

Single Day Event

Shift Left Bringing Validation closer to Users

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A&R Platform – A Workhorse for Clinical Submission

A Good Platform !

- Scalable, intuitive application integrating modern tech and languages
- Manage workflow, enable collaboration, automate tasks
- Provide analytics and metrics to track value and opportunities
- Cloud-based platform to improve quality, decisions, and accelerate drug delivery

And it's Benefits !

- Improved productivity via standardization and automation
- Faster time to submissions and accelerated delivery
- Enhanced real-time data access for quicker, higher quality decisions
- Easier regulatory review and oversight
- Reduced costs, risks, and learning curves

When building a complex system like an A&R Platform, thorough testing is essential, yet inherently difficult.

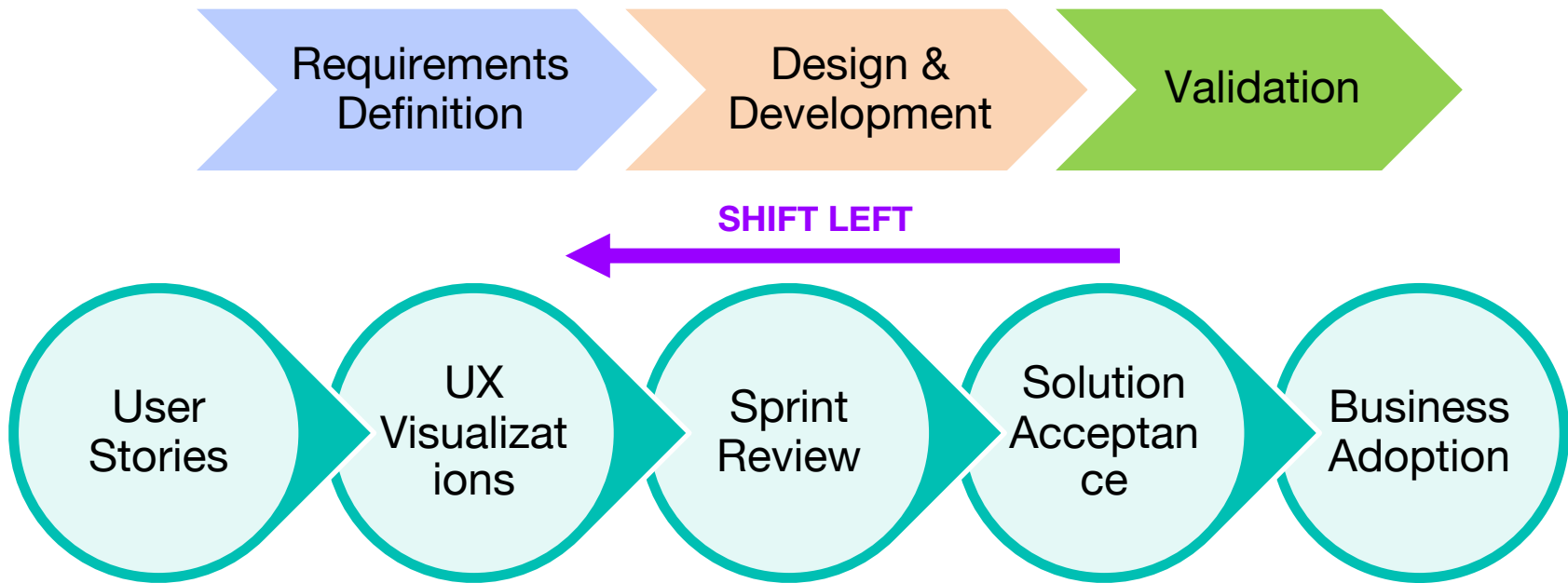


BRAIN (Biometrics Reporting & Analysis Information Network)

- The Next Gen A&R Platform (Tech Case Study)

- Large client replacing their proven legacy platform
- 5 key modules
 - Data Lake foundation
 - Statistical Computing Environment
 - Digitized Specifications
 - Knowledge Graph
 - TLF Renderer
- User experience is the key
- 24 months to develop
- 300+ user stories
- 120+ member team
- 14 Sprints

Solution to Validation – User Engagement through Shift Left approach



Sprints are planned to progressively build the solution with continuous user feedback

1. Requirements Definition

Dedicated core user team defines the requirements with Statistical Programmers and Biostatisticians from the implementation team

- Define what is required in the 'future' instead of how it is currently performed
- Elaboration and review of user story
- Finalize the user story through collaboration
- Assess feasibility and finalize solution in consultation with Digital / Technical teams



Left Shift:

Collaborative solutioning prior to detailed design and development

2. UX Visualization

Modern UX that promotes productivity is paramount to the users as SCE is a high use platform

- UX Engineers and User team agree on the overall UI framework
- Solution SMEs groom UX Engineers for each User Story
- UX Engineers develop visuals indicating user interactions
- Solution SMEs review and provide feedback
- Subset of visuals are presented to core User team to solicit feedback



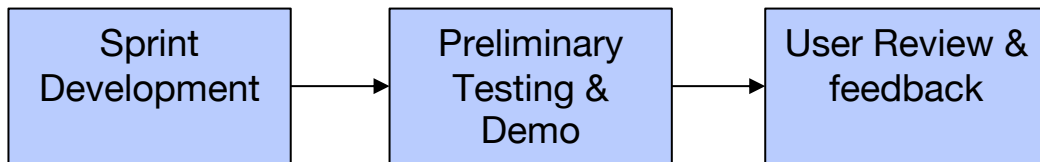
Left Shift:

Finalize UX prior to initiating a Development Sprint

3. Sprint Review

Every development sprint is followed by core team users actually testing the system after a general Sprint Demo

- Development team designs and builds the functionality
- Testing team does a preliminary testing of each user story
- Solution SMEs review and demo the solution to the core users
- Core users test the application and provide feedback or identify issues



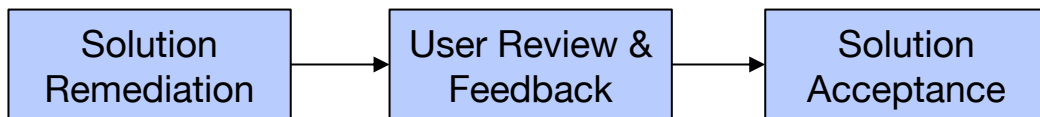
Left Shift:

Users interact with the solution immediately after sprint and on an ongoing basis to understand/define new functionality

4. Solution Acceptance

Issues and user feedback are resolved and each User Story is accepted for use by core users

- Solution SMEs review user feedback and collaboratively define the remediations required
- A special Development pod team remedies the solution without impact ongoing Sprint development
- Core users retest the remediations and accept the solution
- Issues requiring further updates are implemented and accepted



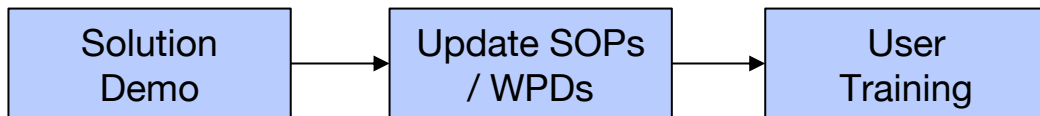
Left Shift:

Each User Story is individually accepted long before the UAT

5. Business Adoption

Solution is periodically presented to Business Adoption Team base who also get to interact with the solution

- Solution is demoed to champions from the larger user base after every Three sprints
- Further, they get to interact with the solution and develop familiarity.
- Business adoption champions update the SOPs/WPDs
- Champions become in-house trainers for the user base after in-depth training by the solution SMEs



Left Shift:

Define the pathway to business adoption usage long before UAT



Left is right when it comes to validation

The **Shift Left** approach

- Make quality a focus of everyone on the team
- Improve software quality by detecting changes and defects early
- Distribute testing throughout the project duration

Build a solution that you will love to interact with...

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