk** decreased the level of effort to provide updates from **3 hours** to **15 minutes** per week
- **JumpStart** leveraged a customized Kanban board to increase capacity to analyze new drug applications by **200%** and provide complete **visibility** across all project team members



Business & IT Alignment

Bridges the gap between stakeholders and the development team facilitating a collaborative environment.

- **Statistical Programming Support** implemented scrum methodology to develop **2x** the number of generic and therapeutic analysis tools customized to user needs
- **Data Management** used scrum to iteratively develop documents (Process Guides, SOPs) and coined the effort **DocOps**



Time to Market

Allows for the rapid delivery of highest priority by focusing on value-add tasks and utilizing a cross-functional team.

- **Core DataFit** prior to Agile delivered 5 services in 6 months, after implementing Agile the service was able to provide **3x** more critical data quality information services to drug reviewers
- **Data Management** established an increment cadence with the intent to **release on demand**



Offices

Office of Computational Sciences, Office of Information Management and Technology, Office of Clinical Pharmacology, and Office of Bioinformatics

Moving Forward

Continuous Exploration (CE) Bring together business, development, and operations to explore innovative, quality, and integrated solutions that deliver business value.

Continuous Integration (CI) Implement a development practice that requires developers to integrate code into a shared repository several times a day.

Continuous Deployment (CD) Utilize a technical practice in which teams deploy software to production on a continuous basis.

Release on Demand Employ a software engineering practice in which software is released to end users on demand.

