



RADAR: Rapid AGILE Development and Automated Reporting for Clinical Data Standards

Using R-Shiny based Application

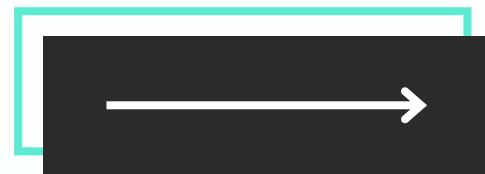


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Meeting Agenda



What is AGILE and Why?

How R Came Into Picture?

Components of RADAR App

Proposed Case Study

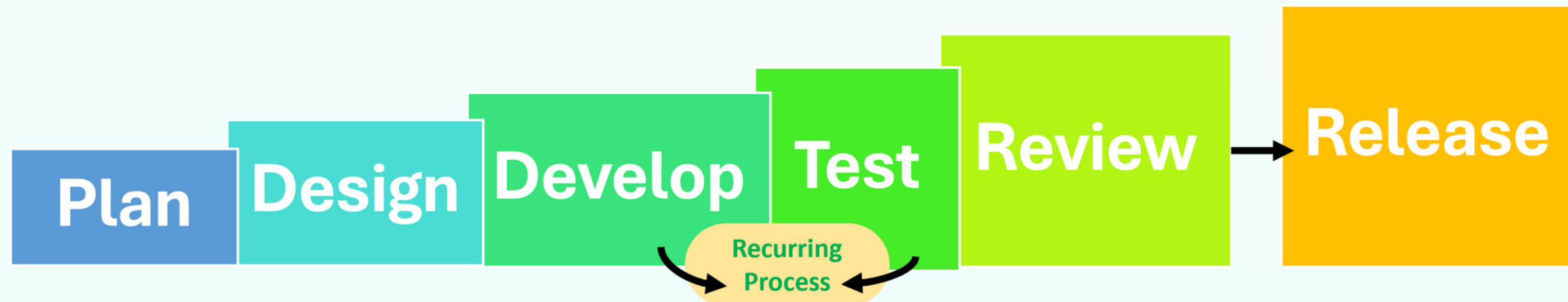
Future Directions and Evolution

Concluding Statement

Thank You

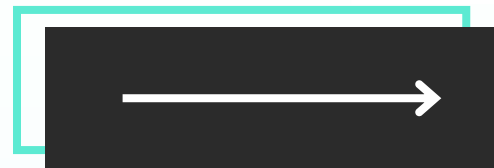
What is AGILE and Why?

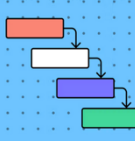
Agile is an iterative, flexible approach to project management and software development that delivers work in small, incremental cycles called sprints





What is **AGILE** and Why?



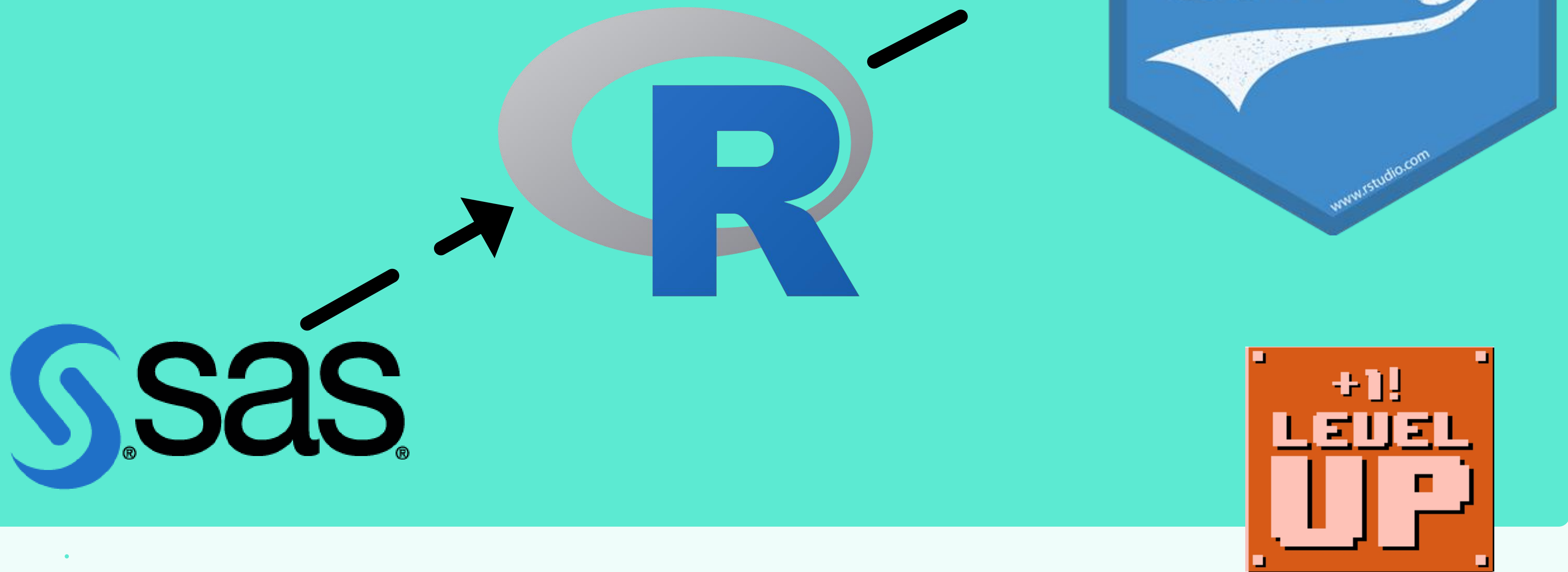
Aspects	 AGILE	 WATERFALL
Approach	Iterative & Incremental	Linear & Sequential
Flexibility	Highly adaptable to changes	Rigid, changes are costly
Customer Involvement	Continuous throughout	Mainly at beginning and end
Delivery	Frequent small releases	Single final delivery
Testing	Continuous throughout	After development phase

How R came into picture?

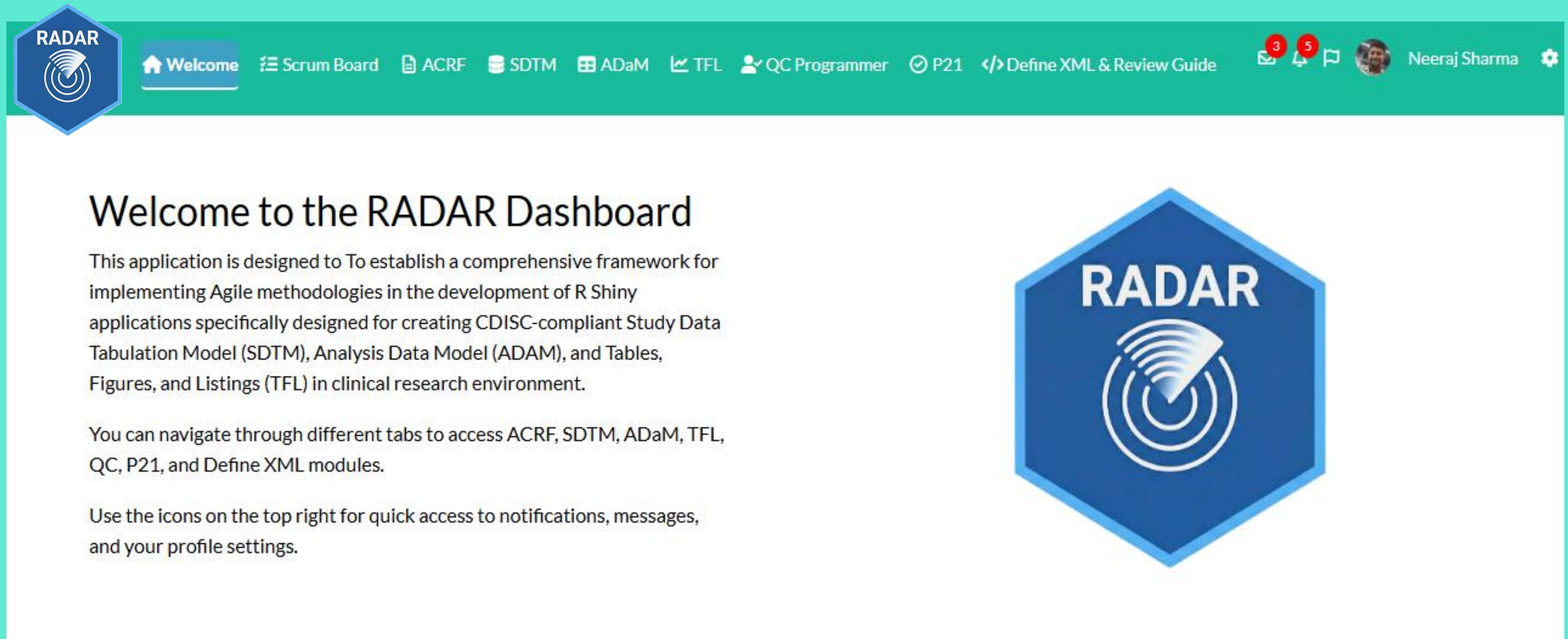
- Open-Source
- Faster Processing
- Cost Efficient
- In-built GUI support (R-Shiny)
- Power Packed Stats
- Validated R Packages (like pharmaverse, admiral etc.)
- Flexibility



How R Shiny made it all pretty?



THE ADAPTED AGILE FRAMEWORK (RADAR)



The screenshot displays the RADAR Dashboard interface. At the top, a teal navigation bar contains the RADAR logo on the left and a series of menu items: Welcome, Scrum Board, ACRF, SDTM, ADaM, TFL, QC Programmer, P21, and Define XML & Review Guide. On the right side of the navigation bar, there are notification icons with counts (3 and 5), a user profile picture for Neeraj Sharma, and a settings gear icon. The main content area has a white background. On the left, the heading 'Welcome to the RADAR Dashboard' is followed by a paragraph explaining the application's purpose: 'This application is designed to establish a comprehensive framework for implementing Agile methodologies in the development of R Shiny applications specifically designed for creating CDISC-compliant Study Data Tabulation Model (SDTM), Analysis Data Model (ADAM), and Tables, Figures, and Listings (TFL) in clinical research environment.' Below this, it states: 'You can navigate through different tabs to access ACRF, SDTM, ADaM, TFL, QC, P21, and Define XML modules.' and 'Use the icons on the top right for quick access to notifications, messages, and your profile settings.' On the right side of the main content area, there is a large blue hexagonal logo with the word 'RADAR' in white and a white radar icon below it.

Welcome to the RADAR Dashboard

This application is designed to establish a comprehensive framework for implementing Agile methodologies in the development of R Shiny applications specifically designed for creating CDISC-compliant Study Data Tabulation Model (SDTM), Analysis Data Model (ADAM), and Tables, Figures, and Listings (TFL) in clinical research environment.

You can navigate through different tabs to access ACRF, SDTM, ADaM, TFL, QC, P21, and Define XML modules.

Use the icons on the top right for quick access to notifications, messages, and your profile settings.

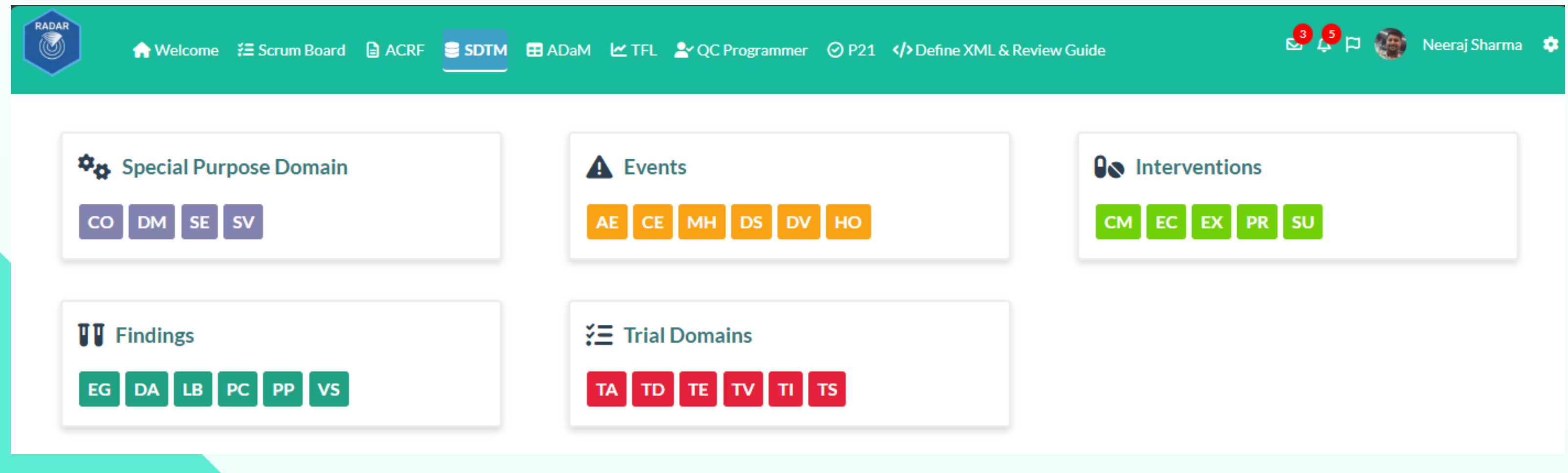
PLAN

- R Shiny application setup, project setup and initialization.
- Plugging all necessary documents such as aCRF, Protocol, dummy metadata into the app.

The screenshot displays the RADAR application interface. The top navigation bar is teal and contains the RADAR logo, a 'Welcome' button, and several menu items: 'Scrum Board', 'ACRF' (highlighted), 'SDTM', 'ADaM', 'TFL', 'QC Programmer', 'P21', and 'Define XML & Review Guide'. On the right side of the bar are notification icons (3 and 5), a user profile for 'Neeraj Sharma', and a settings gear icon. Below the navigation bar is a dark grey toolbar with various drawing and editing tools, a page indicator '7 of 157', and a date selector 'MM DD YY'. The main content area is titled 'DEMOGRAPHICS' in a black box. It contains three form fields: 'Date of birth' with a red highlight 'Not Entered In Database' and a date input field with labels 'MM', 'DD', and 'YY'; 'SEX' with a red highlight and two radio buttons labeled 'F Female' and 'M Male'; and 'RACE' with a red highlight and a radio button labeled 'CA Caucasian (European, Mediterranean, Middle Eastern)'.

DESIGN

- Designing the specifications for SDTM, ADaM and TFL generation.
- Uploading TFL Shells and SAP as per study requirements.
- Deciding on number of datasets/TFLs must be created in co-ordination with biostatistician.





DEVELOP

- Edit and update specifications as per requirements.
- Generate datasets and TFLs as per plan in design phase with minimal coding.
- Discussing and reporting data issues with upstream team

Welcome Scrum Board ACRF SDTM ADaM **TFL** QC Programmer P21 Define XML & Review Guide35Neeraj Sharma

Tables, Figures & Listings Status

Tables

Table 10.1-1: Subject Disposition Completed

Table 14.1-1: Summary of Demographic Chacacteristic of Subjects included in the Safety Population In Progress

Figures

Figure 14.2.2-115a: Mean(SD) Plasma Concentrations - Linear Scale In Progress

Figure 14.2.2-115b: Mean(SD) Plasma Concentrations - Semi Log Scale Not Started

Listings

Listing 16.2.2-1: Protocol Deviations Completed

Listing 16.2.6-2: List of Individual Pharmacokinetic Parameters In Progress



TEST

- Create QC datasets and TFLs to validate developer outputs.
- Generating Pinnacle21 (P21) reports for compliance quality checks.



[Welcome](#) [Scrum Board](#) [ACRF](#) [SDTM](#) [ADaM](#) [TFL](#) [QC Programmer](#) [P21](#) [Define XML & Review Guide](#)

3

5

 Neeraj Sharma 

 QC Status Report

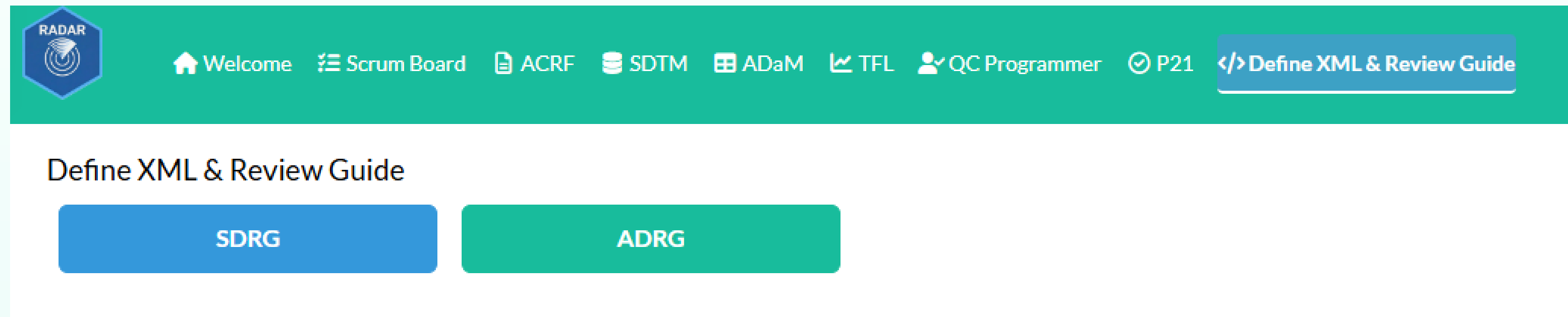
Search:

TYPE	NAME	STATUS	COMPLETED	REMARKS
SDTM	DM	Completed	Yes	All checks passed
SDTM	SV	In Progress	No	Pending review
SDTM	SE	Completed	Yes	All checks passed
ADAM	ADSL	In Progress	No	Pending review



REVIEW

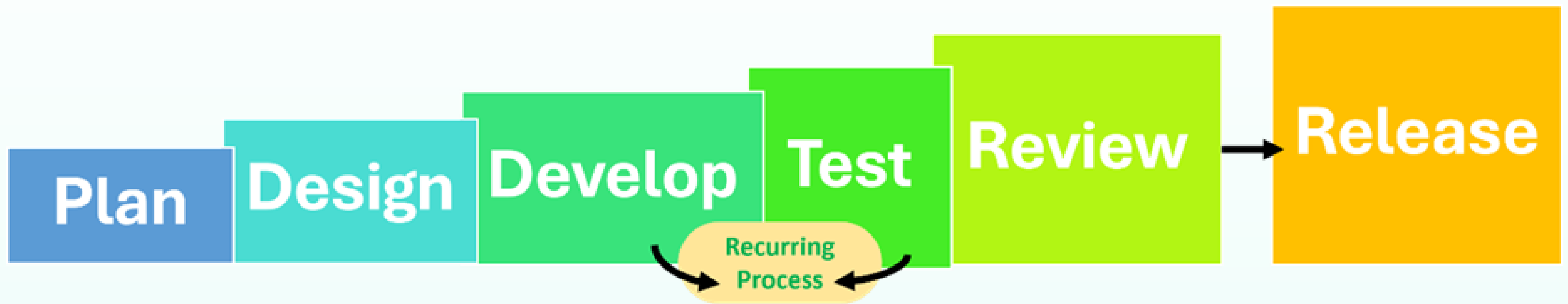
- Special portal access and provisions are introduced for the QA (Quality Assurance) team to access data and validate quality using pre-defined tools.
- Generate all documents (SDRG, ADRG, define.XML) automatically with minimal editing from the R-Shiny app.





RELEASE

Achieve final labeling and production status for final production or IA (Interim Analysis) with just a few clicks.



Sprint Structure and Timeline

Sprint Duration: 2–3 weeks, aligned with clinical milestone schedules rather than arbitrary time boundaries.

Foundation Sprint

Sprint 0 (Foundation Sprint – Happens before FPFV):

- Environment setup and configuration management
- Regulatory requirements gathering and creating aCRF
- CDISC standards review and mapping (Creating dummy metadata)
- Risk assessment and mitigation planning



Sprint Structure and Timeline

Development Sprints

(After the raw data has been received by statistical programmers):

- Feature development with continuous clinical validation
- Creating E2E CDISC compliant datasets (SDTM and ADaM) and TFLs
- Iterative testing with QA
- Reviewing raw data for data issues and consistency checks

Development
Sprint



Sprint Structure and Timeline

Hardening Sprints

(During the IAs – Interim Analysis and submissions)

- Comprehensive validation testing (QA final testing)
- Documentation completion (Review Guide and Define.XML)

Hardening
Sprint



Sprint Structure and Timeline

Sprint Kanban Board

WelcomeScrum BoardACRFSDTMADaMTFLQC ProgrammerP21Define XML & Review Guide35Neeraj Sharma

Your workProjectsFiltersDashboardsTeamsAppsCreate

Clinical Study Name: CTJSD4623ABC | Sprint: E2E 001⚡★🔗🔗Complete Sprint⋮

	To Do	In Progress	QA	In Review	Done
NAVIGATION  Kanban Board  Timeline  Backlog  Sprints  Reports  List  Goals	SDTM Special Purpose Domain - SE Assignee: Prog 1 Priority: High SDTM Events - AE Assignee: Prog 2 Priority: High ADAM Efficacy - ADRS Assignee: Prog 3 Priority: Medium Listing 16.2.2-1 Protocol Deviations	SDTM Special Purpose Domain - DM Assignee: Dev B Priority: Medium SDTM Special Purpose Domain - SV Assignee: Dev C Priority: High ADAM Demographics - ADSL Assignee: Dev D Priority: Medium Figure 14.2.2-115a Mean(SD) Plasma Concentrations	SDTM Findings - EC Assignee: Dev C Priority: Medium ADAM Safety - ADLB Assignee: Dev D Priority: High	ADAM Safety - ADVS Assignee: Dev D Priority: Low	SDTM Special Purpose Domain - CO Assignee: Dev E Priority: High SDTM Findings - VS Assignee: Dev L Priority: High SDTM Findings - EG Assignee: Dev M Priority: Medium



**Product
Owner**

**Development
Team**

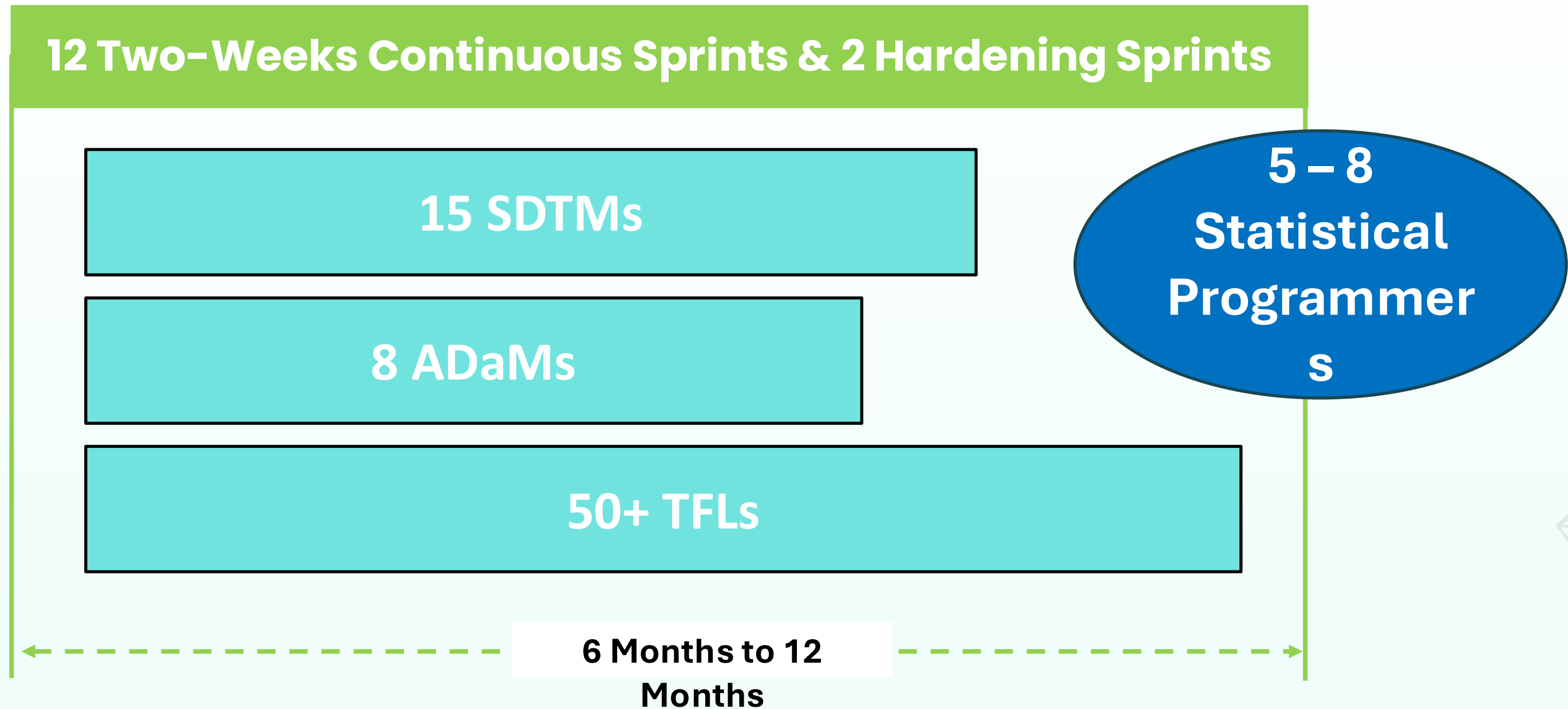
**UNIQUE
ACCESS**

**Role Definitions
and
Responsibilities**

**Scrum
Master**



PROPOSED CASE STUDY FOR IMPLEMENTATION OF RADAR METHODOLOGY





FUTURE DIRECTIONS AND EVOLUTION

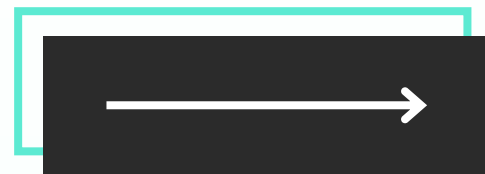
The rapid evolution of R packages for clinical programming suggests several areas for framework enhancement:

- **Artificial Intelligence Integration:** Incorporation of automated data quality checks, LLMs (large language model) and anomaly detection capabilities.
- **Cloud-Native Development:** Adaptation of the framework for cloud-based development (Posit cloud, Domino etc.) and deployment environments.
- **Advanced Visualization:** Integration of modern data visualization techniques (plotly, ggplot2) and plugins for enhanced regulatory reporting.





CONCLUSION



We can summarize the whole approach in the following points:

- 1. Practical Framework:** A detailed, implementable framework that balances Agile principles with regulatory requirements and providing CDISC compliant outputs.
- 2. Validation Strategy:** Comprehensive approaches to testing and validation that address both technical and clinical requirements.
- 3. Implementation Guidance:** Practical recommendations for organizational adoption and change management.
- 4. Performance Metrics:** Demonstrated improvements in development efficiency and output quality.



**THANK YOU TO THE TEAM AND
THE WONDERFUL AUDIENCE.**



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