SCDM Live

Sept. 29 – Oct. 2, 2024 | Boston, MA

SCDM 2024 Annual Conference

Festival of Opportunity

Applying SCRUM Methodology to Database Lock

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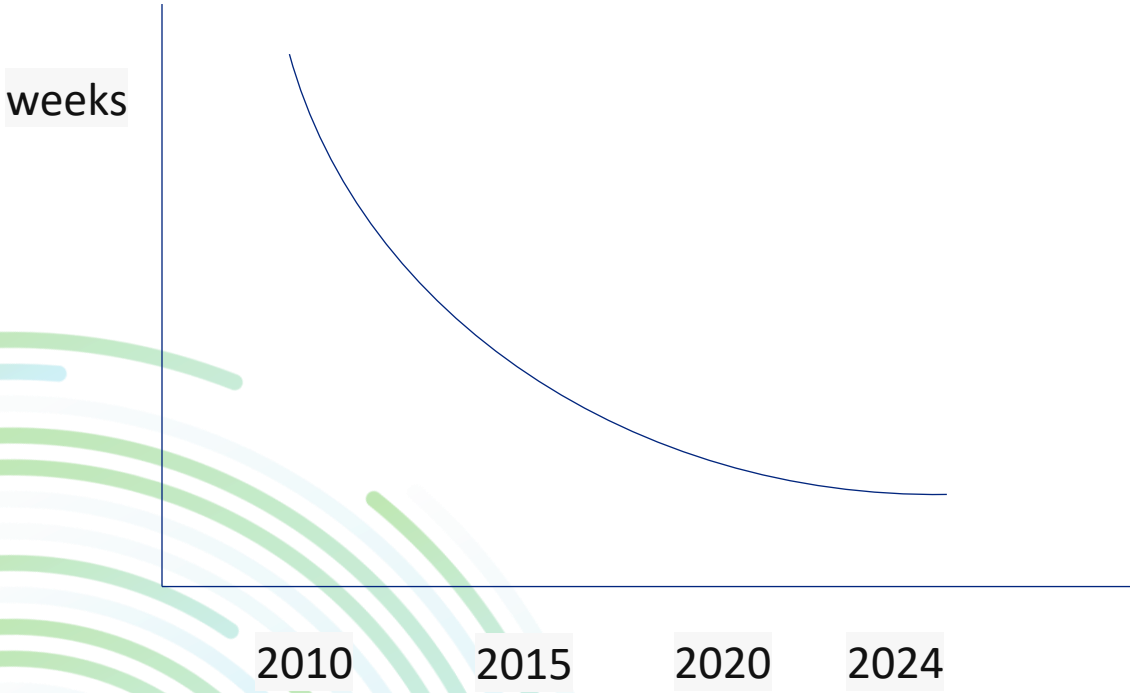
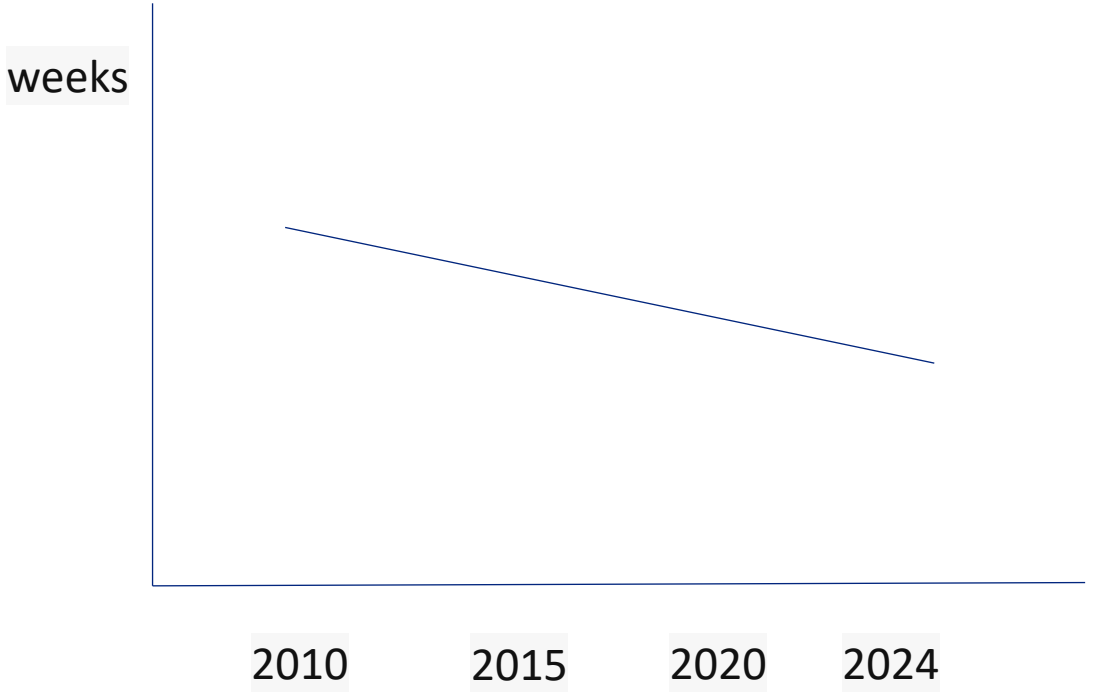
Be “Lock Ready” at all times ..!!!

Let’s check how the KPIs in setup/startup & closeout phase have changed over the period

final protocol to study go live



LPLV to database lock



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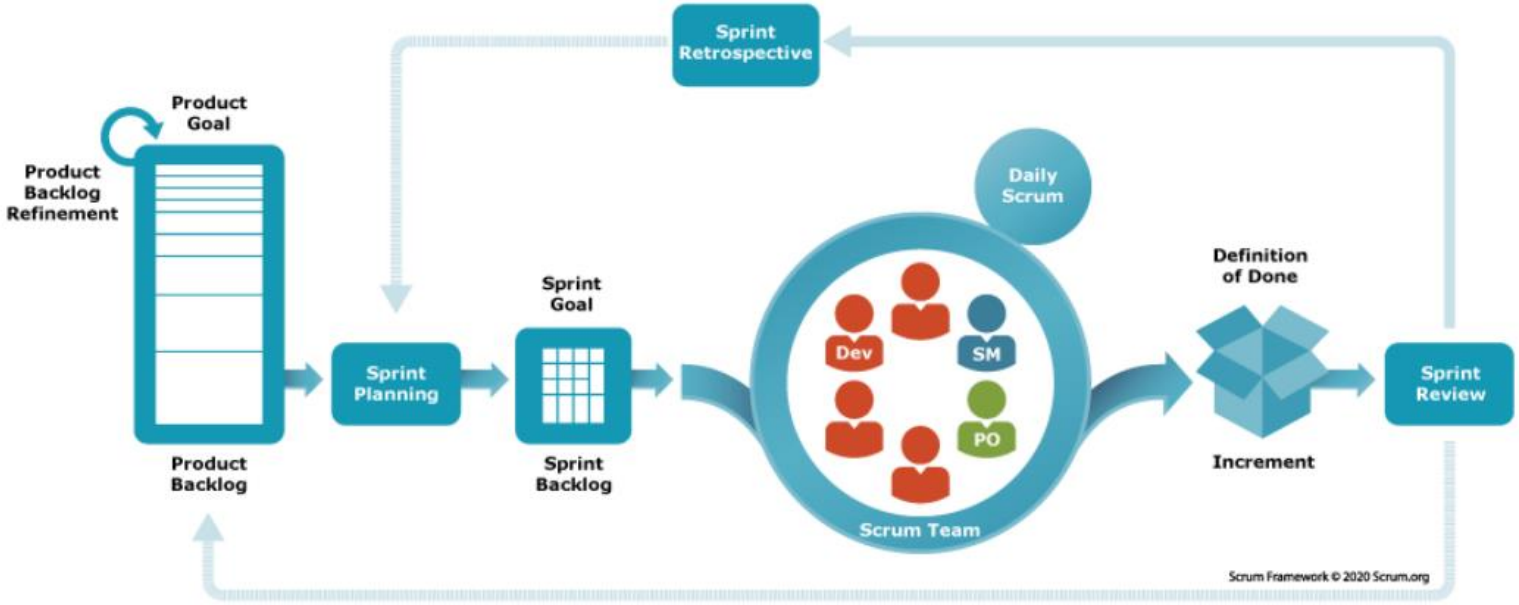
SCRUM Values

SCRUM Principles

- Empirical Process Control
  - Transparency
  - Inspection
  - Adaptation
- Self-Organization
- Time-Boxing
- Value-Based Prioritization
- Iterative Development
- Collaboration

Agile Process Flow Diagram



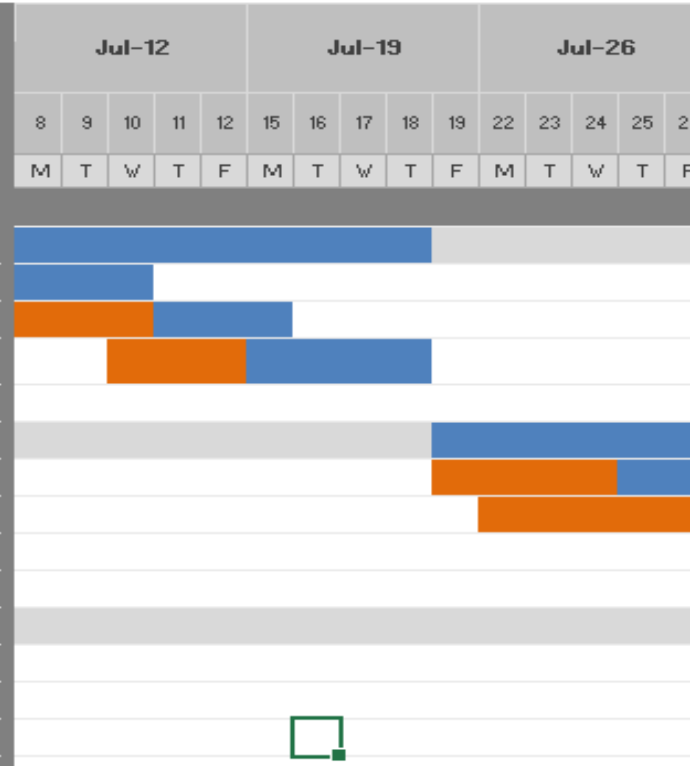
Sample Sprint Project Plan DBL

Sprint Project Tracker

Task in Progress Task Completed

LPLV	Date 90 Days before LPLV	SCROLL TO WEEK #	2
02-Oct-24	04-Jul-24		

Sprint	Priority	Start	Finish	Duration	Status	% Complete
Project Summary		**04-Jul-24**	########	**65 day(s)**		**49%**
Sprint 1		**04-Jul-24**	**18-Jul-24**	**11 day(s)**		
EDC Data Cleaning/SDV (Batch 1)	High	04-Jul-24	10-Jul-24	5 day(s)	Red	10%
Biomarkers (Batch 1)	High	08-Jul-24	15-Jul-24	6 day(s)	Yellow	20%
Central Lab reconciliation (Batch 1)	Medium	10-Jul-24	18-Jul-24	7 day(s)	Green	30%
Sprint 2		**19-Jul-24**	########	**15 day(s)**		
EDC Data Cleaning/SDV (Batch 2)	High	19-Jul-24	01-Aug-24	10 day(s)	Red	40%
Safety Reconciliation (Batch 1)	High	22-Jul-24	05-Aug-24	11 day(s)	Yellow	50%
ECG data (Batch 1)	Medium	28-Jul-24	08-Aug-24	9 day(s)	Green	60%
Sprint 3		########	########	**26 day(s)**		
EDC Data Cleaning (Batch 3)	Low	09-Aug-24	22-Aug-24	10 day(s)	Yellow	70%
eCOA(Batch 1)	High	16-Aug-24	02-Sep-24	12 day(s)	Green	80%
Questionarries (Batch 1)	Medium	10-Sep-24	14-Sep-24	4 day(s)	Red	90%
Sprint 4		########	########	**13 day(s)**		
All Sites PI Signature	Low	18-Sep-24	27-Sep-24	8 day(s)	Green	100%
All Sites Cleaning/SDV	Medium	15-Sep-24	23-Sep-24	6 day(s)	Yellow	15%
Screen Failure	Low	21-Sep-24	02-Oct-24	8 day(s)	Red	25%



Challenges?

The core challenge for every organization is to reduce the duration from LSLV to Lock but what are some of the bottle necks SCRUM could help resolve.

- Coordination and Communication
- Task Management
- Flexibility and Adaptability
- Quality Control
- Stakeholder Engagement

Scenario 1

Issue: Site Utilized an ultrasound device to collect the data and enter the data into EDC. The format of the result file from device created several data entry issues in EDC. Getting high quality data for the study lock required clean data to be available within 6 weeks of identification of the issue.

Solutions that could have been applied

- 100% SDV of these data point which considering timelines wouldn't be feasible.
- Create a data transfer mechanism from each site to sponsor (rather that entry into EDC) which considering they are individual pdf test results wouldn't be feasible.
- Compile the pdf results from the vendor into a tabulated format to reconcile and complete DM and clinical review .

Scenario 2

A design error in the EDC system was identified 6 weeks before DB lock impacting 152 sites and 600 subjects. This system error would require the form to be added to EDC, Site entry completed, data cleaning checks and dashboards updated, data review performed and finally data to be locked within a 6-week timeframe. A typically PPC alone would take 4 weeks.

Agile teams

with technology

This is how all projects work…right?

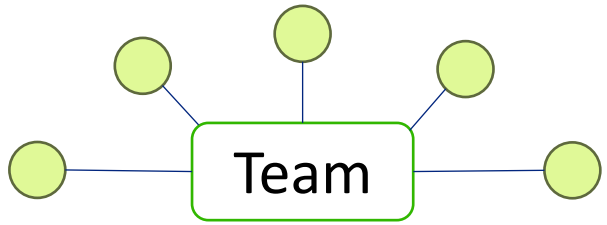
Leader

Define goal

Assign roles

Prioritize tasks

Identify waste



Execute

Execute

Execute

Execute

Or is this how all projects work?

Leader

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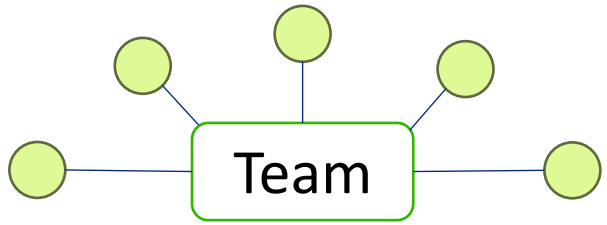
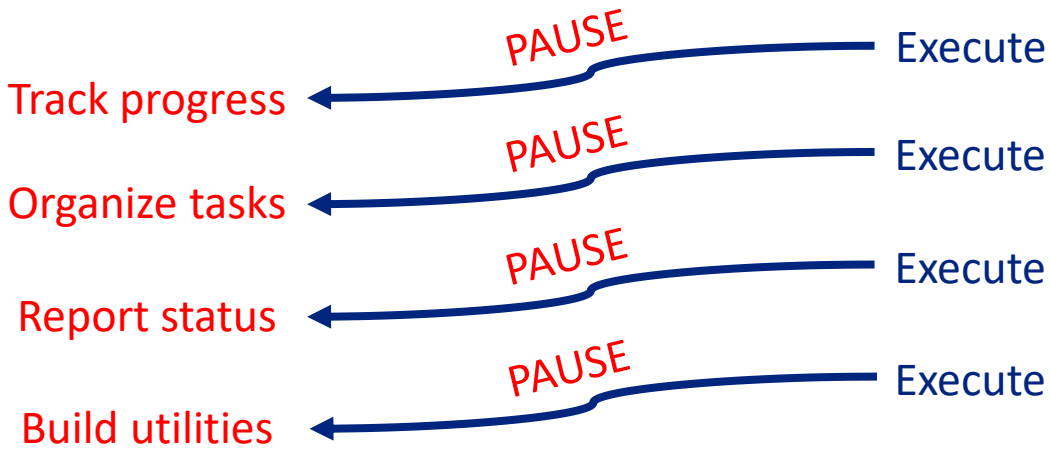
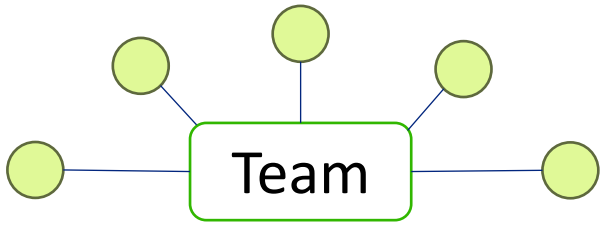




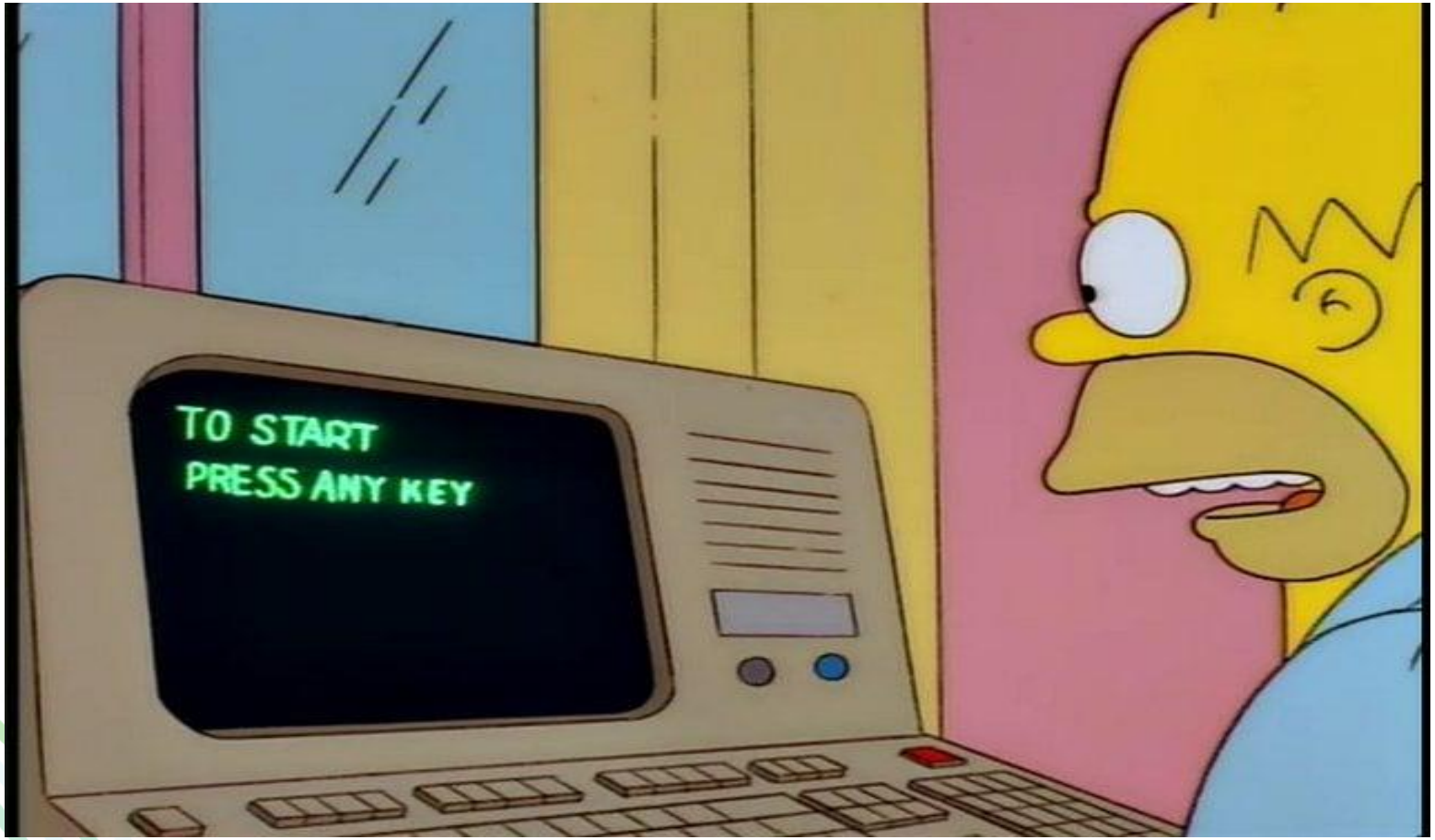
Agile teams level up with technology

Leader	Technology	Team
Define goal	Track progress	Execute
Assign roles	Organize tasks	Execute
Prioritize tasks	Report status	Execute
Identify waste	Automate	Execute



…that is aware of GxP processes

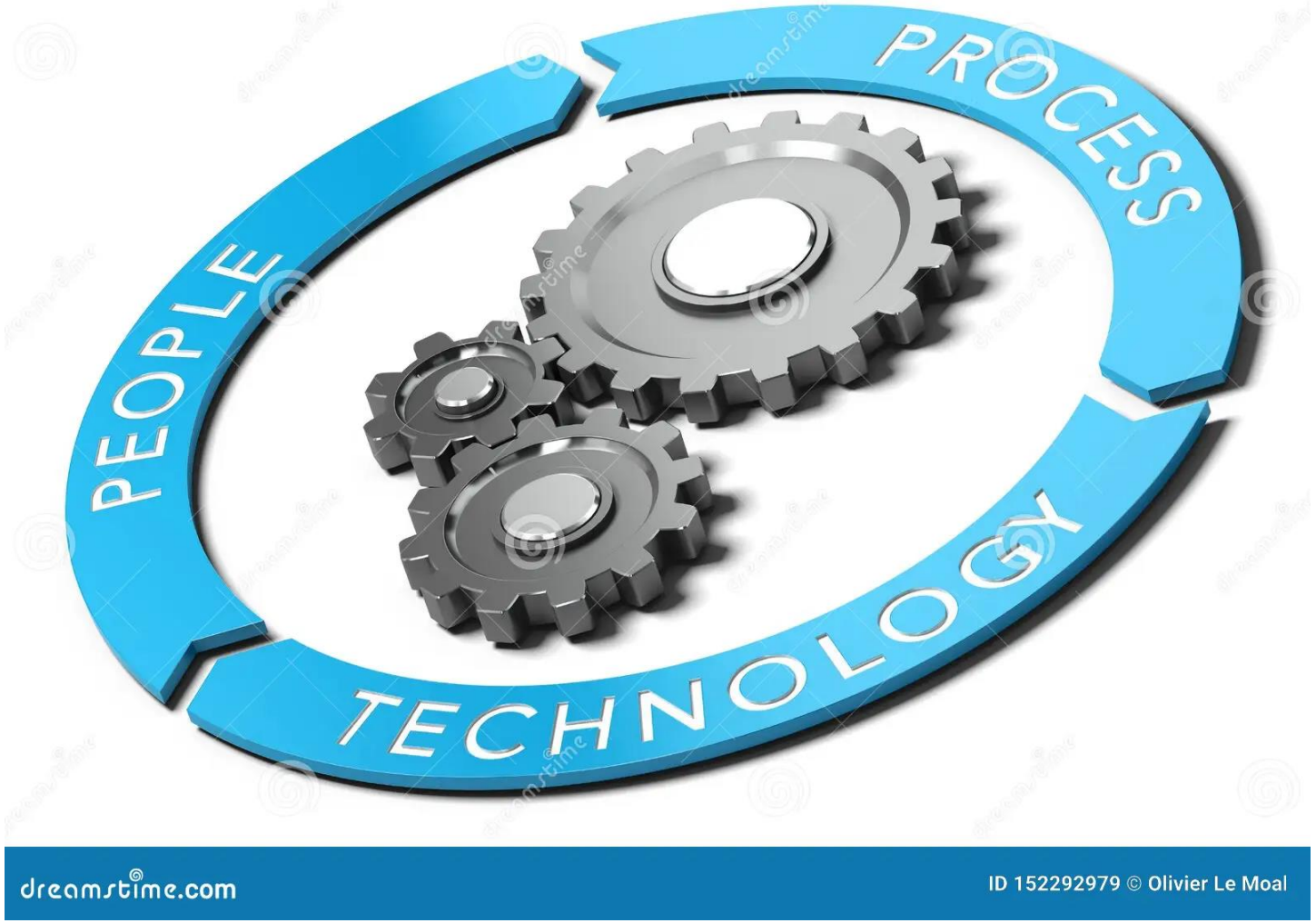
How can technology help?



Useful features to be on the lookout for

- Visual and interactive designs
- Self documenting
- Risk-based / Targeted approaches
- Optimized filtering and bulk management capabilities
- Productive & optimized data integrations
- Reporting and analytics (ideally leveraging AI)

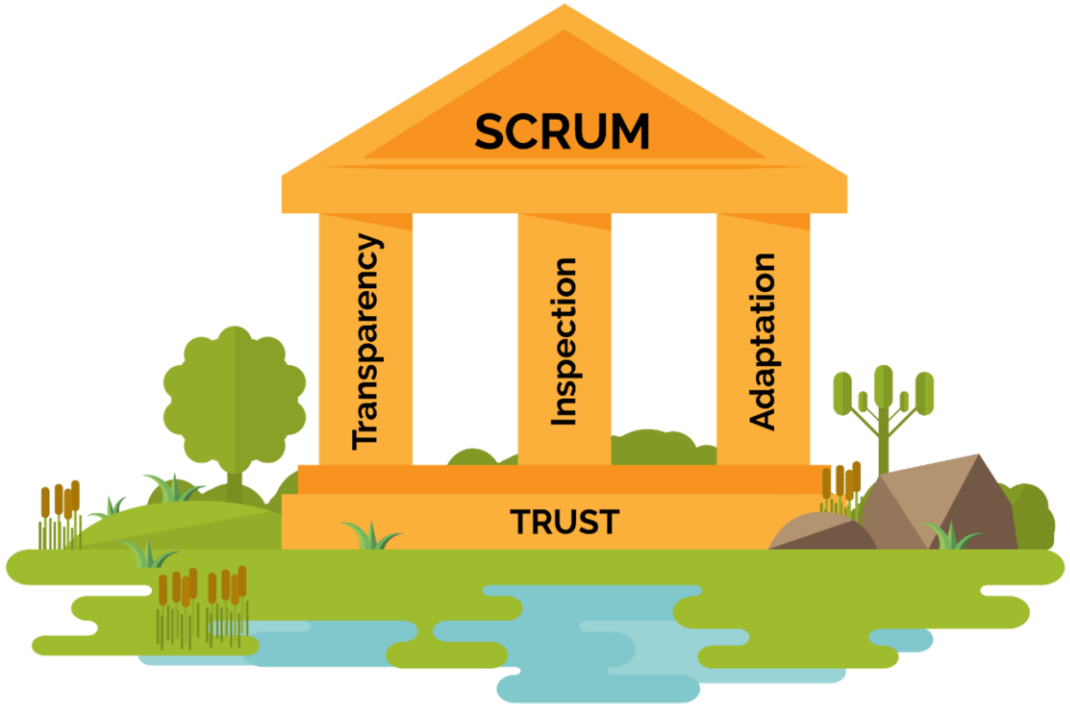
Process & People - SCRUM Methodology for DBL



People & Process are equally as important as Technology

Process Considerations

- SCRUM Process in General (Pillars)
- Technological/Operational/Trial Specific Processes & Considerations
- Project Management
- “Sprints”/Turn-Around-Times
- Multi-level Deliverables
- Frequent Re-assessment and/or Re-prioritization



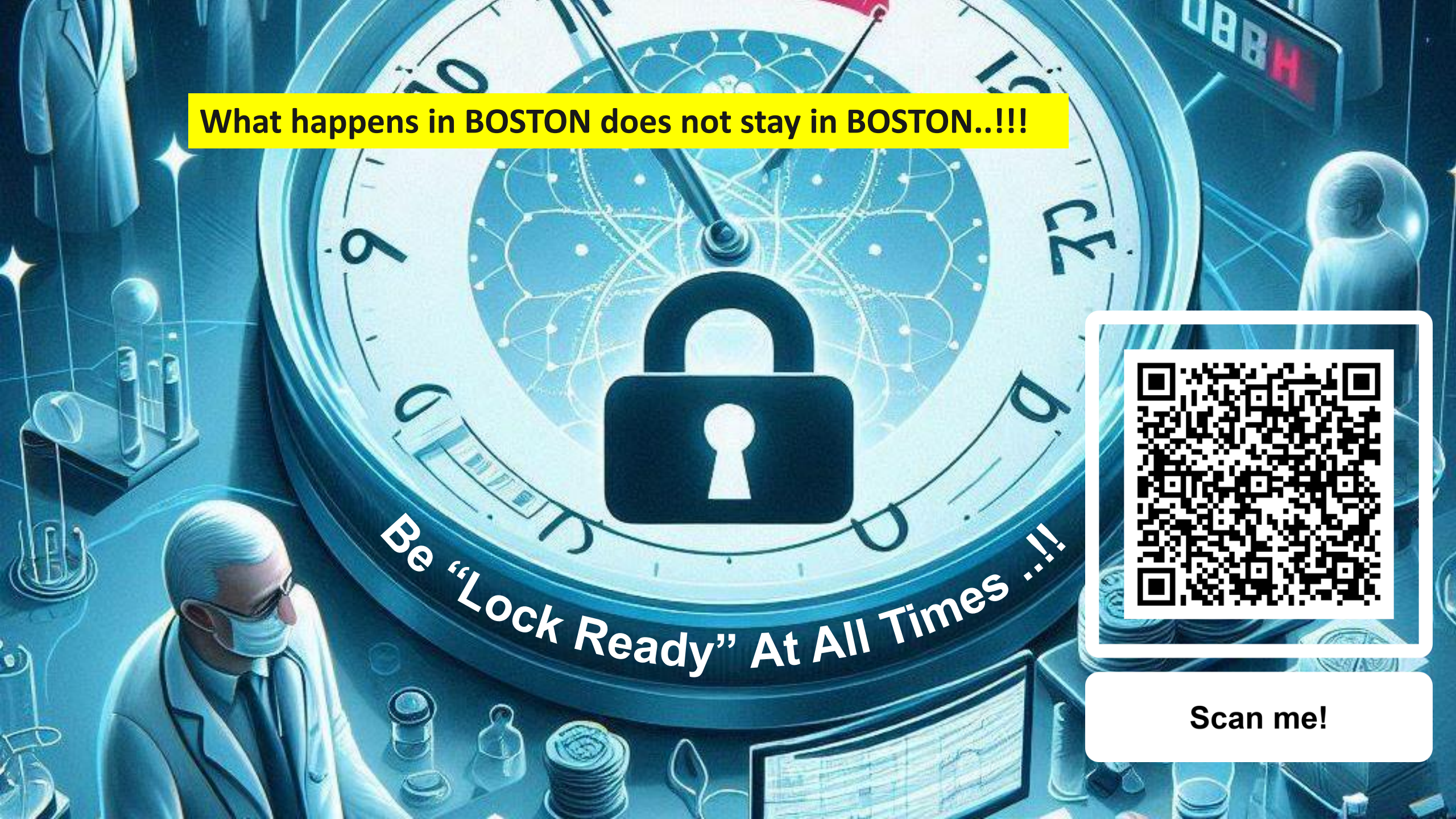
People

- The Drivers
- SCRUM Team Members
  - ScrumMaster=Lead DM
- Various Team Members, Roles, or Multiple Hats
  - “Do-ers”
  - Stakeholders
- Recognize the BST ☺

Q&A with Panellist

Q&A with Audience

Be “Lock Ready” at all times ..!!!


What happens in BOSTON does not stay in BOSTON..!!!
Be “Lock Ready” At All Times ..!!
Scan me!