



AS01: SPACE – Launching GSK Biostatics towards new horizons

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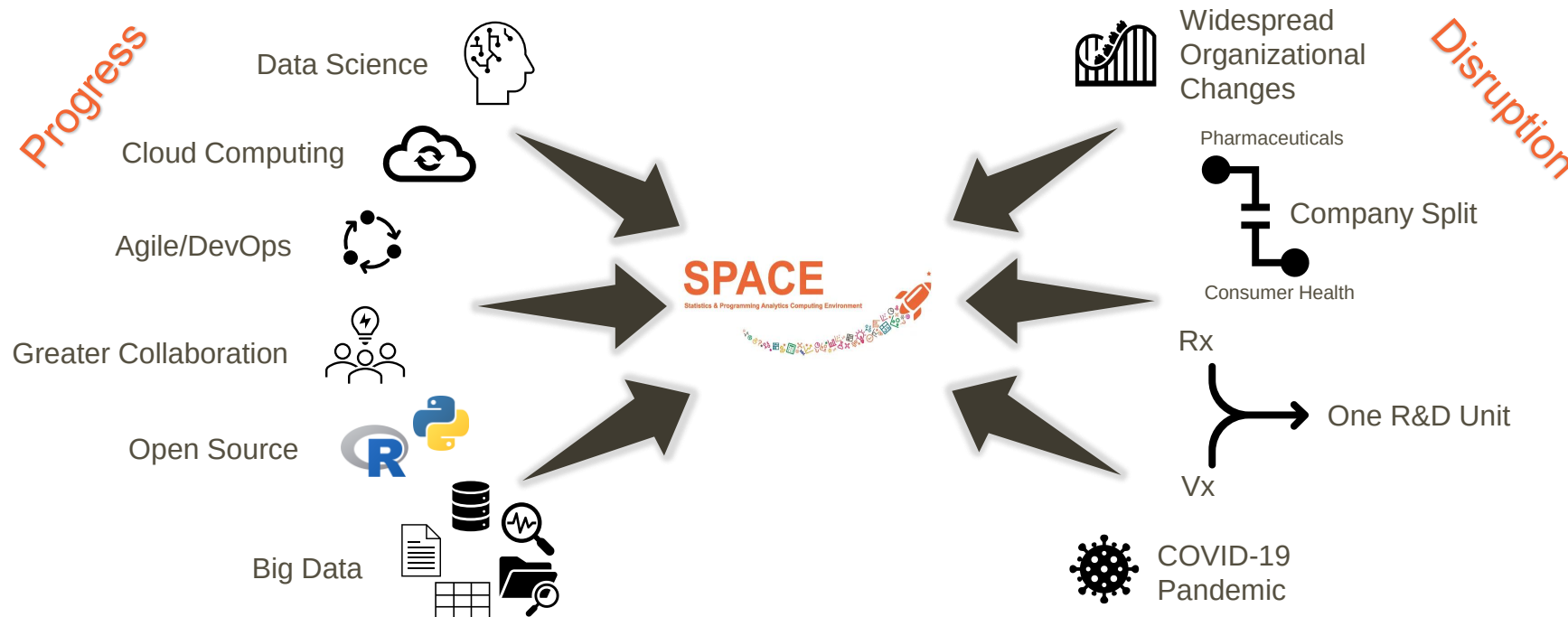
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 - 🚀 SPACE Objectives
 - 🚀 SPACE Delivery Methodology and Structure
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 - 🚀 Key Learnings
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Introduction



SPACE: Modernizing our SCE during a time of change



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SPACE Objectives



Why is SPACE a vital program?

To define, design, execute and embed a fit-for-future transformation of a Statistical & Programming, Analytics Computing Environment to support Clinical Programming, Clinical Statistics, CMC Statistics and Research Statistics

**Maintain
license to
operate**

**Deliver
business
efficiency**

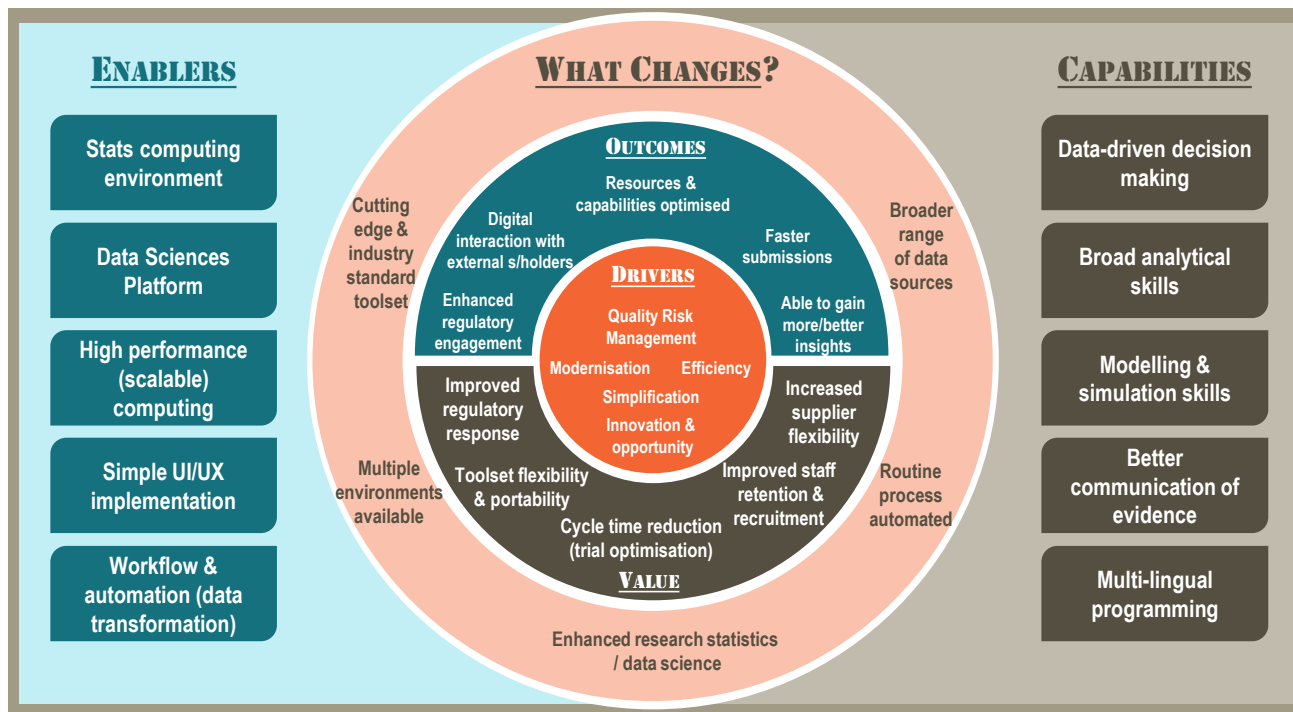
**Provide
enhanced
capability**

**Simplify
our ways of
working**

**Improve
recruitment
& retention**

One company, one platform, one way of working

SPACE Benefits Dependency Network



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What is Agile Delivery?

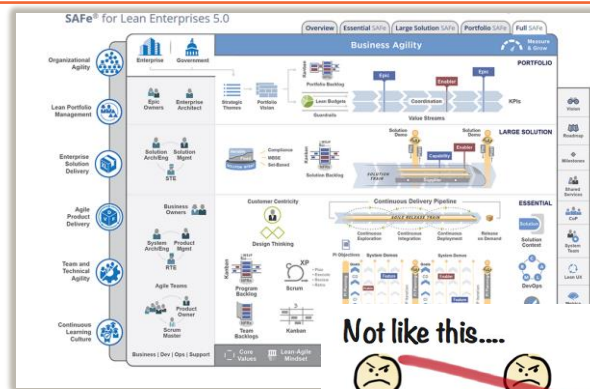


SAFe® Scaled Agile Framework: <https://www.scaledagileframework.com/>

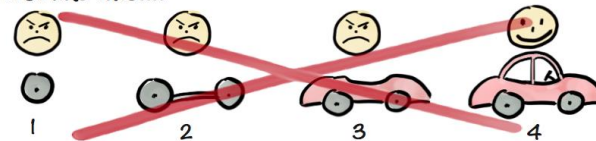
- ❑ The business will **receive working tools and processes earlier to experience real benefits** and to **be able to provide feedback sooner** - than we have come to expect

- ❑ **But we need to be patient and realistic...**

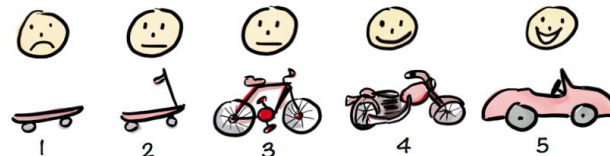
- Initial releases won't cover all the capabilities that users want
- Earlier versions may include some features (or even work-arounds) that won't be retained long-term
- The product team needs ongoing input and feedback to get it right (incl. both features and feature priorities)



Not like this....



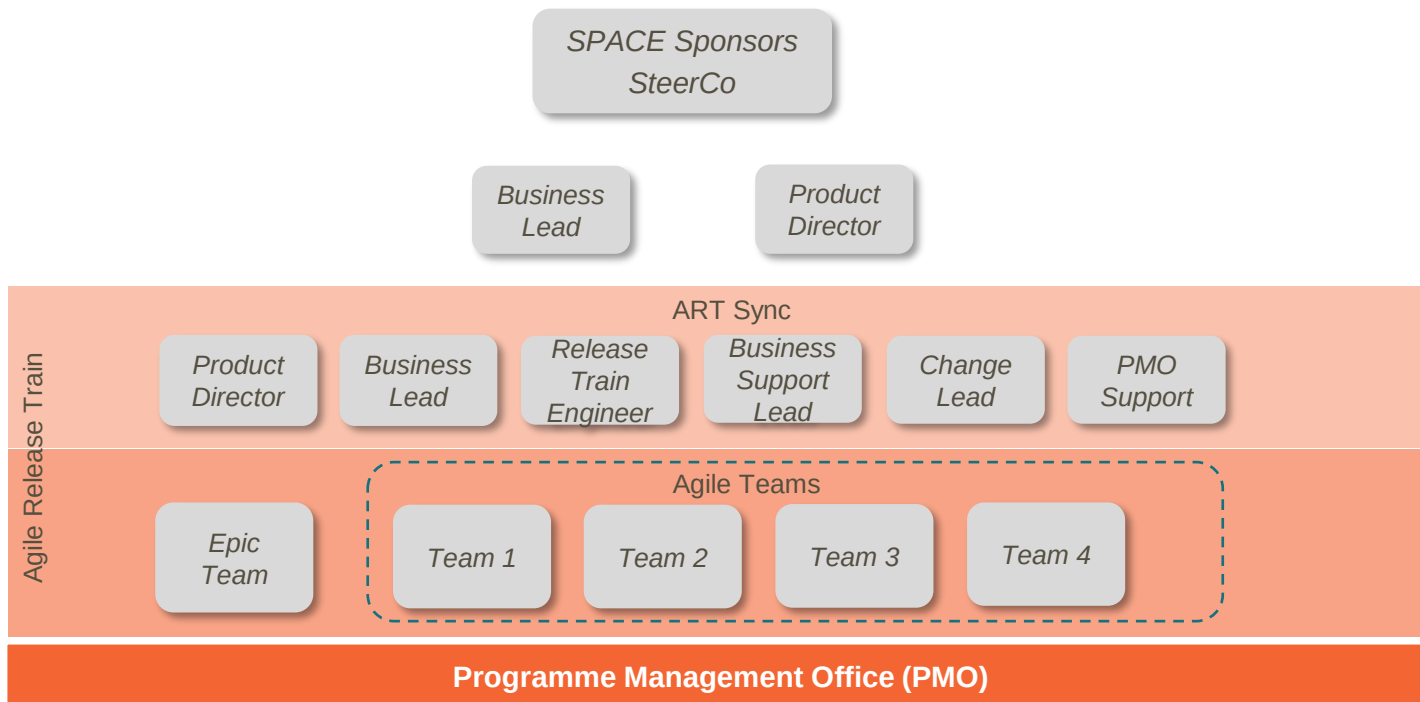
Like this!



SPACE Program Structure



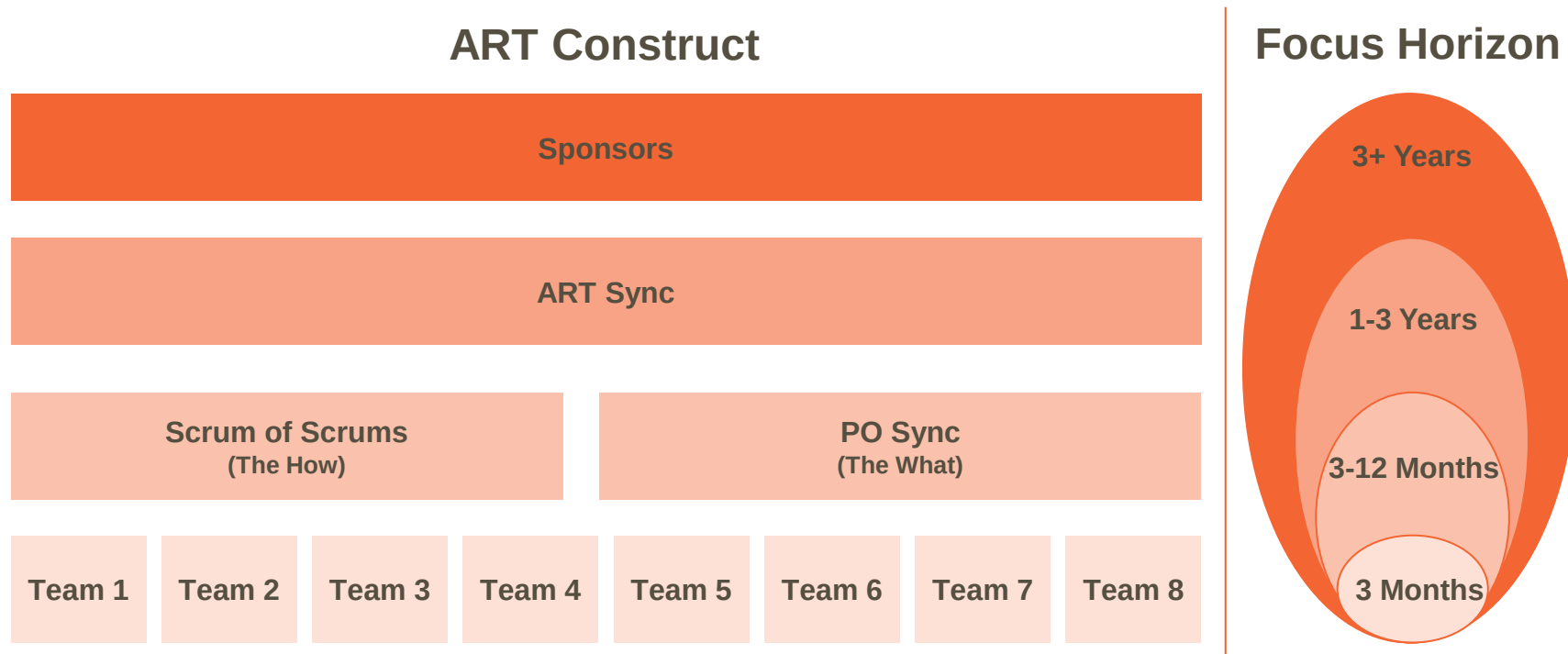
Overall organization



The SPACE Agile Release Train (ART) Schematic



How the ART is constructed indicating the focus horizon each construct operates at



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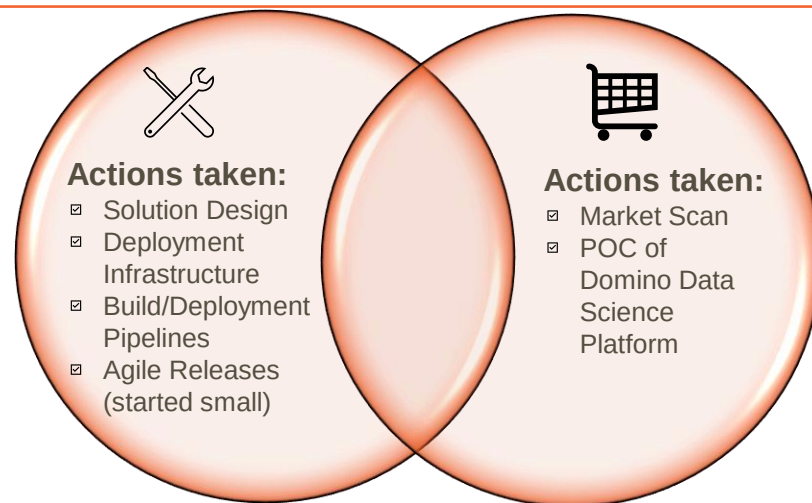
Build vs. Buy



The age-old SCE question

Considerations

- GSK preference was to buy and integrate.
- The SPACE solution would need to evolve with GSK in a changing environment, rather than making progress difficult.
- Capabilities which had not previously existed in traditional SCE solutions (e.g., dynamic statistical displays) were in scope.
- The Scope of the SPACE investment was broader than a traditional SCE pipeline for study submissions (e.g., computing capabilities for non-clinical and research statistics).



Results

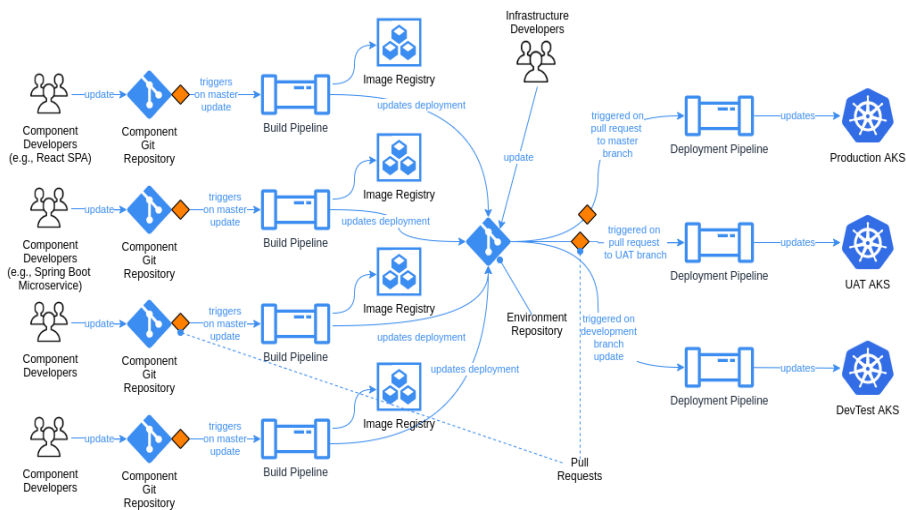
- ✓ Adopt Domino Data Science Platform deployed on GSK's Microsoft Azure cloud environment, integrated with GitHub Enterprise, and design the analysis & reporting workflow using its capabilities.
- ✓ Integrate the workflow with the bespoke applications which were already evolving.
- ✓ Make Domino available for use as a data science platform for other GSK use cases.

Development and Deployment Architecture



Microsoft Azure Cloud

Build and Deployment Pipelines



A few of the technologies used:

- Kubernetes (AKS)
- Data Lake Storage (ADLS2)
- Azure File Storage
- SQL Server
- Apache Kafka
- Docker
- Azure DevOps
- Azure Git
- Selenium is used to automate Gherkin system tests

SPACE Portfolio for the Clinical Study Use Case



Three main components

PULSAR is an application which automates the rendering, bundling and sharing of statistical outputs with medical writers for review and publishing, and shares regulatory submission deliverables, like the Submission Data Package.



METEOR is a multi-lingual code development, execution, and management platform, powered by the Domino data science platform, which manages authorization to our data sources, and allows us to orchestrate our GxP clinical programming efforts. This is our new SCE.



RAPIDO Data Viewer is an application which allows study teams to explore analysis results dynamically, aiding in CSR development, reducing the number of required static outputs in submissions, and influencing adhoc/post-hoc analysis requirements.



Used in orchestration to deliver maximum efficiency in quality statistical analysis and reporting of clinical trial data, reducing time, rework and effort.

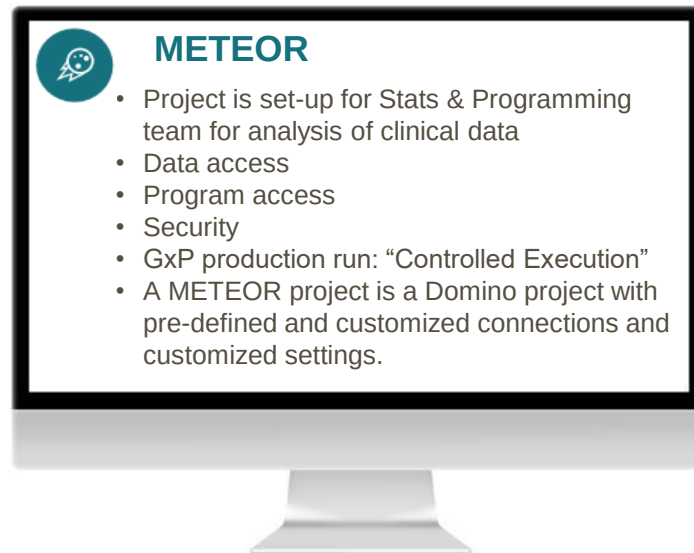
GSK's SCE powered by Domino



Off-the-shelf DOMINO
Data Lab Data Science
Platform



GSK bespoke
customizations for
METEOR

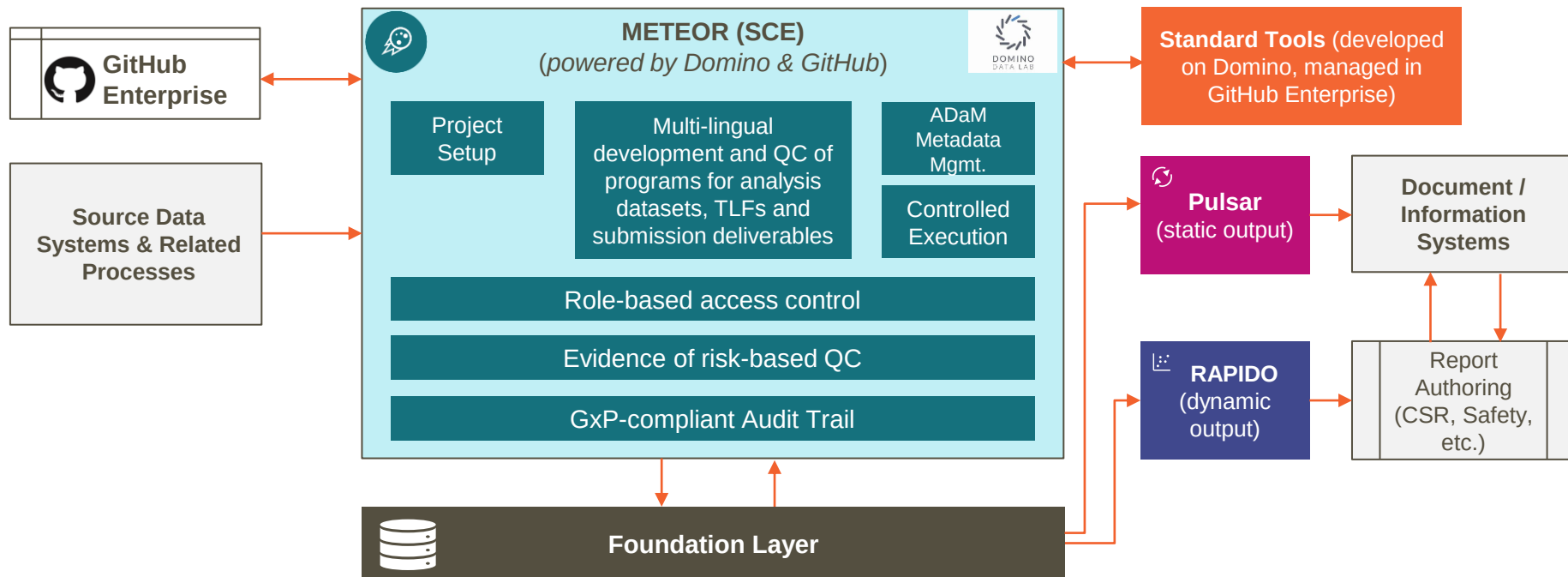


METEOR

- Project is set-up for Stats & Programming team for analysis of clinical data
- Data access
- Program access
- Security
- GxP production run: "Controlled Execution"
- A METEOR project is a Domino project with pre-defined and customized connections and customized settings.

A custom workflow consisting of off-the-shelf and bespoke solutions

METEOR and the supporting foundational tools in the context of SPACE



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Relationship Between Business and IT



Mutual trust + respect + common goal ➡ successful program

Self-organizing teams + clear goals ➡ efficient delivery

Laser focus on measurable value ➡ sound decisions

Working closely together + equal ownership of success
➡ excellent solution designs

Productive
Engaged
Happy



Challenges with Agile Delivery



Learning Curve

- Knowledge gap in team and between Business and Tech
- From Waterfall to mini-Waterfall to truly Agile

Clarity in Roles & Responsibilities

- Applied SAFe ART model and extended to include GSK roles
- Organized the team around the work (leaned to flex and adapt)

Expectations Setting

- Agile maturity of the organization not aligned with program delivery framework
- Mismatched expectations and “disappointment management”

GxP and Agile

- GSK ITMS born from traditional delivery methodology
- Significant overhead in each PI slowed down progress

Global Teams and Resourcing

- Team dispersed locations and multiple time zones not ideal for Agile
- Part-time business resources an ongoing risk



Planning for and Embracing Change: Program Resilience



Managing change as a program and with our user community

How we evolved as a program

- Initial steep Agile learning curve created confusion and anxiety
- Perceived lack of progress shook team's confidence in delivery
- Large and growing SPACE team made effective communications difficult



- Dedicated time and resources to SAFe training and coaching
- Focused on business value and iterative and realistic delivery shown on roadmap
- Intra-program newsletters and clarity in PI planning

How our change management matured over time

- Lack of clarity in what to communicate to user community
- Discomfort with fluid nature of Agile and shorter time horizon
- Essential mindset and cultural shift SPACE is bringing to the organization and ways of working



- A more robust Change Management playbook and approach
 - communicate with purpose/regularity
 - be open and transparent
 - invite engagement and participation
 - combine early awareness with just-in-time training
 - monitor and measure

Planning for and Embracing Change: Solution Resilience



Learning to embrace emerging design and incremental delivery

Action	Result
In the absence of a central services framework for cloud native solutions at GSK, SPACE IT built its infrastructure, while central infrastructure teams raced to build services to support the new patterns SPACE was implementing.	– SPACE influenced the evolution of central infrastructure services – Allowed value-driven development of central services, in line with Agile methodology
At the start, the Business team spent time and effort designing full conceptual applications in the form of clickable wireframes.	– Disgruntled IT team – Disappointed Business stakeholders – Wasted effort
Once the development and deployment framework was in place, applications were developed, tested, and deployed, starting small and evolving.	– Incremental delivery of solutions which provided immediate Business value – Business and IT stakeholders had pride and confidence in the program – User representatives' ideas often changed as featured were delivered

Key Lesson: Starting small, with simple, focused application UI designs to meet simple requirements, allows the right solution to emerge, bringing incremental value, as change in the form of real user feedback and new ideas can be incorporated into the solution without significant wasted effort or impact.

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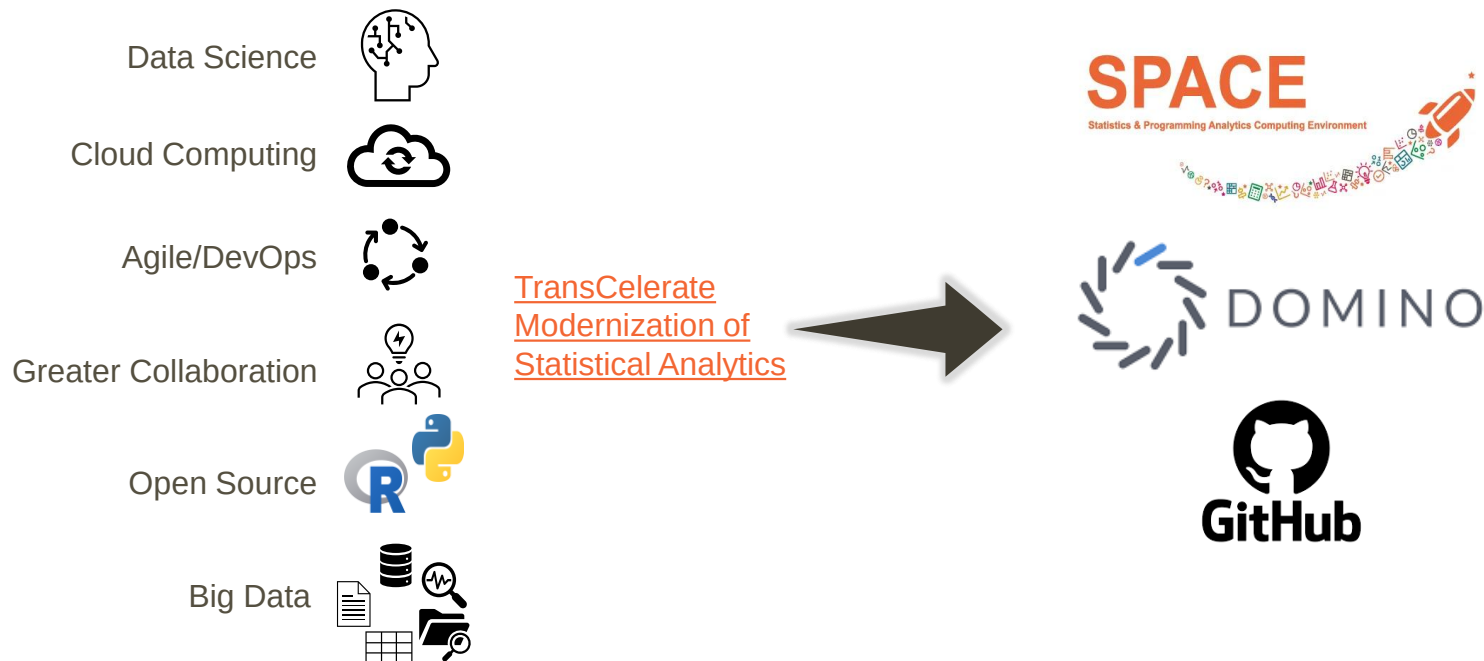


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Industry Trends



Factors that influenced the selection of a data science platform for an SCE



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Conclusion



What have we learned?



Fundamental understanding of Agile is important but we also need to be flexible and practical in our own implementation.



Collaboration and trust between business and IT are essential to our success.



GxP validation framework must leverage and align with agile in order for the system delivery to benefit from the value proposition of agile.



The multi-dimensional transformational change requires proactive and robust change management for making the mindset shift and building technical capabilities.



We must think beyond the traditional SCE to deliver a truly forward-looking and future-proof modern data science platform.

Conclusion



What has fueled our success?



GSK's top-level performance ambitions



Sheer abundance of data and need for advanced digital and analytics



Biostatistics community's eagerness to move beyond the traditional tools



Biopharma industry's shift to modern statistical analytics

SPACE

Statistics & Programming Analytics Computing Environment



Agile Delivery/Continuous Improvement

Business and IT Partnership

Strategic Thinking/Industry Awareness

Q&A



Thank you for listening, any questions?



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