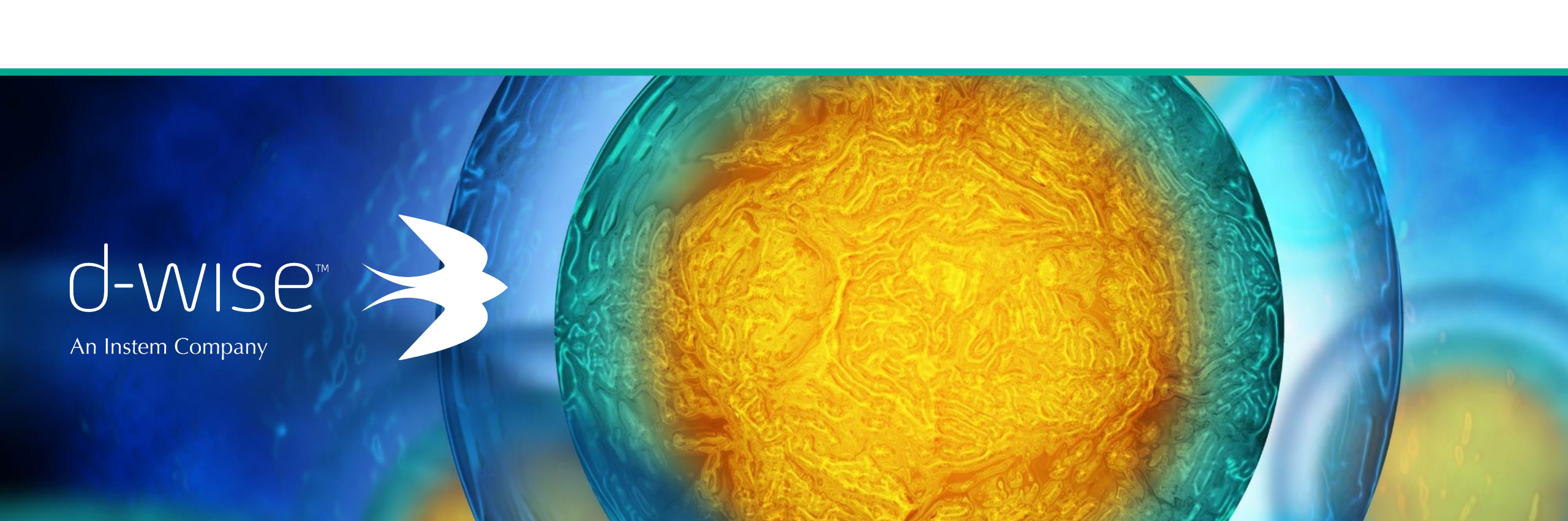




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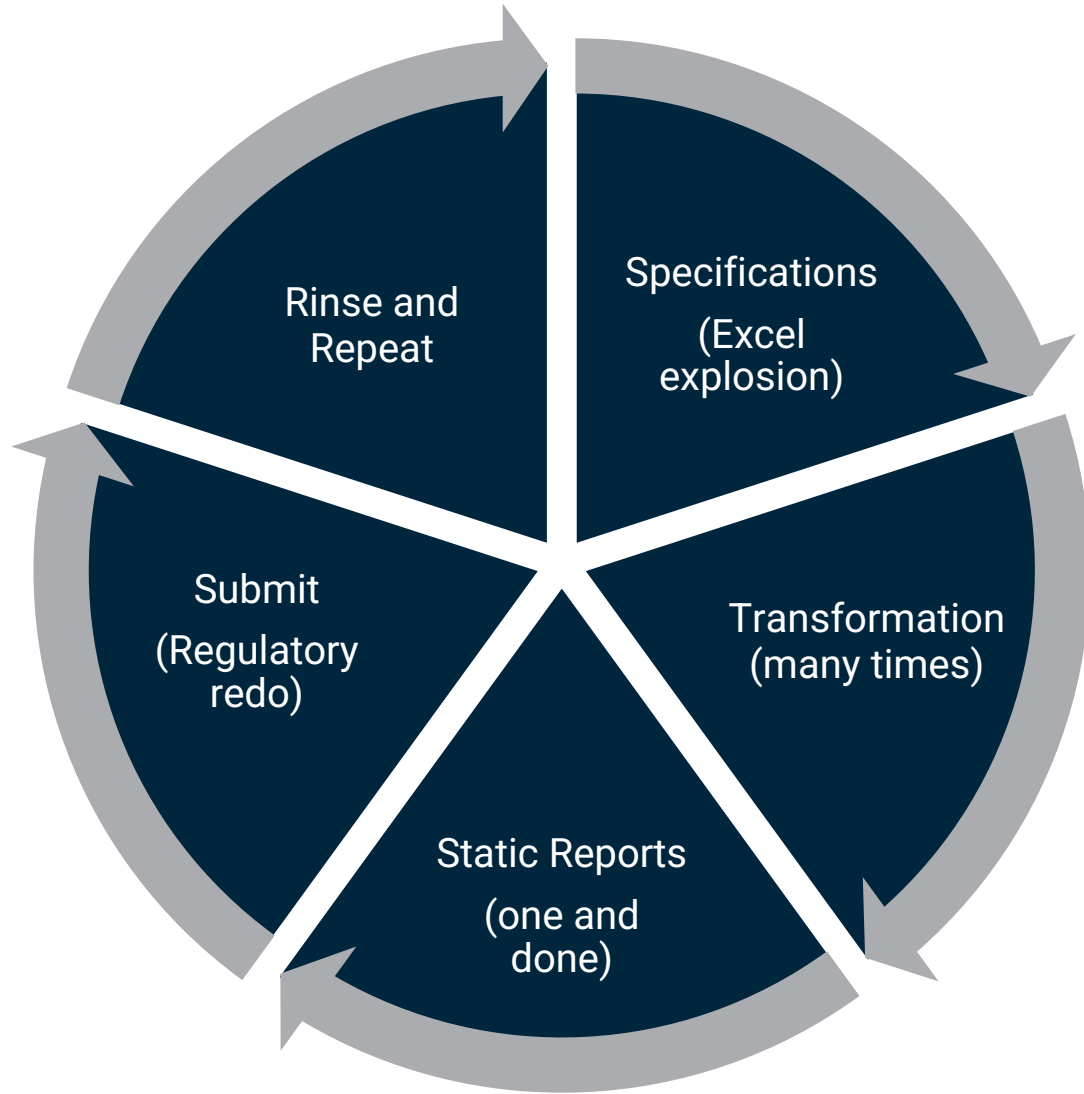
Transformation from Reactive and Prescriptive Clinical Trial Results to Dynamic Data Science Analytics

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Agenda

- Today's Mindset and Challenges
- Today's Architecture and Limitations
- What is a Data Science Platform?
- Merging Data Science with Today's Needs
- Case Studies
- How do we move forward?

What do we do today?



Stuck in a Rut

Why do we produce copies and copies of data?

Why do we write specifications to predefine our data that have no connection to our data?

Why do we capture 2-dimensional data and when real life is multi dimensional?

Why do we check boxes, double program, and validate our validation?



Today's Challenges

- Unintuitive
- Steep learning curve
- Siloed functions

Usability



- Performance
- Validation
- Lack of on demand compute

Scalability



- Rigid process
- Limited access to analytical tools
- Nuanced business needs

Flexibility



- Gaps in access and controls
- Manual and error prone compliance
- Data integrity risks

Compliability



- Lack of robust end to end lineage
- Challenges reproducing results

Traceability



Trends Triggering Transformation

Industry and regulatory trends continue to push pharma towards an innovative, agile, and scalable platforms

Privacy and Security

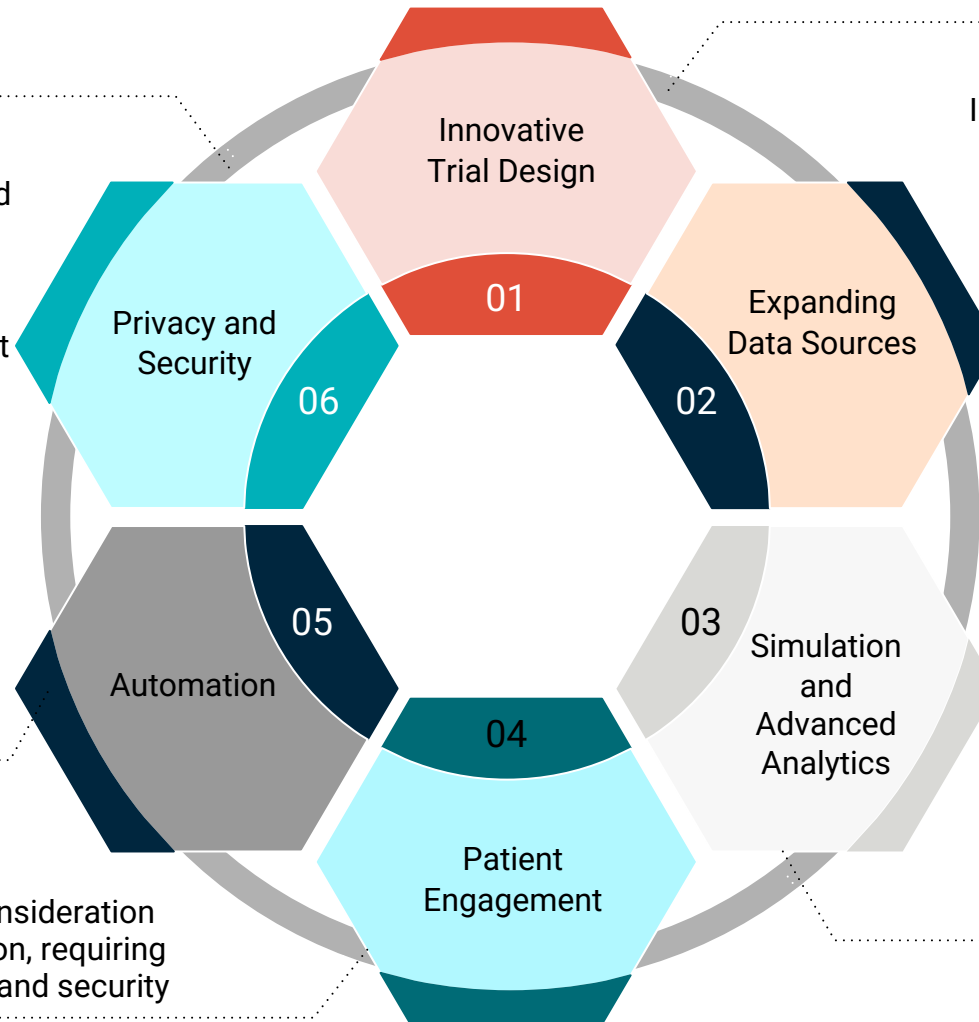
Regulators globally are empowering patients and consumers to better manage the information companies collect on them and how that information is used while also raising the bar on security. Additional consumer data-management activities need be considered in the design of a scalable, secure platform

Automation

Automation technology from RPA to ML/AI is being adopted to reduce manual effort to clean, secure, analyze, and manage data, allowing key personnel to focus on higher-value added and specialized activities

Patient Engagement

Regulators (FDA) are pushing toward greater consideration of patient needs in both trial design and execution, requiring new approaches to patient data usage, sharing, and security



Innovative Trial Design

Increasing usage of adaptive trial design, synthetic control arms, and virtual/remote trials is accelerating the need to gather, ingest, use, and share data in new ways with increased flexibility

Expanding Data Sources

Rapidly expanding sources of trial results data from mobile apps, devices, IoT, integration with healthcare providers, etc. require new and robust ways to collect, integrate, and enrich, data

Simulation and Advanced Analytics

trial design, data sources, and data types require new analytics capabilities to identify and produce insights produced in a scalable manner

Transformation Targets

Consolidation and Flexibility

- Consolidate technology within cloud-based infrastructure reducing validation and optimizing support
- Easier enablement of new or updated tools and programming languages

Leveraging Emerging Technology

- Transition storage of data into a contextual and linked model to realize it's value
- Enable and REALLY use AI/ML to learn and automate mundane and manual activities

Changing Regulatory Mindset

- Eliminate paper (#killListings) and enable real time analytics
- Facilitate real collaboration between regulatory agencies and sponsors (Accumulus)

Exponential Growth in data volume/sources

- Mainstreaming integration of RWD with clinical trial data to make better decisions
- Increase of different devices for collecting patient information

CURRENT PARADIGM: BUY vs BUILD

Produce Statistical Analyses
with control & efficiency

1 COTS



Assumed
quick build



Limited
configuration



Shared cost



Limited control
of roadmap

2 Custom build



Unlimited
customization



Slow build



Control of
roadmap



Expensive costs:
build/own

THERE IS ANOTHER OPTION

After decades of helping clients design, build, and implement clinical computing solutions, we believe today's technology capabilities provide an alternative between COTS offerings and custom solutions

Produce Statistical Analyses
with control & efficiency

1

COTS



Assumed
Quick build



Limited
configuration



Shared cost



Limited control
of roadmap

3

"Third Way"



Pre-built core
components



Quick build



Efficient &
economic



Fit-for-purpose &
adoptable

2

Custom build



Unlimited
customization



Slow build



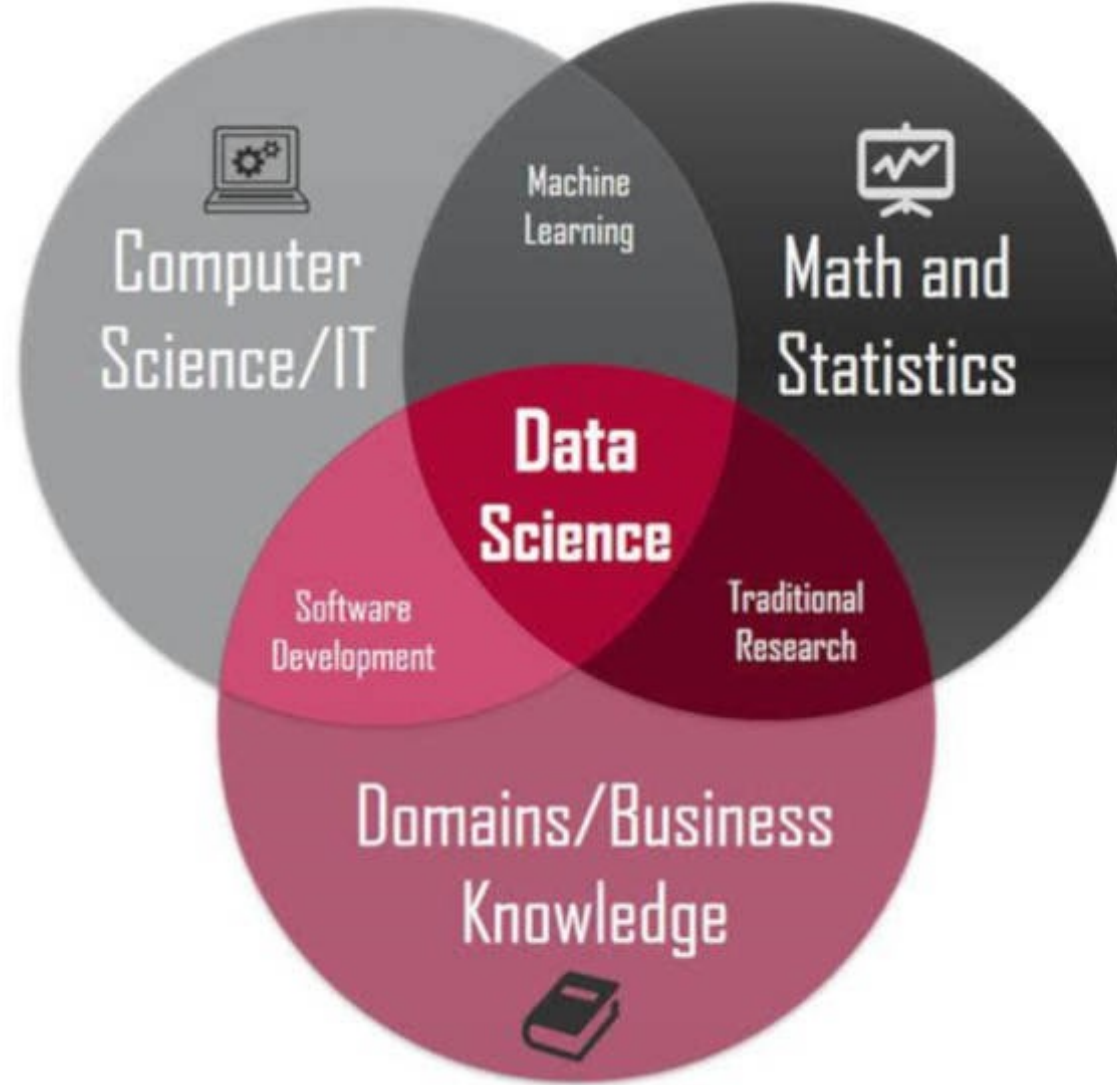
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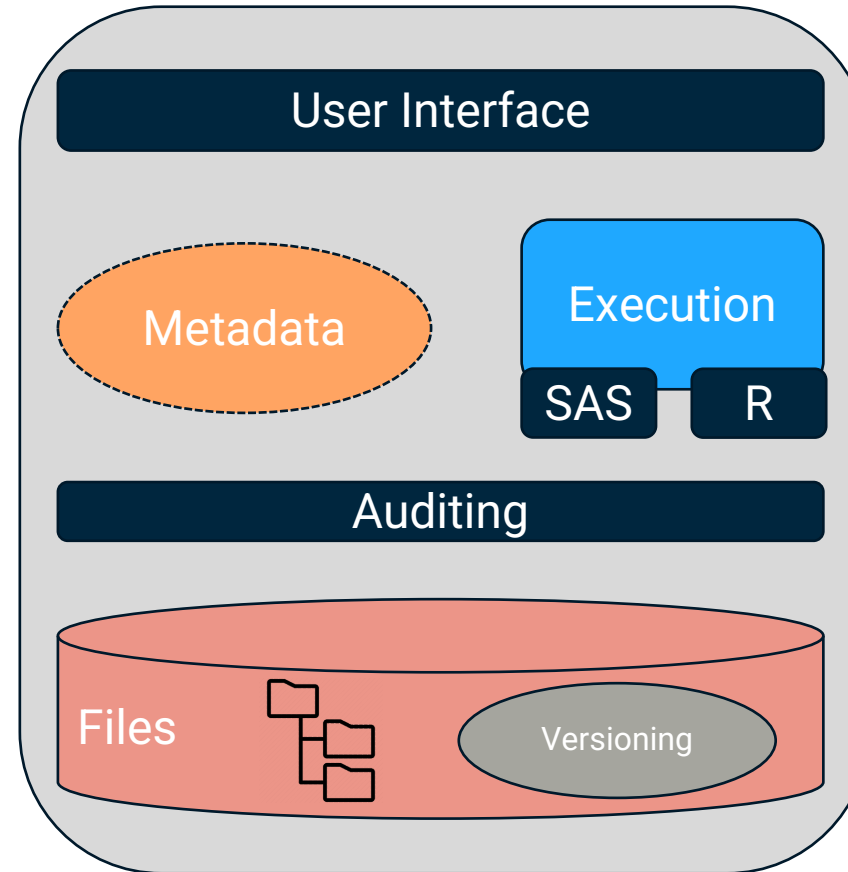
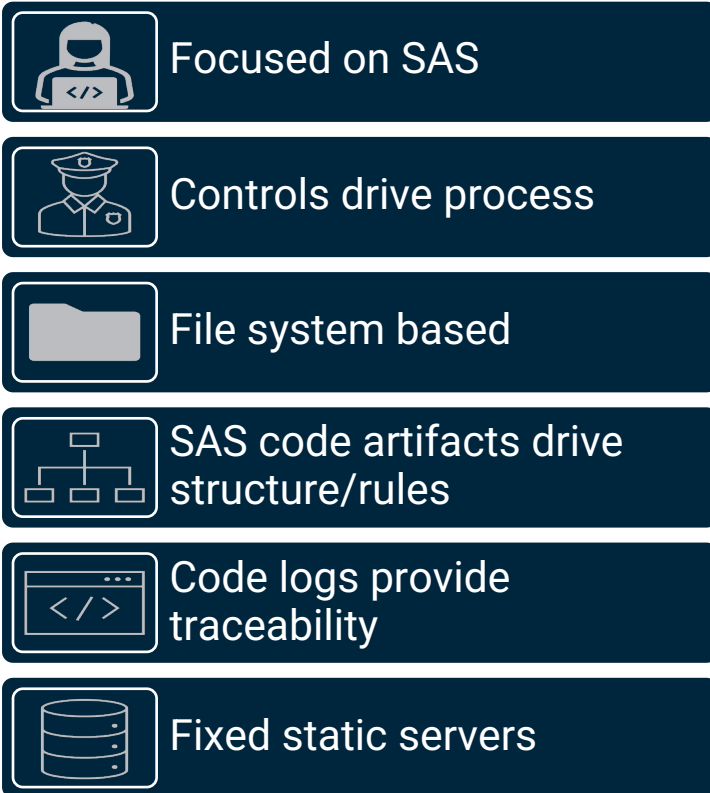
What is a Data Science Platform?

What is a Data Science Platform?



Current State Architecture

Paradigm



Challenges

- Unable to leverage next generation skillsets
- Controls trump user experience
- 1990's file system handcuffs innovation
- Limited code and data structures impedes traceability
- Static server requirements limits scalability and flexibility

Data Science Platforms

Capabilities

- Large data stored in non-traditional data 'lakes' and alternate structures like Linked Graph
- Ingestion of wide range of input data sources/types (Avro, Parquet, CSV, Unstructured)
- Leverage many tools or languages (e.g. Python, R, Julia...)
- Controls less important than access to analytics
- Utilize large data sources for AI/ML training



Amazon SageMaker



Azure Machine Learning

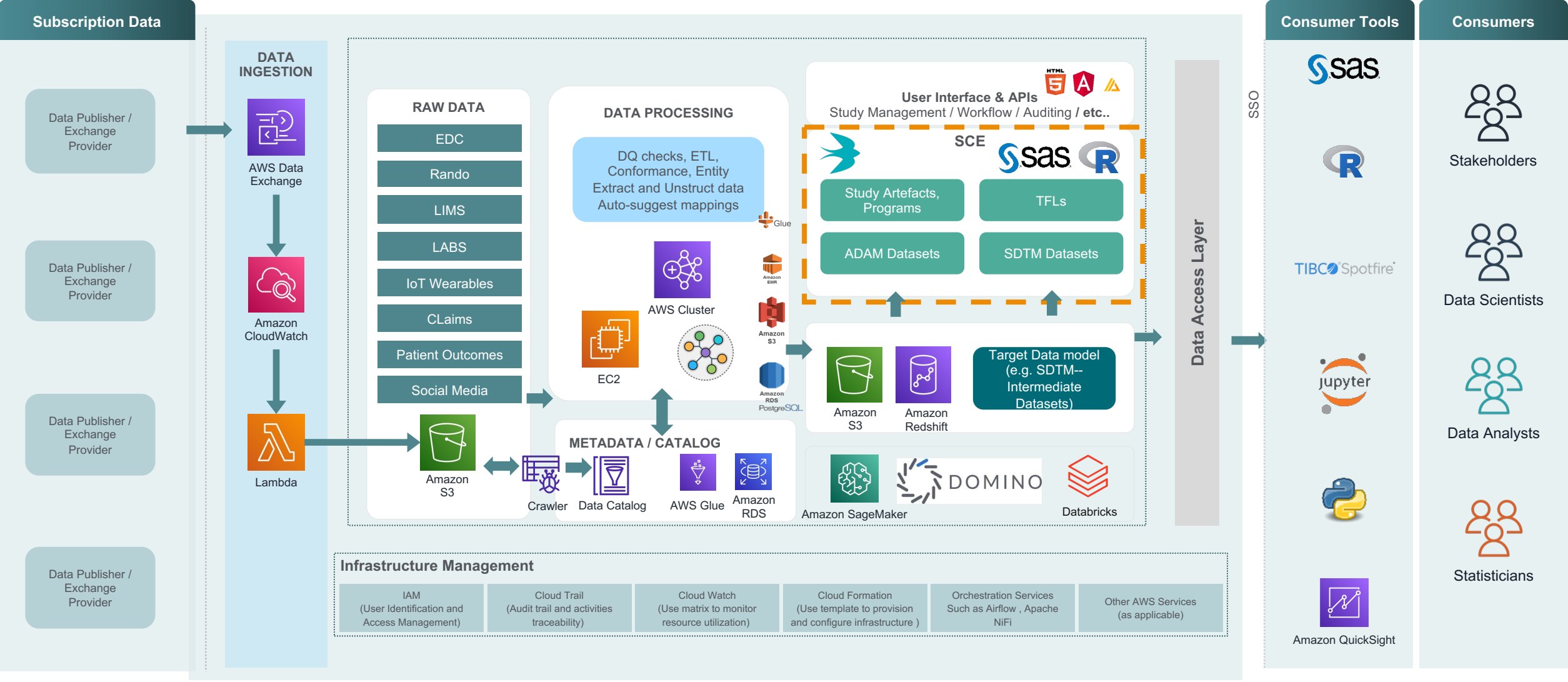


databricks

Enablement

- ✓ Flexible access to wide range of data
- ✓ Dynamic and scalable analyses
- ✓ Use tool or language of choice
- ✓ Burstable scalability
- ✓ AI and ML tools integrated into the process

Merging Data Science Platform with Today's Process



Data Science Merged with SCE Required Controls Provide...



Access to latest ML and AI Technology



Scalable Cloud Enabled Capabilities



Single View of Data Across Organization



Controls Balanced with Flexibility



Query and Investigate Across Data



Case Studies & How We Move Forward

Case Studies: Sponsors are Dabbling

Enabling R Development Pipeline

Business Need:

- Flexible environment focused on collaboration
- Fast, scalable deployment with reproducibility over time

Solution:

- ✓ Containerized R with packages needed for your work
- ✓ CI/CD process to enable development & support workflow

Value:

- Plug-n-Play tools/languages of choice
- Robust and rapid deployment of new capabilities enabling quicker decision making

SCE to the “Cloud”

Business Need:

- Homegrown and legacy tech increasing risk to portfolio
- Push to consolidate on a scalable cloud infrastructure

Solution:

- ✓ Containerized and integrated programming languages
- ✓ UX designed and business rule driven dev → prod workflow

Value:

- Cloud enabled capabilities balanced with get the work done
- Intuitive SCE capabilities users enjoyed working with

Building an Endpoint Library

Business Need:

- Decades of study information buried in documents
- Extracting and populating a library of previous endpoints to inform future design

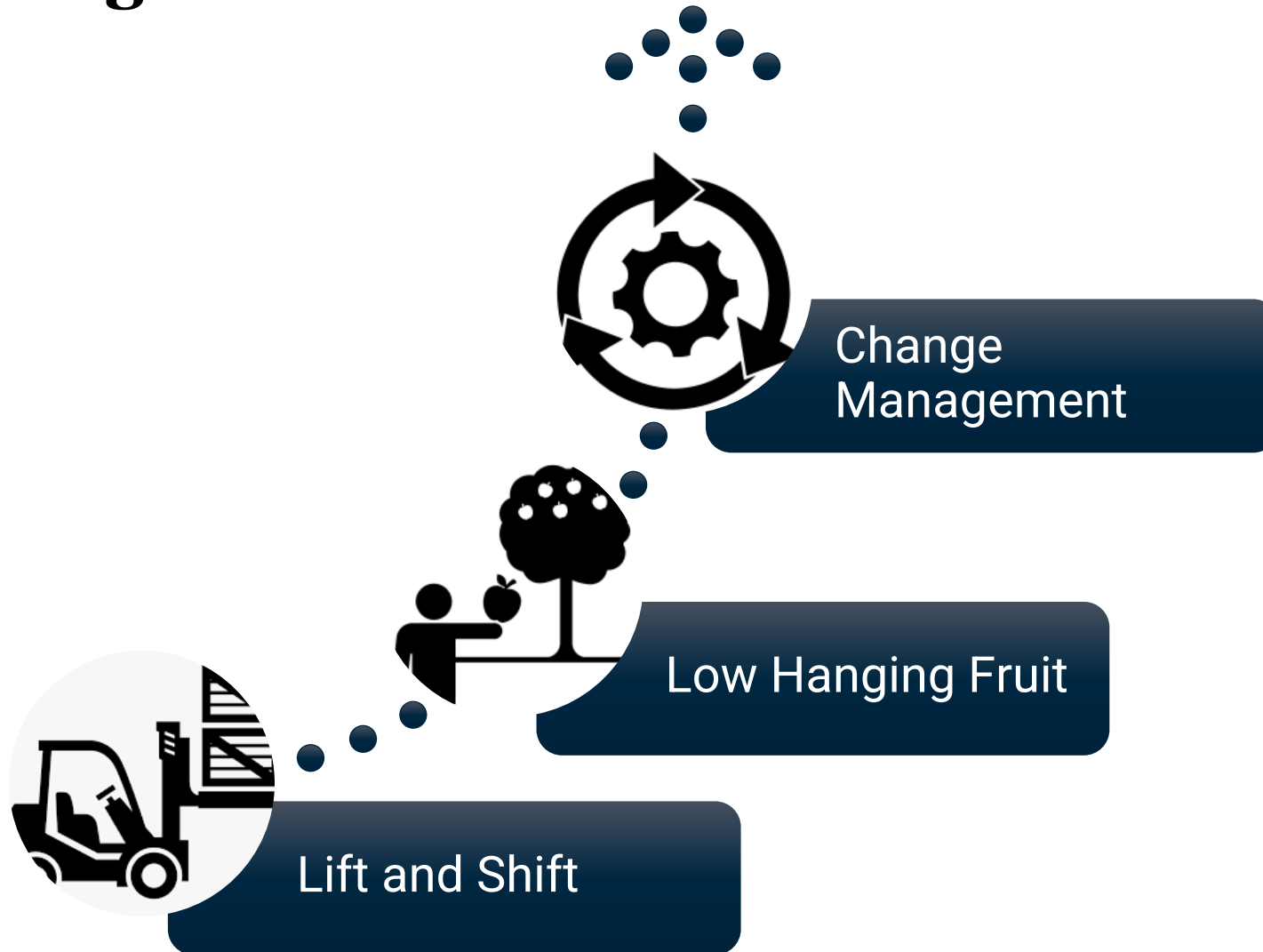
Solution:

- ✓ NLP combined with ML to identify and catalog endpoints
- ✓ Elastic search to find past studies and leverage for new study design

Value:

- Significantly reduce ‘reinventing the wheel’
- Find past analyses to rapidly enable cross study analytics

How do we get there?



Q&A

How is your company moving forward?

