Approaches to maximize benefits of technology, data and agile techniques in clinical research

Phuse SDE
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Presenting today on behalf of GSK Biostatistics and Tech

Samantha Warden

VP, Head Clinical Programming & Business Excellence, GSK

- Influencer in the field of pharmaceutical data science and analytics.
- Career spans three decades, bringing depth and perspective of not only how we manage, analyse and share data, but why we do it.
- Passionate about enabling the data to tell its story to support great decision making as well as innovative design to optimize resources and maximize results.
- Leads GSK's Clinical Programming and Business Excellence function with teams across Europe, US and Asia.
- Previously worked as a technology consultant to the industry, and held leadership positions at CROs, biotech and pharma companies in the UK and Switzerland.
- She is married with three grown up children and a dog and in her spare time enjoys running, sailing and international cuisine

Education & Certifications

- *Sam holds an MBA, and a Bachelor of Science in Biology from the University of Manchester*
- *She is a regular contributor at phuse*

Top 5 Strengths*

Responsibility, Arranger, Futuristic, Learner, Activator

*CliftonStrengths

Disclaimer

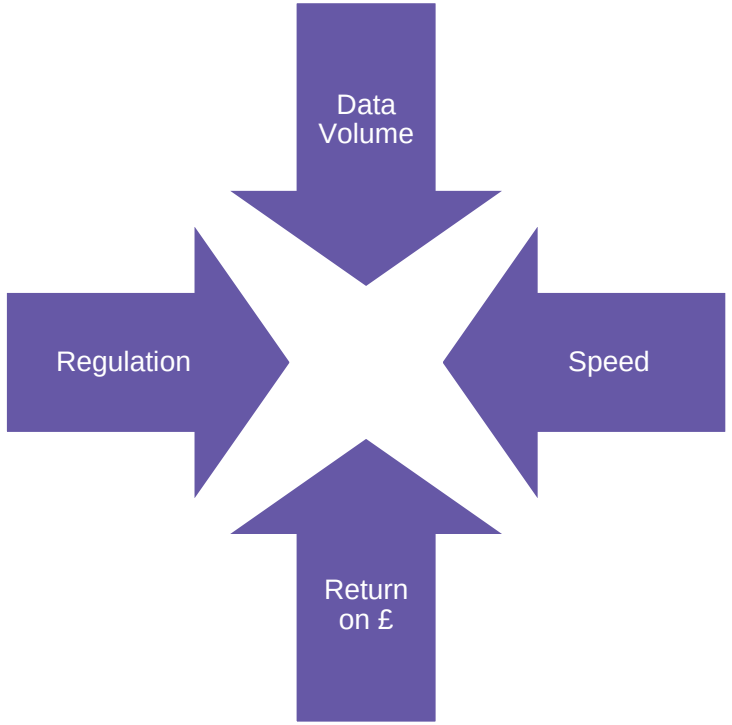
- This presentation is for informational purposes only and should not be construed as professional guidance or advice. The views and opinions expressed in this presentation are those of the presenters and do not necessarily reflect the views or policies of GSK.

Background

In 2020, GSK embarked on an ambitious journey spanning technology, data and workflow to create a future-fit data and analytics capability for GSK

The Clinical Programming community is witnessing an inflection point in clinical data analytics with more traction to use new programming languages, dynamic data visualization tools, and to unravel the clinical evidence leveraging data from various sources and using AI/ML

External	Industry	Internal
• Increase in regulation • Aging population • Global pandemic • Economic Crisis • Data scientist skillset is becoming a «literacy» skill	• New competitors (Google, Apple, Samsung) • Connected health (data volumes) • Personalized medicine (targeting right treatment at right time for the individual) • Wellness vs Illness	• Size & Scale • Technical platforms • AI/ML • War for talent



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Our Ambition

Empower project facing teams with the right **instruments** to transform **data into action** so that we can get ahead of disease together

- Agility in exploration, rigour in delivery
- Enabling computers to mimic (or improve on) human behavior
- Focusing humans to gain insights based on data
- Compliant with regulations & aligned to goals

How have we approached this?

- revolutionised GSK's statistical computing environment to make it a data science platform
- training our teams to leverage multi-lingual programming approaches (mostly R so far)
- Building agile ways of working
- Experimenting with pushing the boundaries of workflow by deploying agile methodologies

Maximizing Benefits

- Create a clear North Star
- Identify the benefits and commit to them
  - Accelerated delivery (holistic view, driven with metrics/KPIs)
  - Released reliance on proporietary software (bold decisions)
  - Reduced cost of delivery (holistic view, accompanied by budget target)
  - Quality paramount (culture & KPIs)
- Strong Tech-business partnership
- Build in slices, and iterate
  - SPACE platform
  - SPACE apps
  - Automation
  - Process & Organization

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Technology

From presentations by Eileen Ching & Saurin Mehta

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Adopting New Ways of Working

Moving FROM

- Creation of static tables/listings/figures delivered to medical writers, repeating this process with new/updated requests
- Publishing study results and submission packages to downstream consumers with multiple manual steps
- Two separate clinical reporting environments running different processes; monolithic, slow, complex and rely on legacy tools
- Having to go to different environments to run SAS, R, Python, etc.
- Disparate environments and tools for clinical and non-clinical Biostatistics and data scientists

Moving TO

- Dynamic dashboards allow medical writers to explore data and find the data visualizations they need .
- Publishing study results and submission packages to downstream systems with an easy-to-use and more automated tool
- A statistical computing environment powered by modern data science platform with redesigned business processes
- A single platform with multilingual support that lets you use the right tool for the job
- A single unified, flexible, and scalable platform for GxP/regulated and non-GxP/exploratory work

Key Design Principles

Cloud-native

Flexible

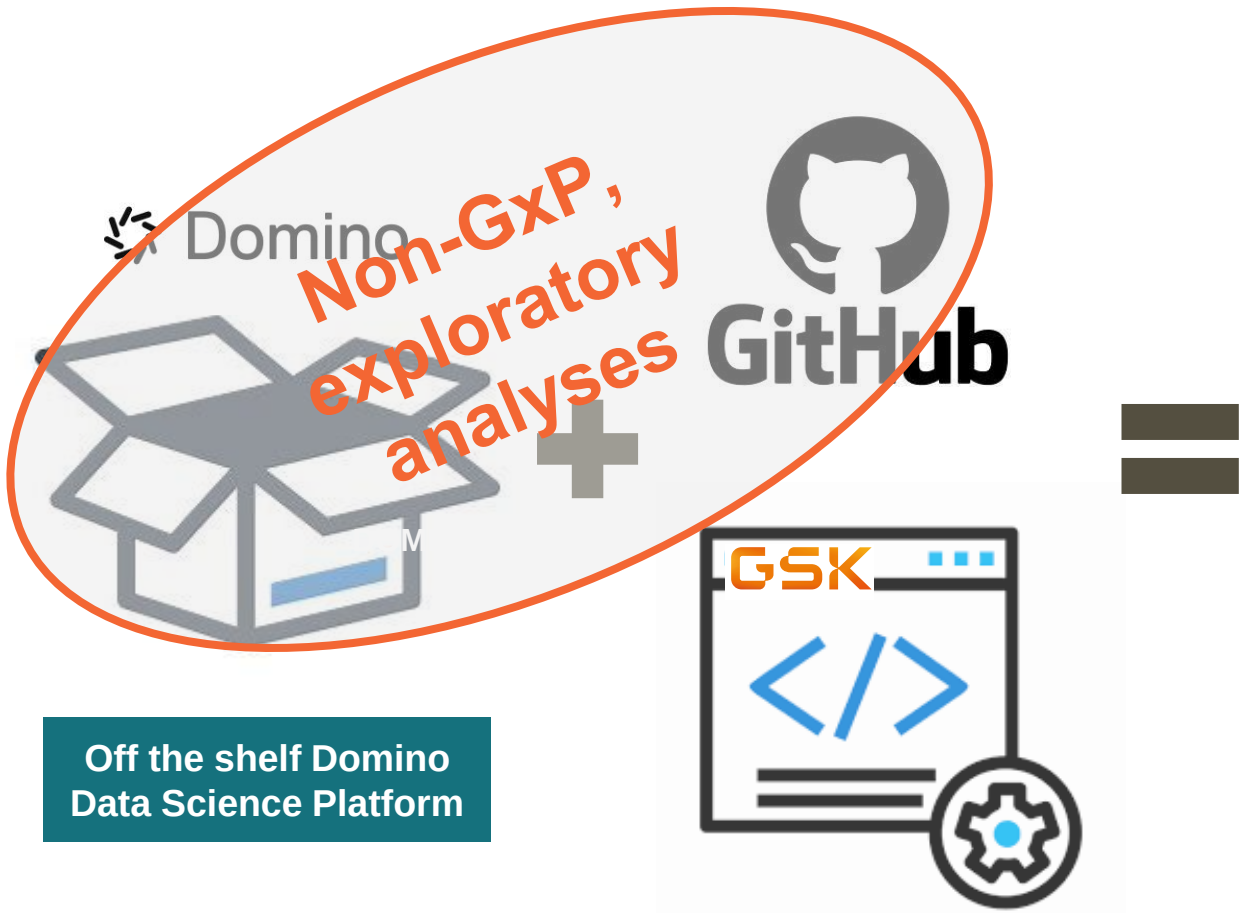
Extensible

Multilingual

Scalable

Usable

Modern SCE Powered by Domino



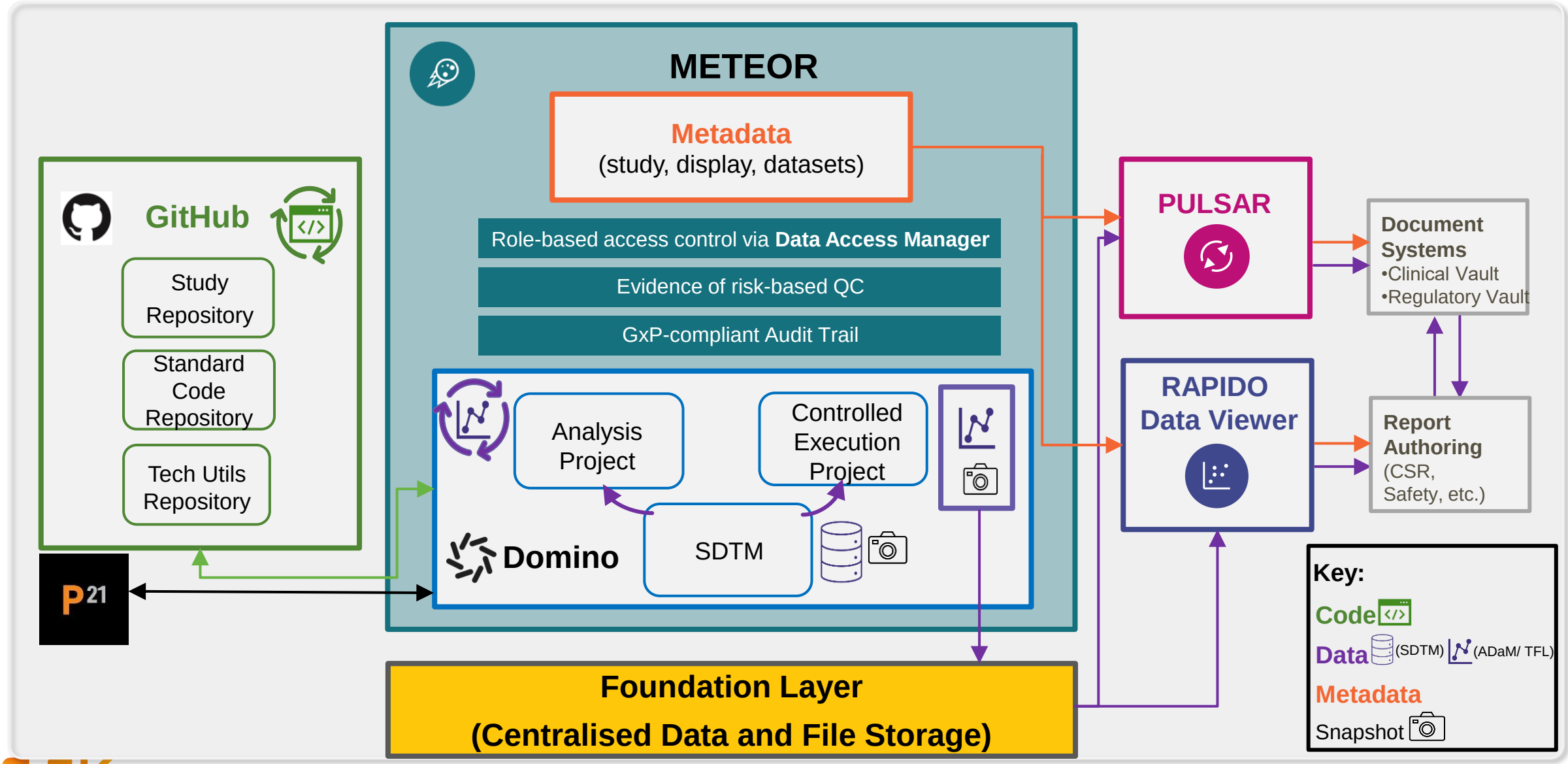
Off the shelf Domino Data Science Platform

GSK bespoke customisations

METEOR (GxP)

- **Domino® Data Science Platform** is a cloud-based, open, flexible, scalable, and multi-lingual platform for programmers, statisticians, and data scientists.
- ***Key features that will power SCE:***
  - **Detailed logging** throughout the programming and execution process
  - Robust dataset features like **versioning**, **snapshots**, and **sharing** between projects/planned analyses
  - Using **multiple languages** within one project, under the same process, with integrated IDEs
  - **Flexibility** in how we do our work combined with **necessary controls** for GxP compliance: the freedom of “dev”, with the control of “prod” in one place
  - Robust **security model** with granular access controls and “read-only” user type
  - **Powerful APIs** that allow us to build our SCE and workflows upon the foundational capabilities provisioned out of the box
  - Domino Platform fits with our **cloud-first, data fabric, and data platform architecture strategy**.

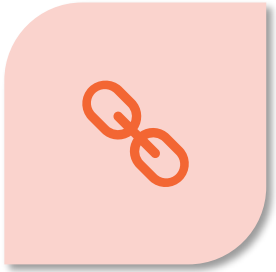
Clinical Reporting in Modern SCE



The Modern SCE is …

Multilingual

Use the right tool for the job, including open-source



Extensible

Integration and automation; extensible through API

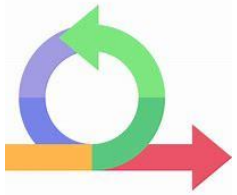
Compliant

Automatic versioning and audit; traceability and reproducibility

Unified

Diverse use cases and workflows in the same environment

turbocharged by …



Agile Ways of Working

Data

From presentations by Jorine Putter & Laura Zupko

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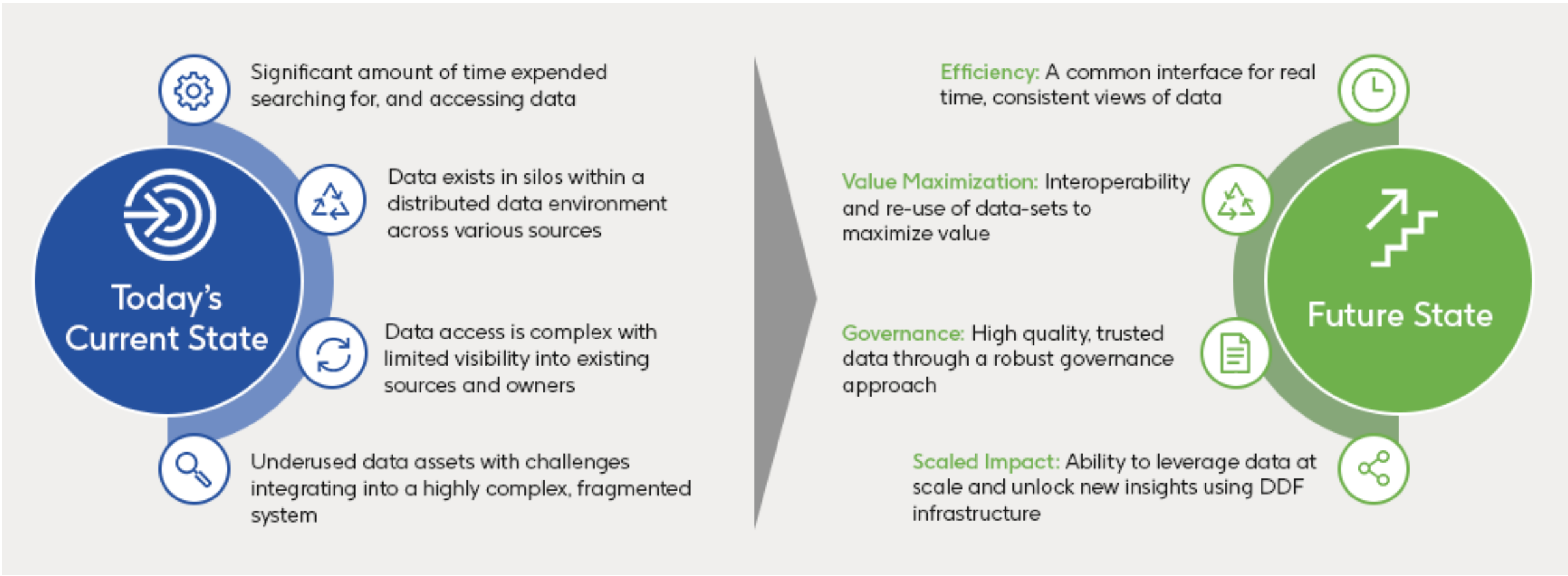
Enabling Data Centricity and Access



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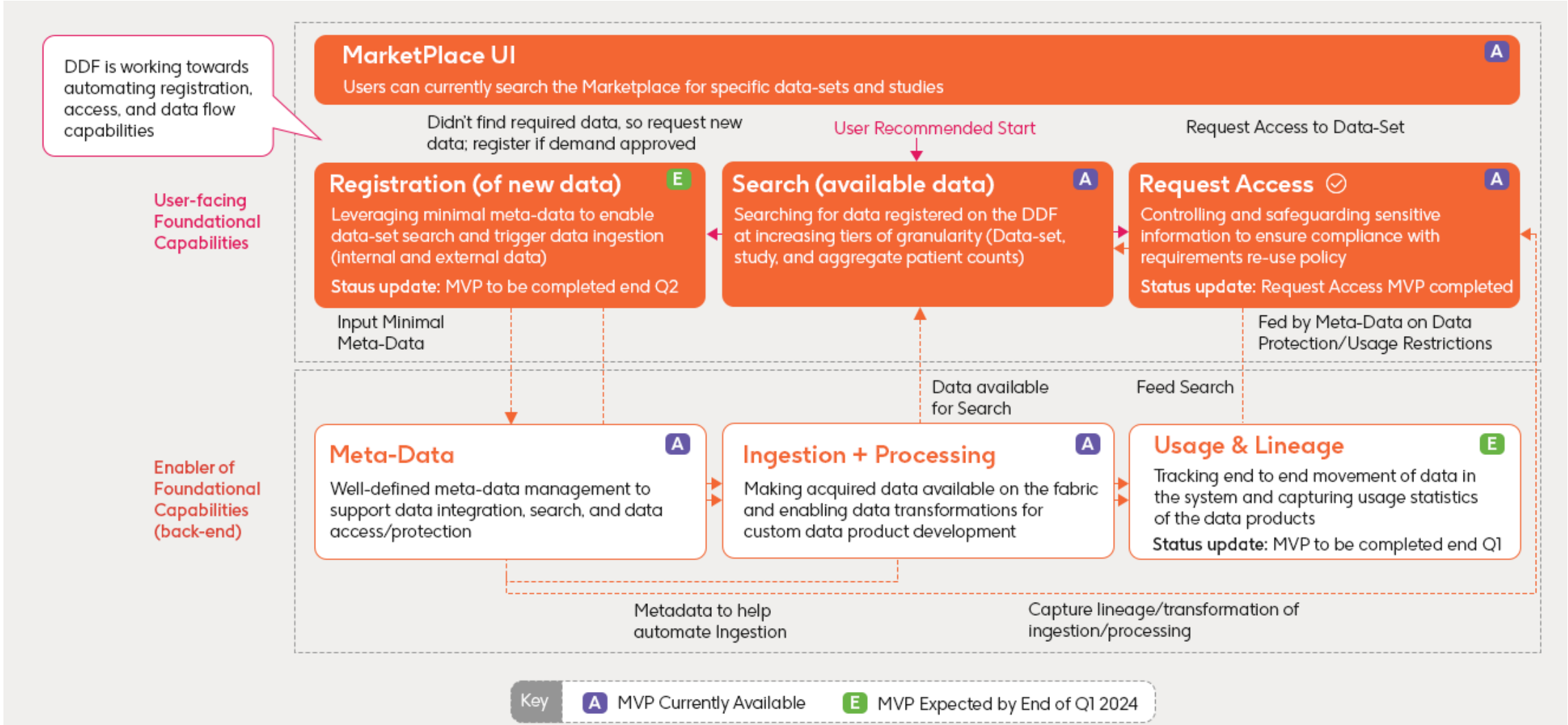
Solution


DDF is working towards automating registration, access, and data flow capabilities
MarketPlace UI
A
Users can currently search the Marketplace for specific data-sets and studies
Didn't find required data, so request new data; register if demand approved
User Recommended Start
Request Access to Data-Set
User-facing Foundational Capabilities
Registration (of new data)
E
Leveraging minimal meta-data to enable data-set search and trigger data ingestion (internal and external data)
Staus update: MVP to be completed end Q2
Search (available data)
A
Searching for data registered on the DDF at increasing tiers of granularity (Data-set, study, and aggregate patient counts)
Request Access
A
Controlling and safeguarding sensitive information to ensure compliance with requirements re-use policy
Status update: Request Access MVP completed
Input Minimal Meta-Data
Fed by Meta-Data on Data Protection/Usage Restrictions
Data available for Search
Feed Search
Enabler of Foundational Capabilities (back-end)
Meta-Data
A
Well-defined meta-data management to support data integration, search, and data access/protection
Ingestion + Processing
A
Making acquired data available on the fabric and enabling data transformations for custom data product development
Usage & Lineage
E
Tracking end to end movement of data in the system and capturing usage statistics of the data products
Status update: MVP to be completed end Q1
Metadata to help automate Ingestion
Capture lineage/transformation of ingestion/processing
Key
A MVP Currently Available
E MVP Expected by End of Q1 2024

Agile techniques

From presentations by Sheetal Patel & Manesh Patel

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Project Orbit

Better collaboration among pipeline teams

Better use of modern technology

Project Orbit will; transform the way we work in clinical study reporting, strengthen our ability to use new capabilities, and deliver results at a faster pace - with a highly engaged team

Ability to deliver key study results within hours of DBF

Greater job satisfaction for programmers providing leadership and technical career pathways

Always Improving Mindset	Collaborative Workflow & Tracking Tools	Better Workload Forecasting and Transparency	New Enhanced Roles

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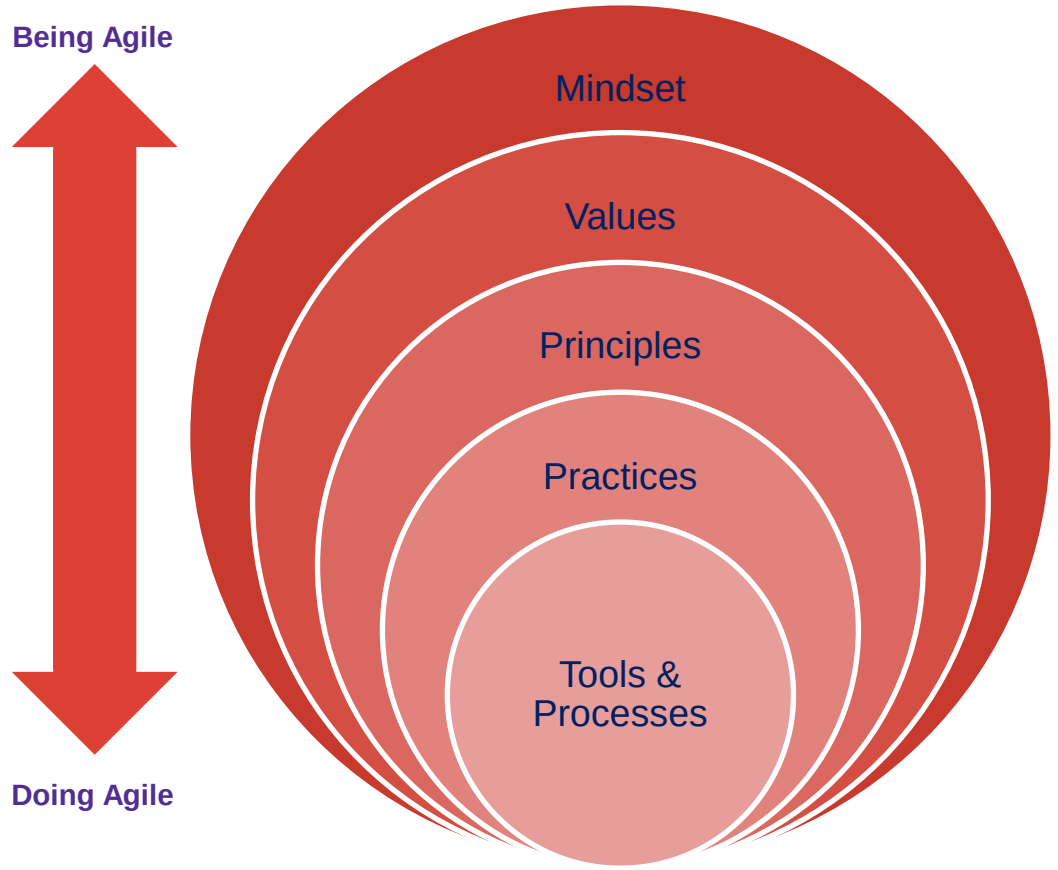
Being & Doing Agile can move us

Empowering us to flourish by developing leadership, culture and practices

The Agile Onion



Move towards a learning organization

Requires structure & cultural change

Can be adopted in a Command & control culture

- Growth Mindset
- Psychological Safety
- Servant Leadership
- Empowerment
- Transparency
- Iterative way of working
- Cross functional teams
- Continuous Improvement

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Implementing Agile in Your Organization

Agile mindset principles

- Start small and recognize success
- Celebrate any failures as opportunities to learn
- Be vulnerable
- Feedback

Create your North Star

Define outcomes

Rretrospectives for continuous improvement

Make it your **priority**

- Reinforce when this works

Don’t be afraid

..and iterations across technology, data and people/process

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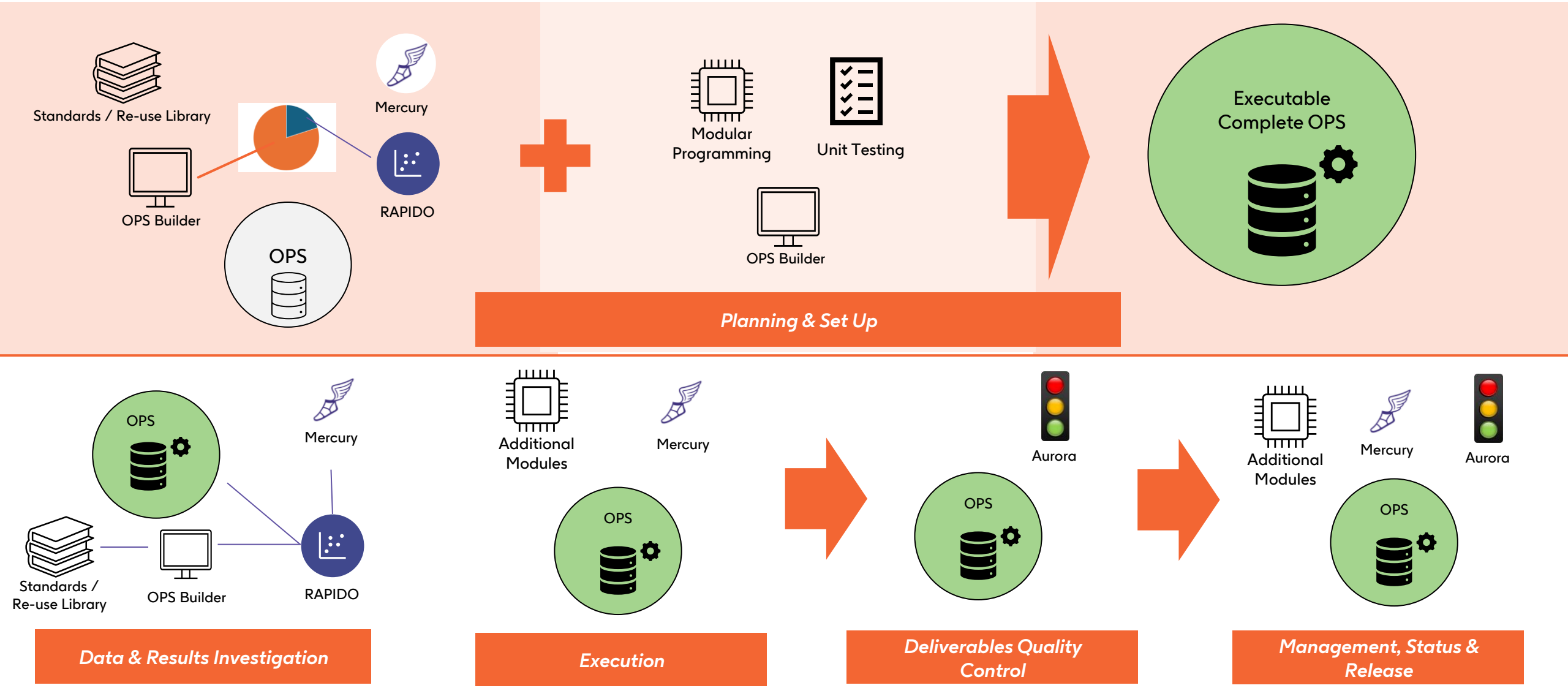
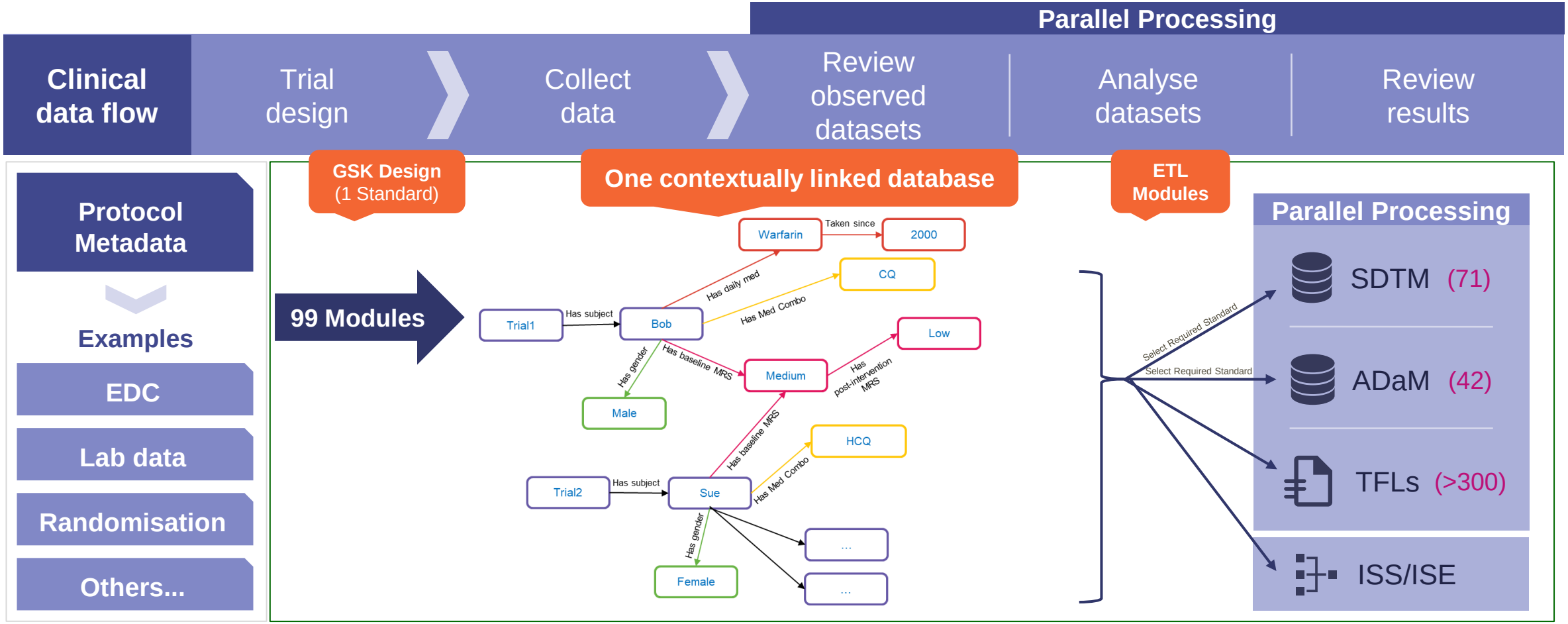
Future User Journey for a Clinical Programmer

Technology progress



Clinical Linked Data (CLD)



MAIN DIFFERENCES FROM WHAT WE DO TODAY

- Output & ADaM specs, CDISC Data Standards, Reporting tools, Patient Level Data, Results Data, etc. **stored within the same contextually linked database**
- **Modular concept-based orchestration** (Biomedical & Analysis Concepts, contextual linked data standards, reporting tools, etc.) of our data pipelines
- **Automated ETL data pipelines to render contextually linked knowledge** for study reporting and regulatory artefacts

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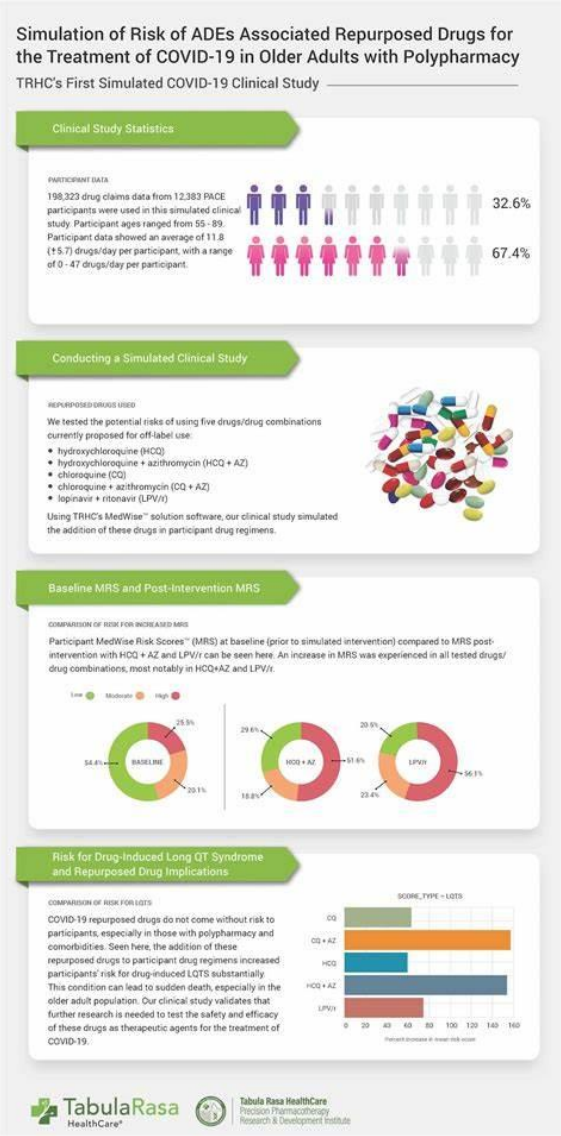
Automating data linkage to generate results

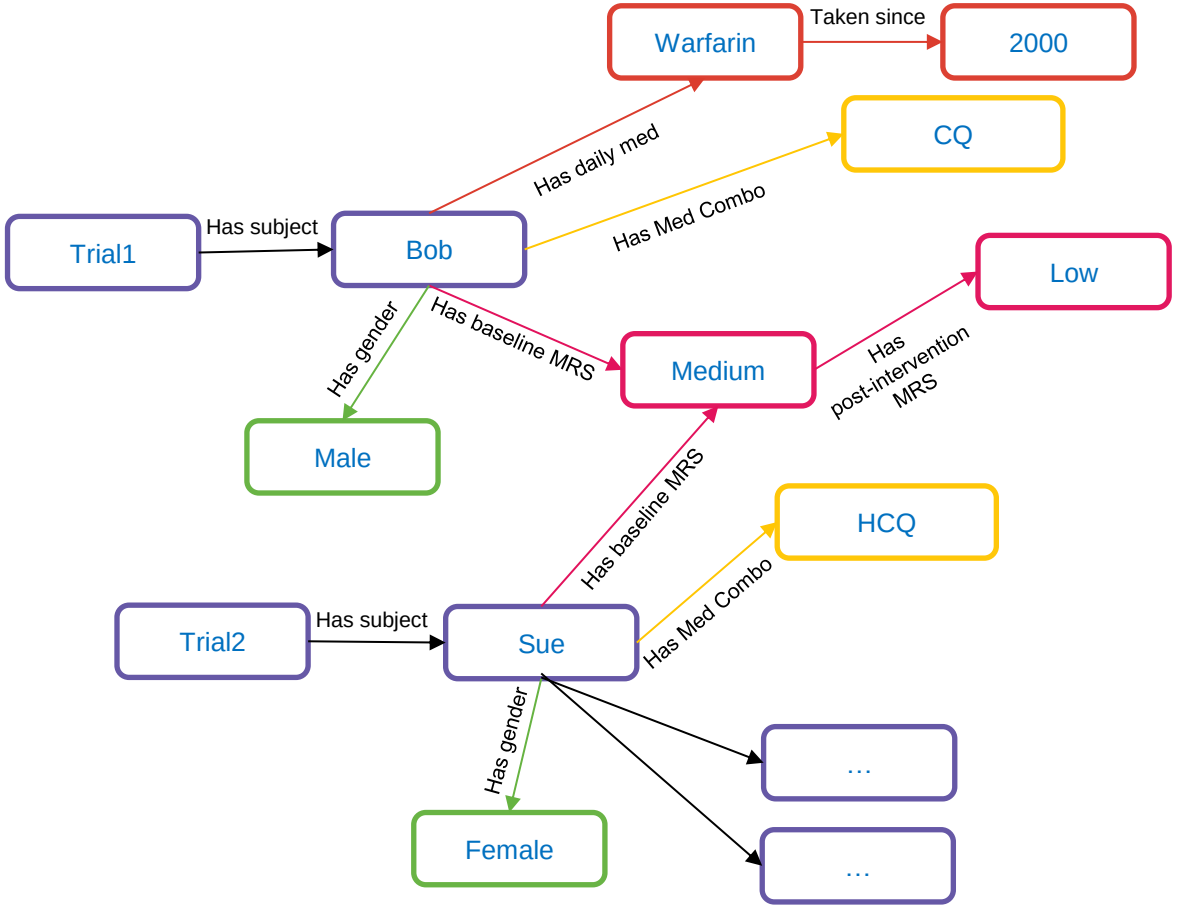


- Gender
- Age
- Medications taken daily

- Calculate patients on specific Medication Combinations

- Baseline Medwise Risk Score (MRS)
- Post-intervention MRS

- Long QT Syndrome



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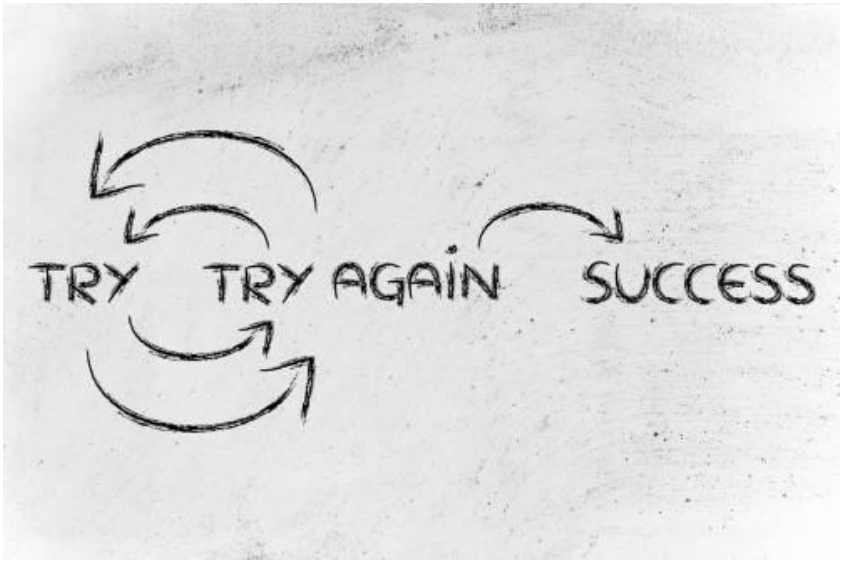
…and we will carry on with process enhancements

Energized global teams which leverage their strengths

- More engaged at work
- More productive in their roles
- Happier and healthier



Cliftonstrengths

Thank you

Any questions?