

Agile Development Methodology for Delivery of the Clinical Data Pipeline

PHUSE 2021

Objective

Provide overview of Agile methodology and its implications.

Review an Agile Proof of Concept and discuss lessons learned and future state.

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What is Agile?

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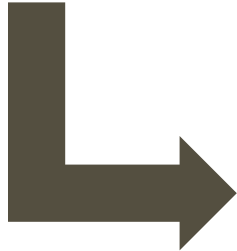


Agile is iterative

Methodology for project management and software development which helps teams **incrementally deliver value** to their customer **faster**.

Agile is time-boxed

Methodology focuses on breaking projects down into little bits of functionality, prioritizing them, and delivering them in **short two-week cycles**.



A light-weight framework delivering value through **self-organizing, cross-functional teams**.

Scrum emphasizes **learning through experience** while working on a solution that adds value and **continuously improving** through reflection on wins and losses.

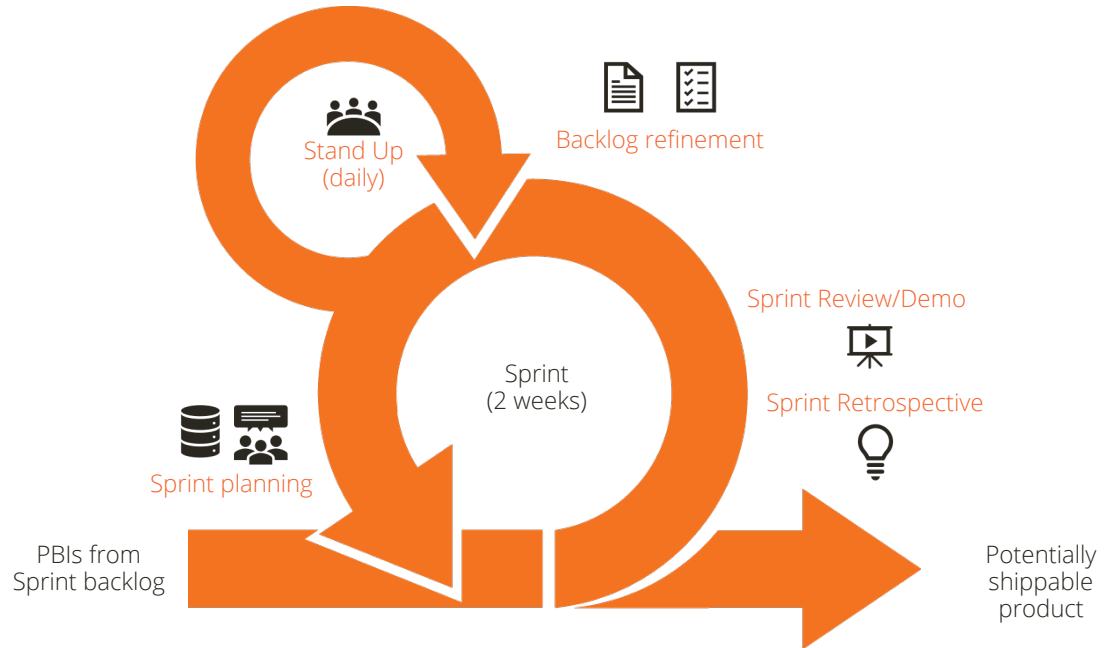
What is Scrum?



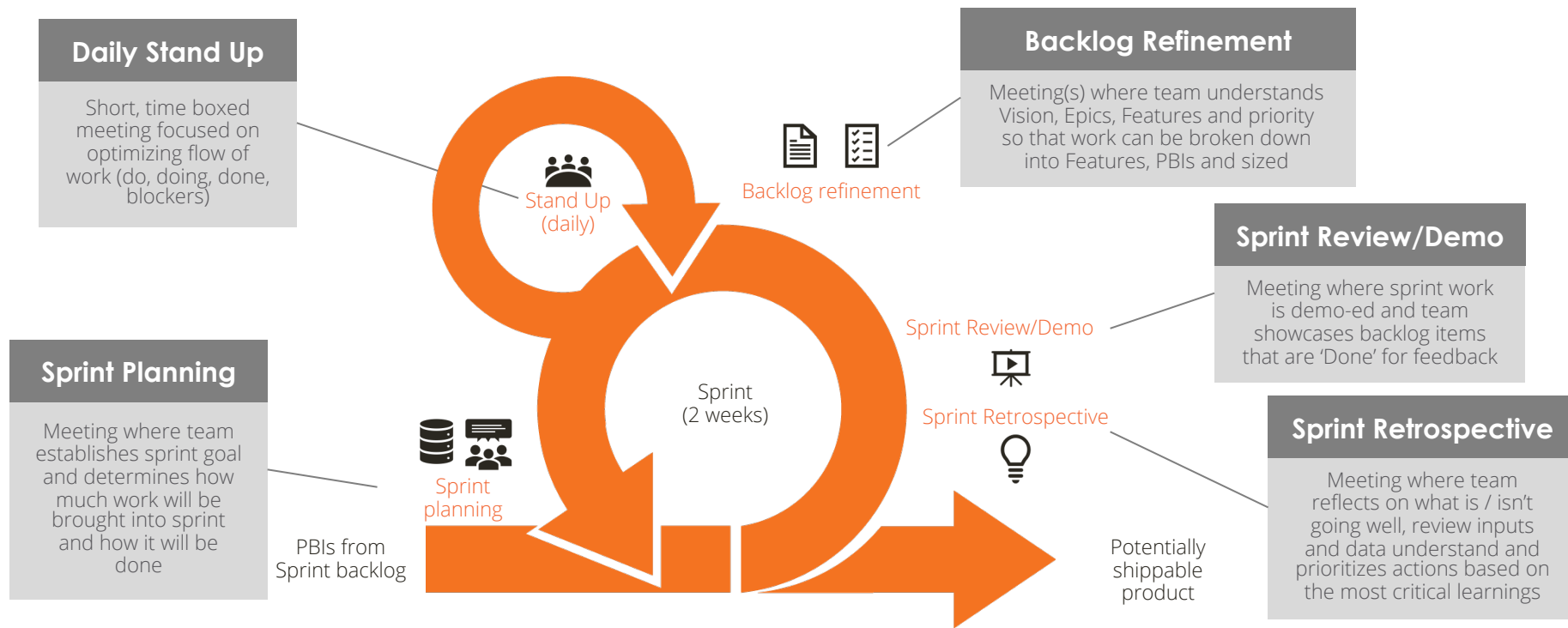
Definition and Purpose

Scrum is comprised of **ceremonies**, **roles** and **tools**, that work in concert to help teams structure and manage their work. The purpose of Scrum is to deliver solutions incrementally, in short iterations, so customers and teams have frequent opportunities for review and feedback. This keeps the work aligned to the desired outcome and allows the solution to develop as context evolves.

Scrum ceremonies are conducted on a regular basis, as this allows teams to deliver thin, vertical slices of value that in the aggregate address a business need or deliver a desired business outcome.



What are the Ceremonies?

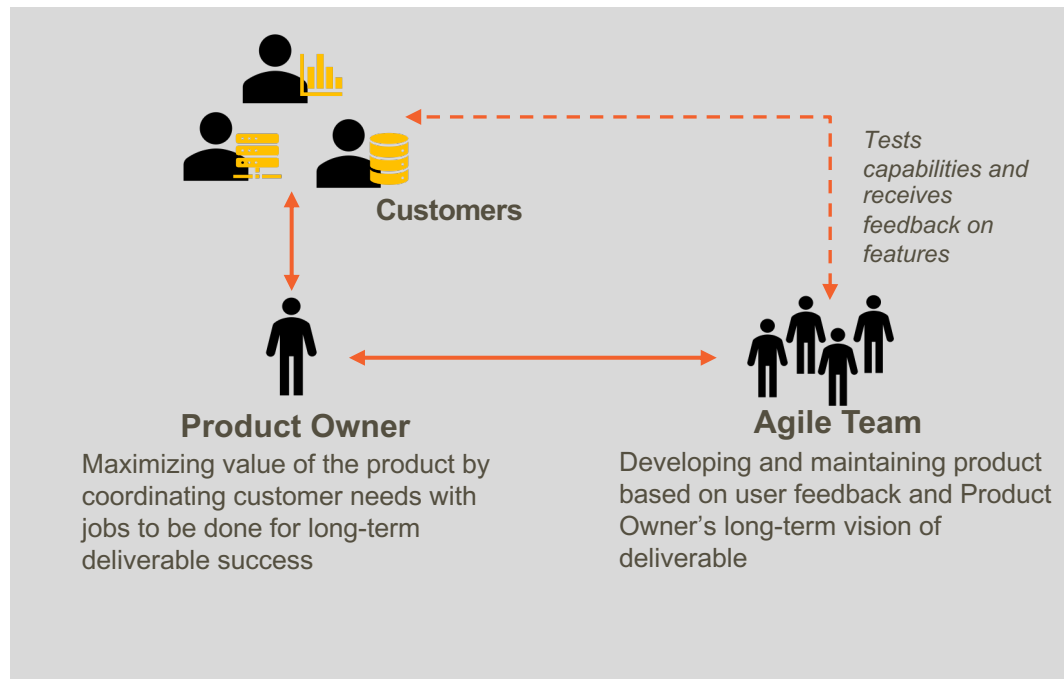


Aligning to the Customer's Needs



Team Structure

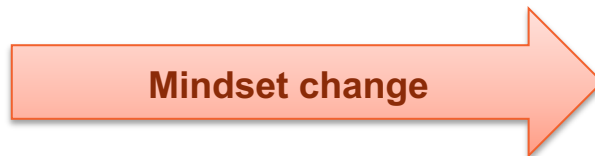
Agile Project Management tries to remove hierarchy and isolate major decisions to one decision maker



Adopting Agile Principles and Agile Mindset



Conventional
Statistical
Programmer



Agile Software
Developer

- Reusable Code
- Modern Software Processes
- Tool Adoption
- Incremental Delivery
- Strategic Task Planning

Implications for Pharma



Depends on the type of deliverable

Static Analyses

- SDTM data
- ADaM data
- Tables
- Listings
- Figures



Dynamic Visualizations

- Shiny apps
- Spotfire
- Tableau



Reusable / Shared Tools

- Reporting tools
(SAS macros, R packages)
- Diagnostic tools
(log checkers, dependency validation)



Implications for Pharma



Conventional (Static) Datasets, Tables, Listings, Figures (DTLFs)

Current State

- Spreadsheet tracking mechanism
- Regular team meetings??
- Task assignments: Production and QC
- When task is complete – complete date
- Lead Programmer ‘keeps an eye’
- Allows for ‘% Complete’ to be tracked

Adopting Agile Concepts

- Maintenance of **product backlog**
 - Break work down into task level, not individual output level
- **Frontload planning** and adjust as work progresses
 - Prioritized and focused (e.g., organize by domain)
 - Be deliberate and strategic
- **Ceremonies:** scrums/stand-ups, backlog refinement
- **Sprints:** Incremental delivery of subsets of DTLFs
- Assign **score** to each task
 - Enables metrics such as velocity and burndown
- Full team **focus**
 - Face the same problems together
 - Knowledge sharing
 - Develop shareable tools



R4QC ADaM PoC

An Agile Use Case

Proof Of Concept Background

Scope

- 9 ADaMs to be shadow developed in parallel with study team

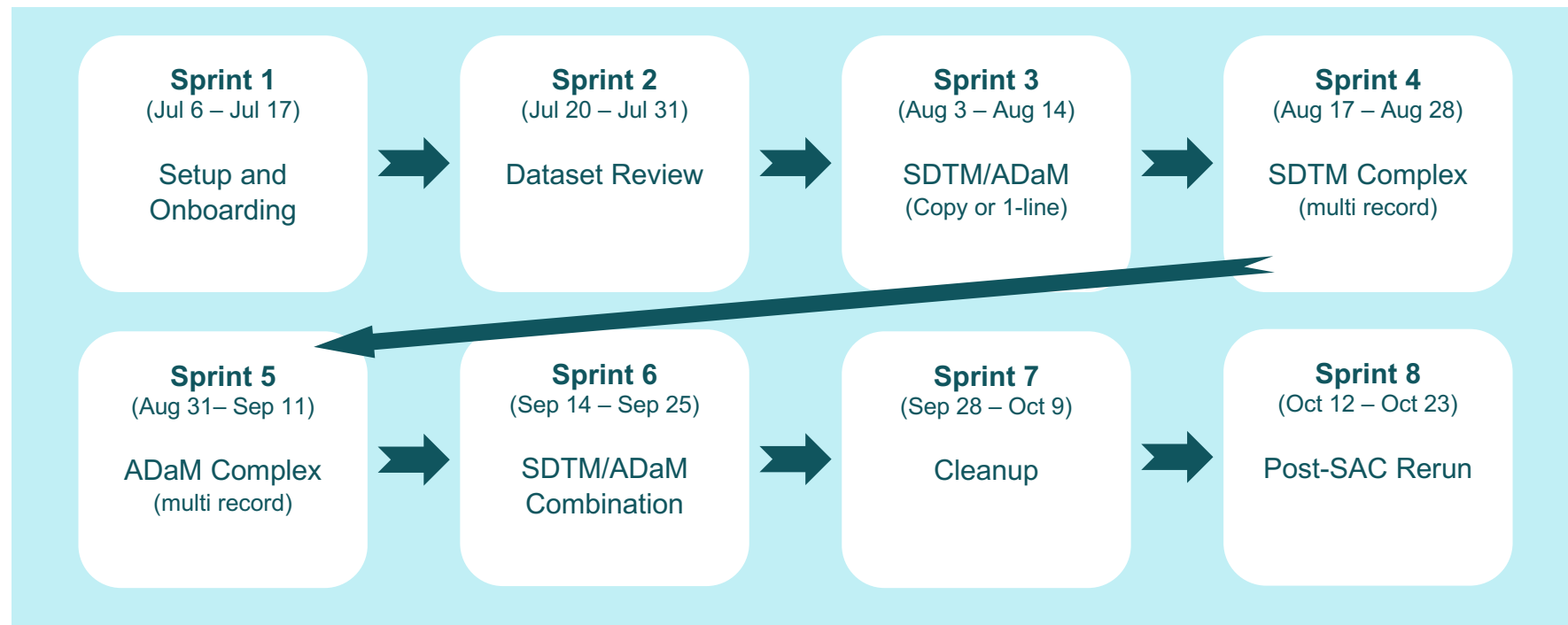
Agile Design

- Small team of R programmers
- Two-week sprints
- MWF Standups
- Excel-based backlog
- Loosely prioritized tasks based on complexity

Agile Development



Planned Sprints – High Level



The Product Backlog



Backlog Structure

- Organized by PBI and task, according to complexity
- Weekly grooming – pull into two-week sprints
- Start at variable or parameter level
- Consider to increase or reduce granularity

A	B	C	D	E	F	G	H
Proposed Sprint	Backlog Item	Product Backlog Item	Task	Additional Detail	ADaM	Comments	Dependencies
4	9001	VS Domain Timing	Create Timing Variables	Derive APHASEN, APHASE, AVISITN, AVISIT, ADT, ATM, ADY, ATPTN, ADVS			
4	9002	VS Domain Parameters	Derive Records for Parameters with 1: PARAM, PARAMCD, AVAL, AVALC	ADVS			
4	9003	VS Domain Parameters	Derive Average Records	PARAM, PARAMCD, AVAL, AVALC, DTYPE	ADVS	Records where DTYPE=AVERAGE	
4	9004	VS Domain Parameters	Derive Baseline Records	PARAM, PARAMCD, AVAL, AVALC, AVISITN, AVISIT, DTYPE, ABLFL	ADVS	Records where DTYPE=LVPD	9001, 9002
4	9005	VS Domain Parameters	Derive Min/Max records	PARAM, PARAMCD, AVAL, AVALC, AVISIT, AVISITN, DTYPE	ADVS	Records where DTYPE=MINIMUM, MAXIMUM	9001, 9002
4	9006	VS Domain Parameters	Derive MAP Records	Derive PARAMCD=MAP	ADVS	Based on PARAMCD=SYSBP and DIABP	9001, 9002
4	9007	VS Domain Baseline	Derive BASE, CHG, PCHG		ADVS		9001, 9002
5	9008	VS Domain Analysis Range & Shifts	Create Ranges	A1LO, A1HI	ADVS		9001-9006
5	9009	VS Domain Analysis Range & Shifts	Create Shifts	SHIFT2, SHIFT2N, SHFT2CAT, SHFT2CN	ADVS		9001-9006
5	9010	VS Domain Period Flags	Create EPFL	Evaluation Period Flag	ADVS		9001-9006
5	9011	VS Domain Period Flags	Create SPFL	Stabilization Period Flag	ADVS		9001-9006
7	9012	VS Domain & ADCM - Relationship	Create LVBPMDFL	Last Value Prior to BP Med Change, must be created after ADCM	ADVS		9001-9006
4	9013	VS Domain - Criteria and Analysis Flags	Create CRIT1FL, CRIT1	Must create ANL03FL first	ADVS		9001-9006
5	9014	VS Domain - Criteria and Analysis Flags	Create CRIT2FL, CRIT2	Must create ANL03FL first	ADVS		9001-9006
5	9015	VS Domain - Criteria and Analysis Flags	Create ANL01FL	This should be null for VS records, need to confirm	ADVS		9001-9006
5	9016	VS Domain - Criteria and Analysis Flags	Create ANL02FL		ADVS		9001-9006
5	9017	VS Domain - Criteria and Analysis Flags	Create ANL03FL		ADVS		9001-9006
5	9018	VS Domain - Criteria and Analysis Flags	Create ANL04FL		ADVS		9001-9006

Tracking Progress



Progress How To

- Pull tasks from backlog into task tracker
- Team resource assigned to tasks
- Every-other day sprints to assess progress and blockers
- Track status of tasks during sprints

	A	B	C	D	E	F	G	H
1	Sprint ID	Start Date	End Date	Product Backlog Item	Task	Additional Detail	Responsible	Status
261	4	17-Aug-20	28-Aug-20	Sprint 4: Clean-up and Compare	Compare with primary dataset	Added for Sprint 6	NA	Removed
262	5	17-Aug-20	28-Aug-20	Create Screen Failure Records	Create Screen Failure Records (PARAMCD=SFRES1-SFRES8, SFSTAT)	PARAMCD, PARAM, AVAL, AVALC, AVALORD, ADT, DSSTDTC	NP	Complete
263	4	17-Aug-20	28-Aug-20	Sprint 4: Clean-up and Compare	Add attributes where possible		NP	Removed
264	4	17-Aug-20	28-Aug-20	Sprint 4: Clean-up and Compare	Compare with primary dataset		NP	Removed
265	5	17-Aug-20	28-Aug-20	ADAE: Placebo Run-in Variables and Flags	Placebo Run-in Variables and Flags	i.e. PLRUNFL, PLBSTDT, PLBENDT,	TA	In progress
266	4	17-Aug-20	28-Aug-20	ADAE: Add APHASE	Add APHASE		TA	Complete
267	4	17-Aug-20	28-Aug-20	ADAE: Derive Period Flags	Derive Period Flags	PREFL, FUPFL, PSTRNDFL, etc.	TA	Complete
268	4	17-Aug-20	28-Aug-20	ADAE: Derive AE Flags	Derive AE Flags	OTHSIGFL, BPSAEFL, VASIFREL, VASIFCFL, ASDTH, AESPROT	TA	Complete
269	4	17-Aug-20	28-Aug-20	ADAE: Derive Dates based on Dates derived in ADSL	Derive Dates based on Dates derived in ADSL	i.e. ALDWRSDS, ASTRF1DS, ASTRFLDS, TRTEMFL, PREFL	TA	Complete
270	4	17-Aug-20	28-Aug-20	ADAE: Add Core ADSL Variables	Add Core ADSL Variables		TA	Complete
271	4	17-Aug-20	28-Aug-20	ADCM: Derive analysis date and day variables	Derive analysis date and day variables	ASTDT, ASTDY, ASTDTF, AENDT, AENDTF, AENDY, ADURN, ADURU	TM	Complete
272	4	17-Aug-20	28-Aug-20	ADCM: Derive CRIT flags	Derive CRIT flags	CRIT1, CRT1FL	TM	Complete
273	4	17-Aug-20	28-Aug-20	ADCM: Derive Analysis Coded term and Druc collection code	Derive Analysis Coded term and Druc collection code	ADRGCOL, ADECOD	TM	Complete
274	4	17-Aug-20	28-Aug-20	ADCM: Derive PROHMED	Derive PROHMEDS	PROHMEDS	TM	Complete
275	6	21-Sep-20	2-Oct-20	ADCM: Clean-up and Compare	Add attributes		TM	In progress
276	6	21-Sep-20	2-Oct-20	ADCM: Clean-up and Compare	Compare with primary dataset		TM	In progress
277	4	17-Aug-20	28-Aug-20	Copy From SDTM Dataset	Copy From SDTM Dataset	STUDYID, INVID, SITEID, USUBJID, SUBJID, INVNAM, CO UNTRY, AGE, AGEU, SEX, ETHNIC, RACE, ARM, ARMCD, ACTARM, ACTARMCD, BRTHDTC	PK	Complete
278	4	17-Aug-20	28-Aug-20	Derive Death Information and Related Flagging Variables	Derive Death Information and Related Flagging Variables	DTHFL, DTHDT, DTHDTC, DTHDTF, DTHWK, DTHDY, DT HFN	PK	Complete
279	4	17-Aug-20	28-Aug-20	Derive Treatment Dates and Depended Relative Day Variables	Derive Treatment Dates and Depended Relative Day Variables	TRTSDT, TRTSDY, TRTEDT, TRTEDY, TRT01P, TRT01PN, TRT01A, TRT01AN, TRTP, TRTPN, TRTA, TRTAN	PK	Complete
	4	17-Aug-20	28-Aug-20	Add Grouping Variables like	Add Grouping Variables like AGEGRP, CRIT Variables	AGEGR1, AGEGR1N, AGEGR2	PK	Complete

What Went Well

- Positive team feedback
- Discussions aligned to common challenges
- Efficient development of shareable code
- Strategic approach to development plan
 - SDTM copies
 - SDTM to ADaM 'one line' transformations
 - Complex but standard transformations
 - Study specific transformations
- Connect team, working together

Challenges Encountered

- Near daily meetings
- Global coverage of team
- Lead programmer new to agile concepts
- Team new to agile concepts
- Development of initial backlog
 - task granularity
- Use of Github for code development

The Art of the Possible



Imagine a world where...

Analysis package	Broken down into features, PBIs, and tasks
Organized work	Strategically planned and delivered incrementally through sprints
Team communication	Improved and coordinated through agile ceremonies (scrums, sprint reviews, backlog refinements)
Metrics	Indicating both progress and trajectory, accounting for effort of each task (imagine evidence-based resource asks!)
Scope creep	Objectively measure the impact of unplanned requests

Cultural Shifts



How Agile Mindset Impacts Clinical Programming

Adoption of Agile

- It's **not easy** – it requires commitment from all team members
- Requires increased effort on **upfront planning** and **ongoing grooming**
- Spotlight on team member **accountability**
- Commitment to **ceremonies**
 - Regular standups, backlog review, sprint planning, review, and retrospectives
 - Yes, it is more meetings
 - Keep them short and efficient! Extract maximum value!
- Add a **scrum master** – allow the Product Lead to focus on leading

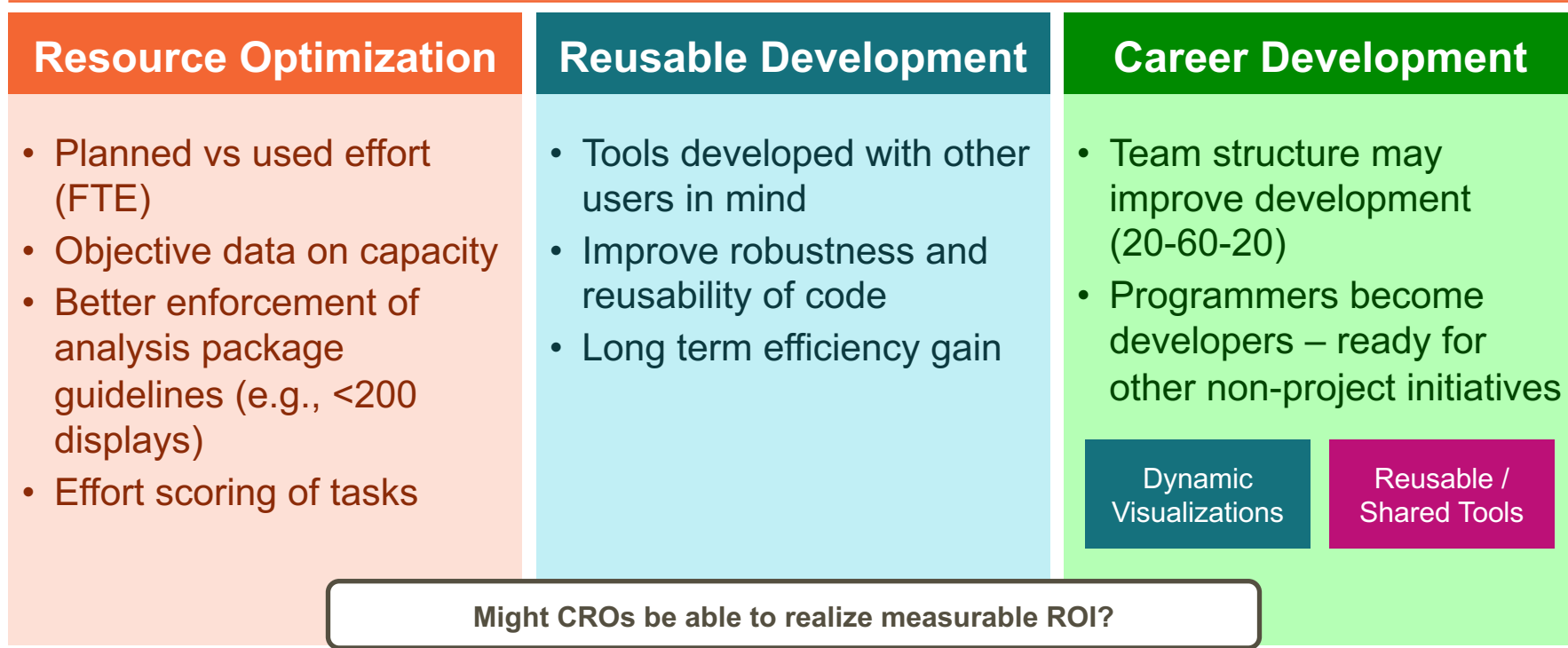
You will get it
wrong the first
time

Remain agile
with your agile

Future State



Tangible benefits identified that can be scaled



Thank you!!!



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