

BMS embarked on Statistical Analysis and Biometrics Reporting Environment (SABRe) project to implement Sycamore Informatics' Clinical Data Repository & Statistical Computing Environment (Sycamore CDR-SCE). This modern, collaborative, and secure cloud-based environment, provides automation and efficiency while maintaining regulatory compliance demands. It supports multiple programming languages, is extensible and scalable while still ensuring audit and end to end traceability of all activities.

SABRe Vision: Governed access to the information needed for smart decision making through highly performant, state-of-the-art tools resulting in increased capabilities for data visualization, machine learning & improved compliance in clinical trial reporting and submission.

Statistical Analysis and Biometrics Reporting Environment (SABRe)

The project to implement Sycamore Informatics Clinical Data Repository & Statistical Computing Environment (Sycamore CDR-SCE)

Sycamore Informatics

Dashboard » Compound501 » Compound501-001 » Tasks

By Task Groups

SDTM
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ADaM
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Tables

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Comments Report

Status Report

Status Report

Issues Report

Reconciling Report

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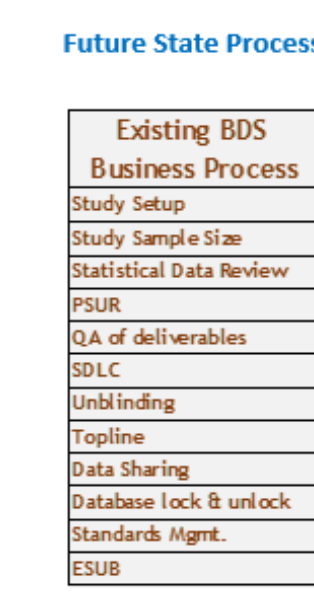
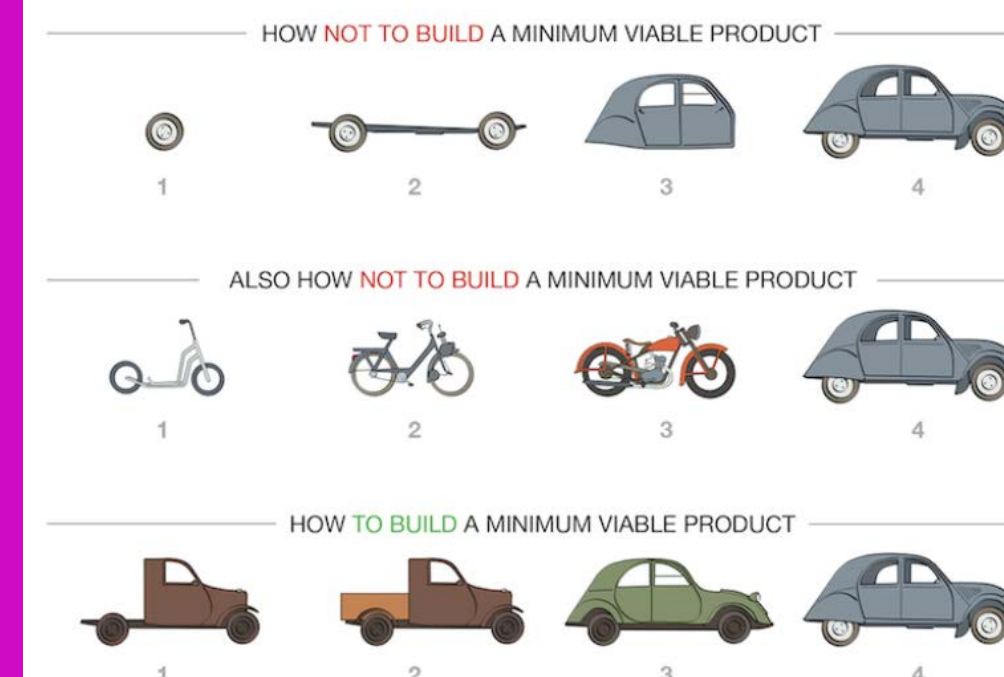
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DELIVERABLES

STATUS

Business Process to Use-Cases and Sprint-Build scope-planning

Focal Points for Success



Our Pilot had 18 Business Use Cases for CDR-SCE

CDR-SCE Use Cases	SCE Use Cases
CDR-1 Data Ingestion & Storage	SCE-1 Set up a study and user work area
CDR-2 Data Management & Transformation	SCE-2 Set up a study design
CDR-3 Analysis, Reporting & Visualization	SCE-3 Development of statistical analysis programs
CDR-4 Data Processing & Governance	SCE-4 Creating, reviewing & managing programmatic artifacts
CDR-5 CDR Interface with SCE & MDR	SCE-5 Source control and configuration management
CDR-6 Secure & User Access	SCE-6 Performing statistical analysis to generate submission ready artifacts
	SCE-7 Creating and scheduling statistical analysis batch jobs
	SCE-8 Workflow management for data and programmatic processes
	SCE-9 Creating submission ready packages after performing statistical analysis
	SCE-10 Traceability of source data, programs & macros
	SCE-11 External data requirements from external source
	SCE-12 Metadata driven integrations with external MDR

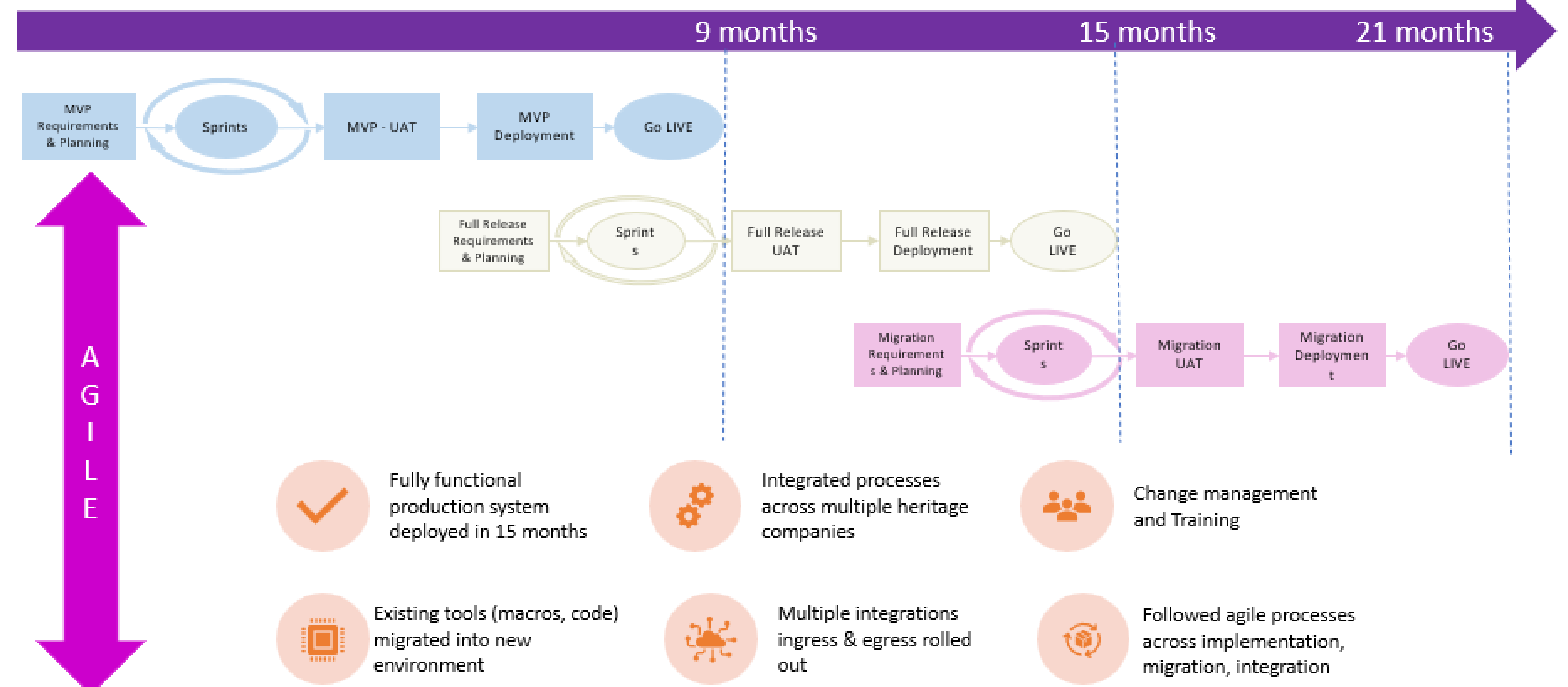
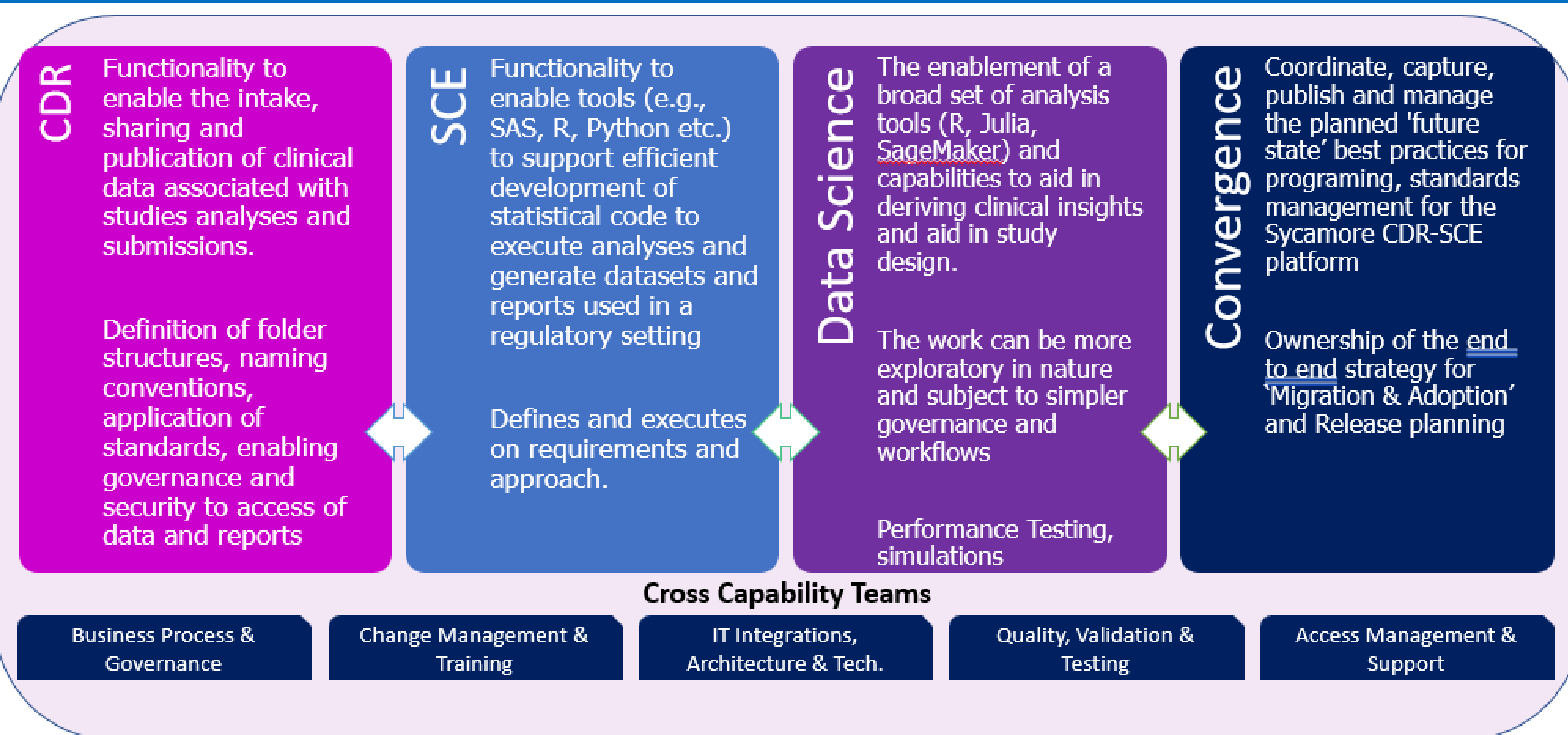
We also need to consider what other Business Use Cases are needed for Data-Import-export & Programmatic, etc.



Build approach for SABRe Releases



Defining the SABRe Work-streams



SABRe Implementation outcome



- ✓ Qualified R
- ✓ Exploratory R
- ✓ Python

SABRe Today!!!

1000+ Containers for Studies and Milestone analysis

20+ terabytes of active study artifacts created in Sycamore CDR-SCE

Submitted over 15 milestone analysis

90+ terabyte of Migration data for Studies and Milestone analysis

~500 Users

SABRe capability Summary By Sycamore CDR-SCE Release

Capability	Benefit	MVP Release1	Full Release 2	Migration Release 3
Clinical Data Ingress from CDW	Ingress of clinical data from CDW for both stable and snapshot transfers into a single centralized CDR	✓	✓	✓
Program Compliance	In-built program version control & traceability of program artefacts	✓	✓	✓
Data Integrity & Security	Preserves data integrity, recording who had made changes, to what and when	✓	✓	✓
SDLC Workflow	In-built workflow procedures ensures appropriate hand-off between roles and preservation of the software delivery cycle	✓	✓	✓
Task Management	Assign programmers/statisticians to each programming task in the system and associate workflows	✓	✓	✓
Dashboarding Capabilities	Visual tracking of the progress of tasks	✓	✓	✓
VSWB Automation	Metadata captured from tasks and workflows will automatically populate the VSWB via a report	✓	✓	✓
Clinical Data Egress (downstream systems)	Integrations with downstream systems: e.g. Cara PRISM, ODT, P21, sFTP, TMS	✓	✓	✓
Additional Clinical Data Ingress	Additional integrations/ingestion for CP&P, IPS, IRT, MDR	✓	✓	✓
Clinical Data Ingress/Egress for Migrations	Capability to start moving from BCE and SAS AWS into new SABRe environment once all integration points established e.g. EmBARC,	✓	✓	✓

9 Months

15 Months

21 Months

