SCE Market Pulse 2019

Ali Dootson

October 25, 2019

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Accelerate to the Speed of Life

Agenda


Understand the past
to shape the future
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Accelerate to the Speed of Life

Agricultural Age

0 – 1750

LAND=WEALTH

Industrial Age

1750 – 1950s

MACHINES=WEALTH


Distribution Age
1950s – 1978
OUTLETS=WEALTH

Technology Age

1978 – 1994

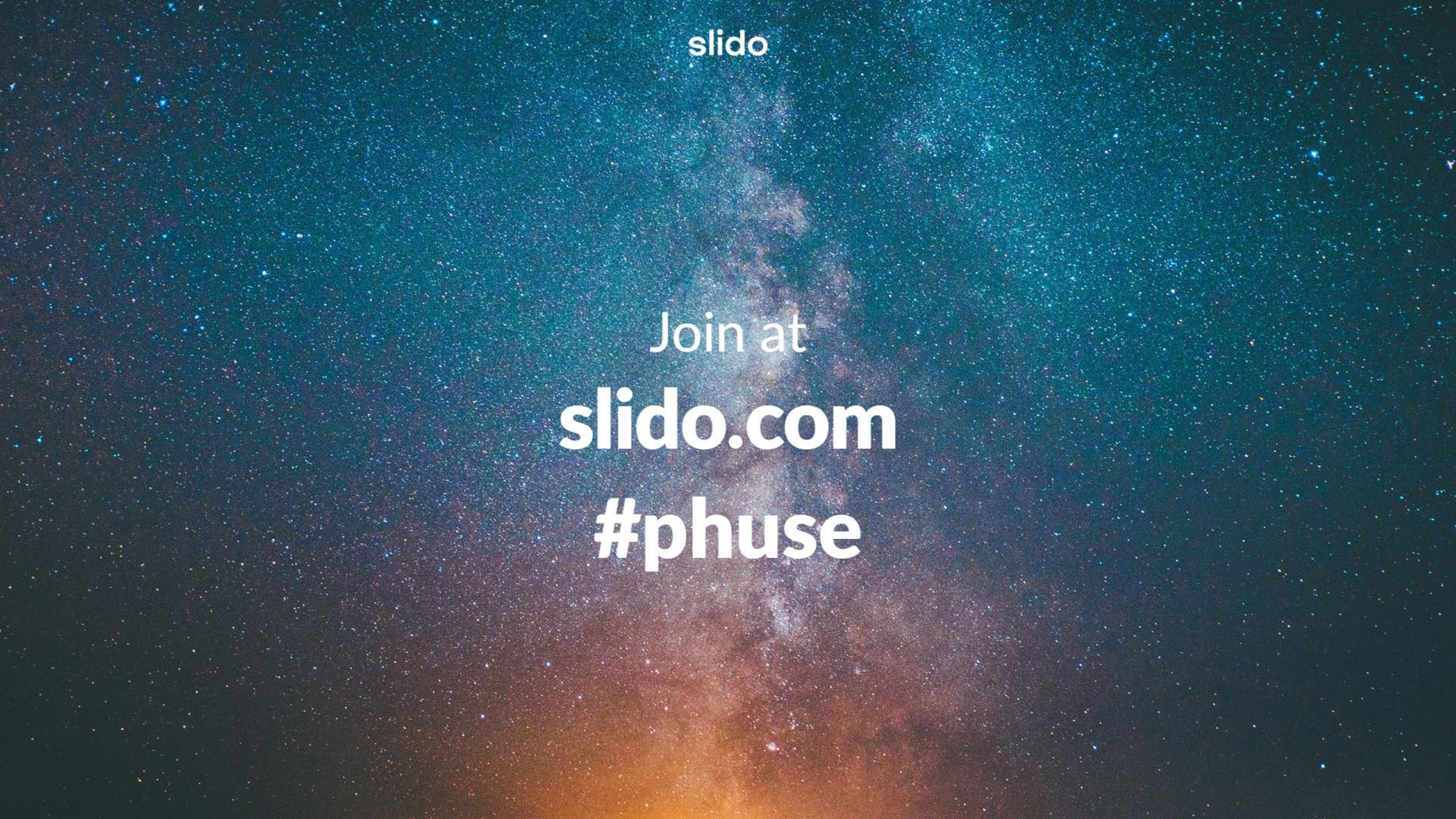
TECH KNOW-HOW=WEALTH


Information Age
1994 – 2003
INFORMATION=WEALTH


Infotainment Age
2003 – 2008
FM 3
Wednesday
23 January 2019
Studio
Phone
Media

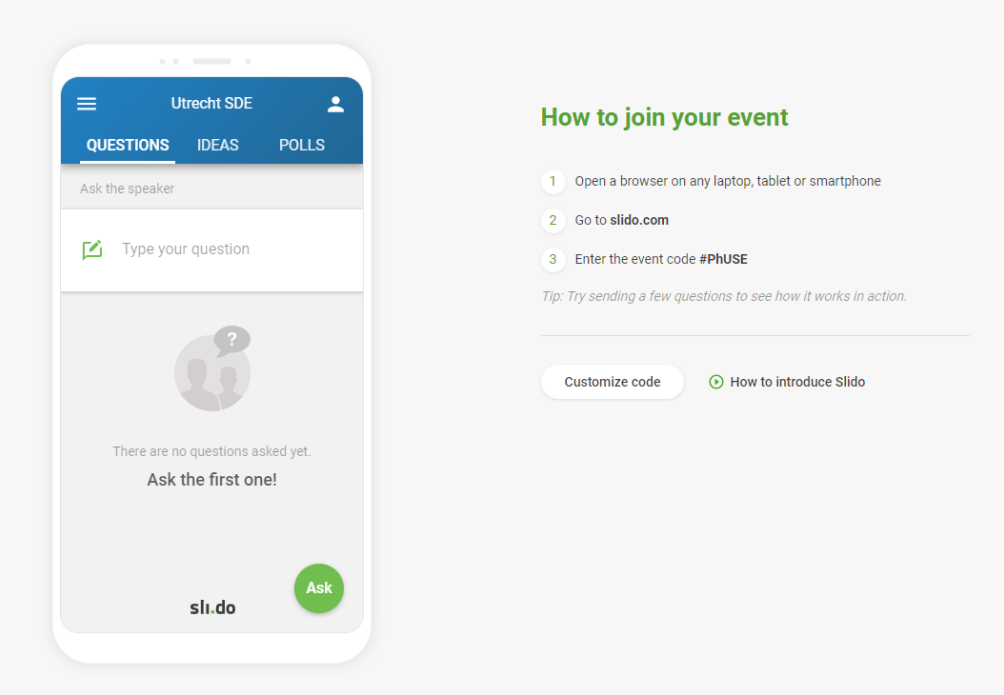

Partnerships Age
2008 – Present
PARTNERSHIPS=WEALTH

Participate


slido
Join at
slido.com
#phuse

Participation

- We will be using **Slido** in this presentation
- Get out your phones or tablets and open up slido.com
- Enter the code **# phuse**
- Participate in the polls and ask questions!



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Worldwide Offices & Life Science Leaders

CLINICAL TRIAL INNOVATORS

Clinical Trial Acceleration

- 16+ years heritage
- 78 life science clients
- Vendor independent
- +90% of top 20 modernizations
- Fully managed cloud/hosting services
  +5000 managed users
- 20 fully managed private cloud clients

Clinical Trial Transparency

- 5 years
- 11 life science clients
- Blur: leading tool in quantifiable risk & anonymization
- +30 policy 0070 submissions
- +5500 redacted documents

Statistical Computing Environments

What is an SCE?

- Take 2 minutes and discuss
  "what is an SCE?"
- Add ideas in Slido…
- What did you find out?
- **S**tarfleet **C**orps of **E**ngineers *(Star Trek)*

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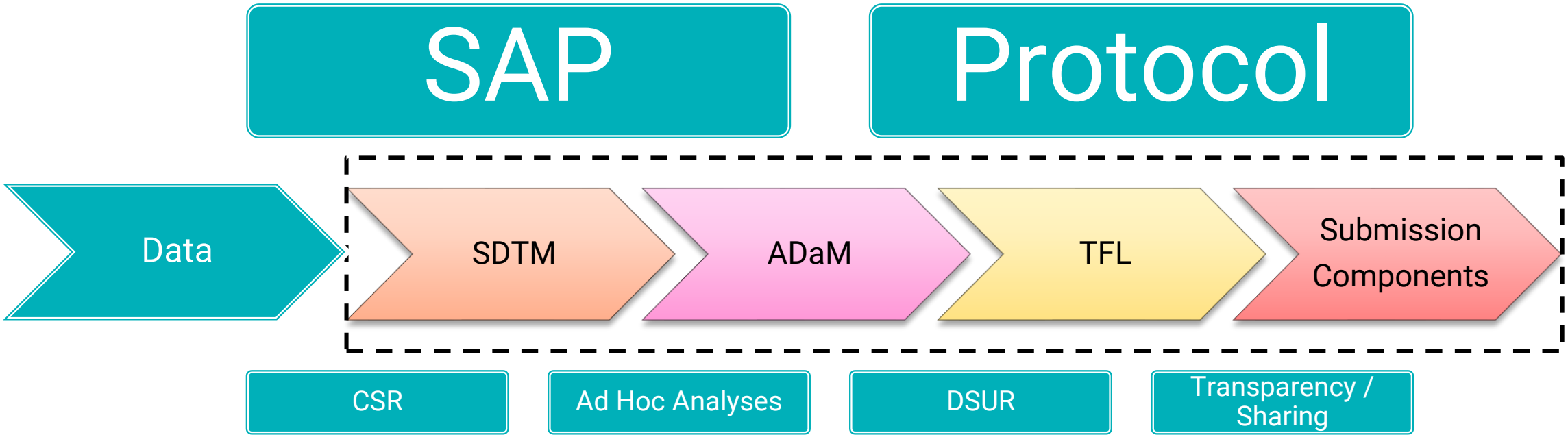
Definition of SCE



- https://www.phusewiki.org/docs/Deliverables/state-of-the-sce-white-paper-2016-11886.pdf

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Components

- Add the components you think make up part of an SCE into the ideas section of Slido…

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SCE Components

Components

- Computing platform
- Code editor (SAS, R, Ultraedit …)
- Security Model
- Folder Structure
- Specifications
- Program Standards (SDTM, ADaM, TFL)

- File Movement
- Metrics & Reporting
- Workflow
- Version Control
- Audit Trail
- Traceability
- Programme planning
- Job Execution & Monitor
- eSignatures
- Archive
- Diff tool
- Communication tool (Notifier)
- Compliance tool

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Statistical Computing Environments and the Practice of Statistics in the Biopharmaceutical Industry

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Key Words
Good statistical practice; Statistical operations; Data standards; Metadata; IT architecture; Statistical programming

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A structured statistical computing environment (SCE) enhances rigor in operational implementation of statistical analyses of clinical studies through process transparency, allowing reproducibility of results by independent reviewers. Desirable features and associated benefits of an SCE system are described. Minimum SCE requirements discussed in detail consist of a structured programming environment, an operational analysis data repository, and a metadata-driven architecture containing information about data and status of various processes. The metadata provide a foundation for connecting multiple processes and systems, thereby allowing the creation of tools that largely automate the analysis process. Standards drive productivity enhancement for creating statistical deliverables based on metadata obtained from the development plan, protocols, and analysis plans.

Not all the features discussed are available today in commercial systems. In the future, nearly all information about clinical trial analytics can be driven by a standards-based, metadata-driven architecture. To accomplish this goal, metadata need to be available about all the processes used to collect, transform, and analyze the patient data. Further standards development will be necessary to fully describe the entire statistical analysis process.

Our vision

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Current State

Active poll

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Does your company at have a cloud initiative for your SCE (AWS/Azure)? 0 0 0

Yes - in process

0%

Yes - Not started

0%

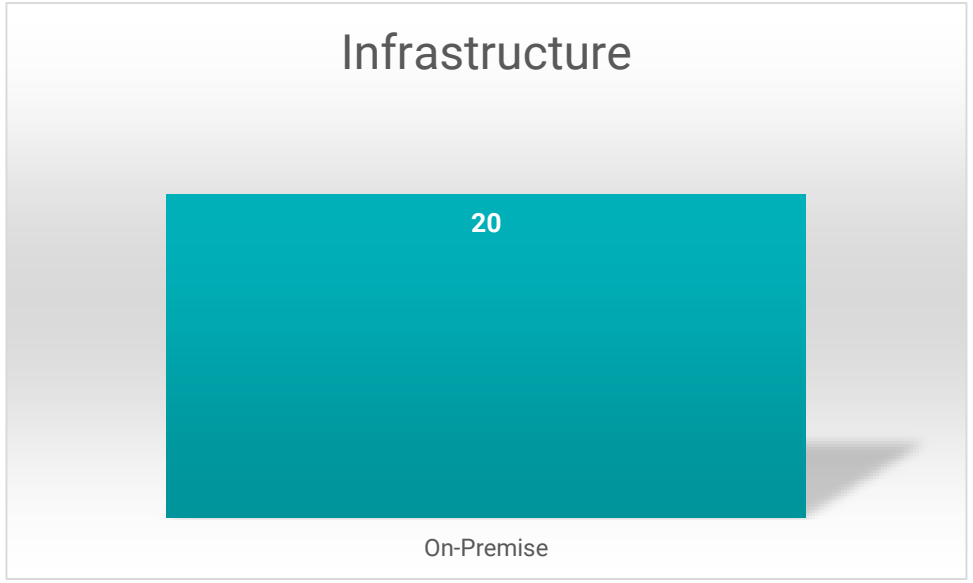
No - but thinking about it

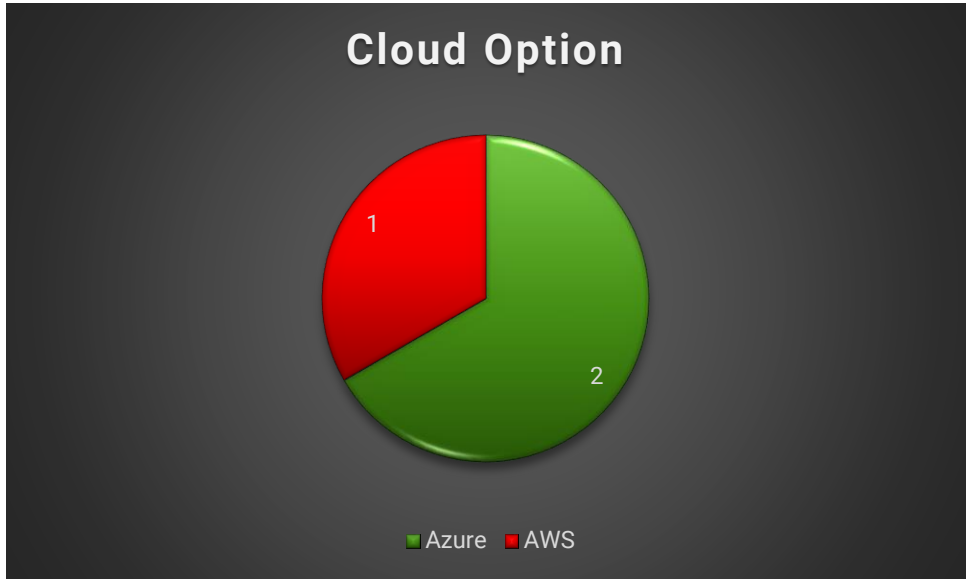
0%

No - not thinking about it

0%

Top 20 Pharma SCE Current State – Infrastructure





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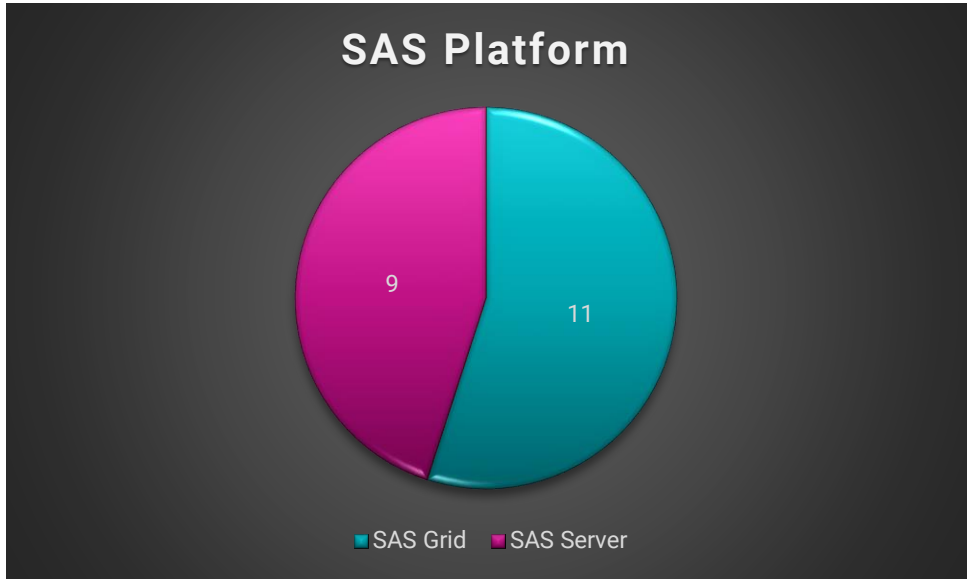
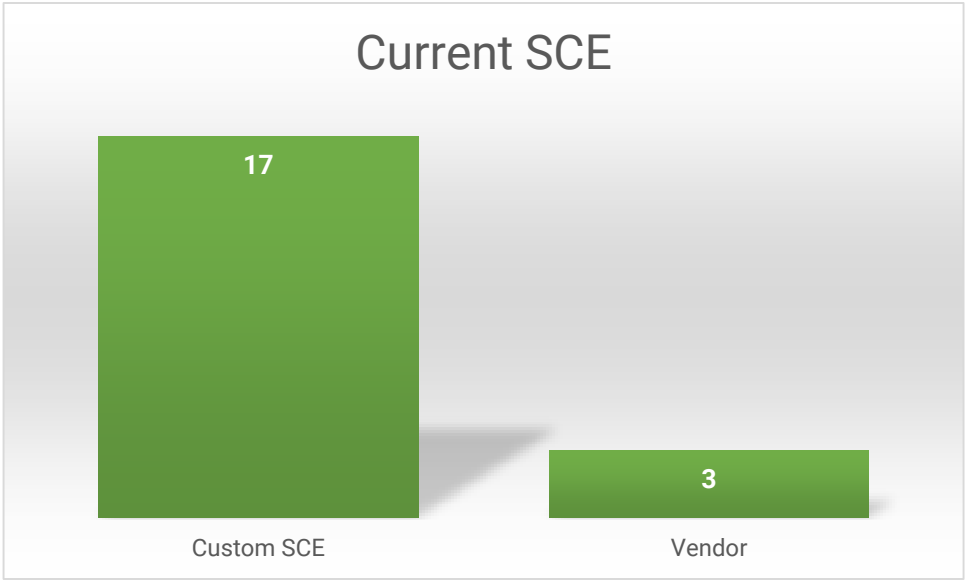
Top 20 Pharma SCE Current State





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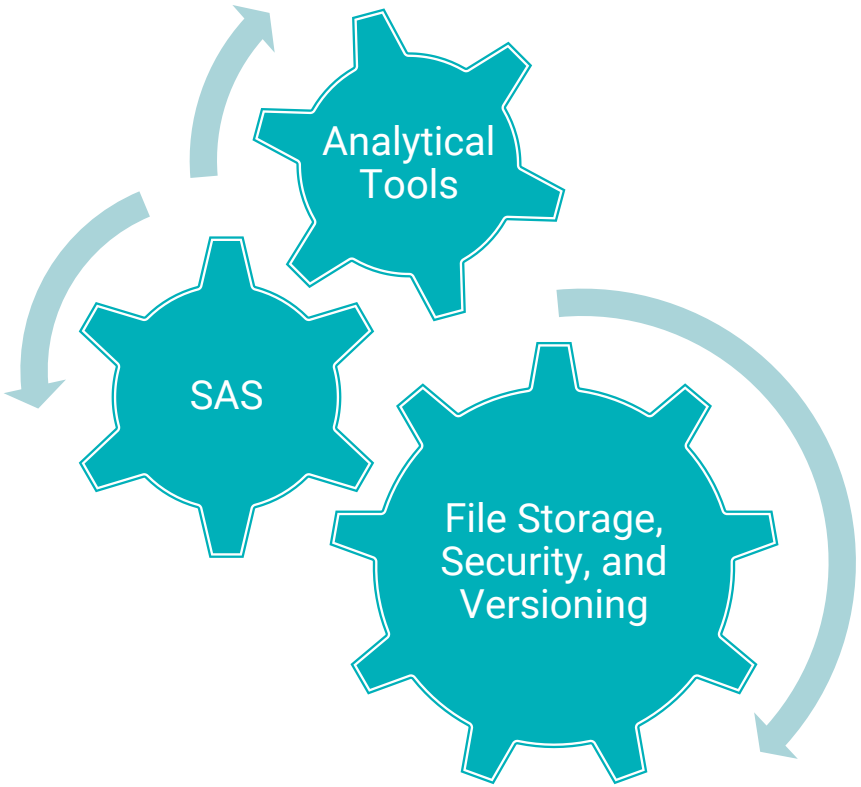
Hybrid Solutions (review of Top 20 Pharma)

Current State SCE Components



The hybrid model can be viewed as a simple, practical, flexible option…..but usually bound with manual process and in-house developed tools

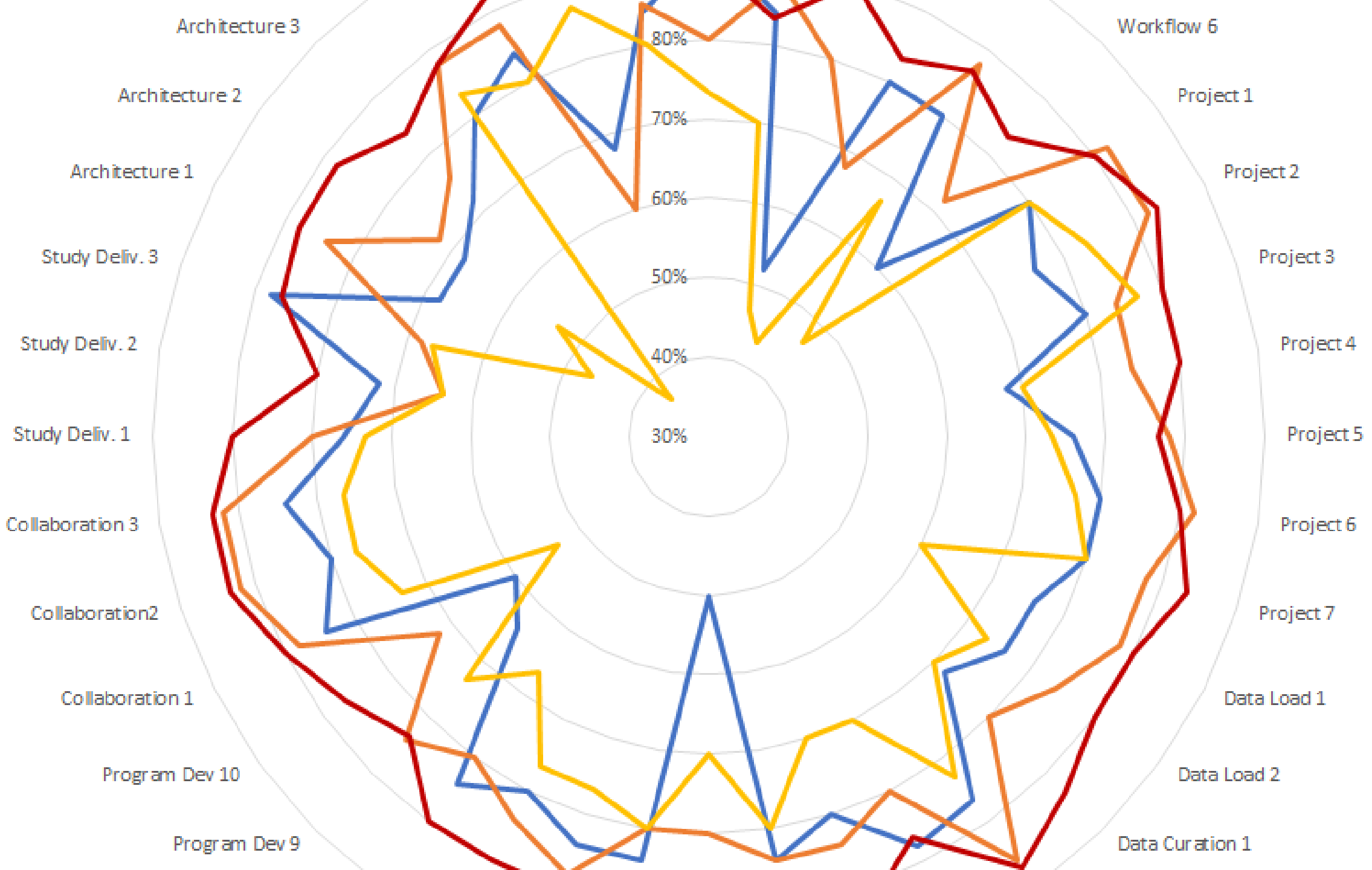
- **17** with custom-built or hybrid solutions based on SAS server/GRID
- **6** actively engaged in modernizing or rebuilding their SCE
- **2** actively engaged in buying a new COTS solution
- **9** have implemented SAS GRID for production reporting
- **2** in PoC or investigation stage for SAS GRID
- **Multiple** assessing and implementing cloud based (AWS)/Azure solutions
- **Many** initiate projects to prove concept and extend use of R & other open source solutions for regulated analytics


Choices!

Example market summary

- Is functional / robust
- Not out of the box / needs work / partial functionality
- Not there

	Access Management	Traceability	Workflow enabled	Dashboards	Flexible High Performance Analytics	Plug-in Analytics	Vendor Maturity	Solution Maturity
Vendor 1	●	●	●	●	●	●	●	●
Vendor 2	●	●	●	●	●	●	●	●
Vendor 3	●	●	●	●	●	●	●	● → ●
Vendor 4	●	●	●	●	●	●	●	●
Vendor 5	?	?	?	?	?	?	●	●
Vendor 6	?	?	?	?	?	?	●	●
	Compliance Tools		**Workflow Management**		**Flexible & Performant Analytics**			


Architecture 3
Architecture 2
Architecture 1
Study Deliv. 3
Study Deliv. 2
Study Deliv. 1
Collaboration 3
Collaboration2
Collaboration 1
Program Dev 10
Program Dev 9
80%
70%
60%
50%
40%
30%
Workflow 6
Project 1
Project 2
Project 3
Project 4
Project 5
Project 6
Project 7
Data Load 1
Data Load 2
Data Curation 1

Issues

- Vendors trying to change the people rather than fitting around the people
- Established programmers and ways of working
- Systems not making things easier
- Where's the added value?
  - How do you define value in your organisation?
- Servers nearing end of life
- License discussions
- "Compliance"
- Future-proofing
- Existing tools not satisfying needs

What are the trends we see?

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Trends

Trends

- SAS Modernization
- Reducing PC SAS (clinical data on laptops)
- Tools
  - Version Control
  - Audit Trail
  - Traceability
  - Managing Workflow (across different companies)
- Analytics (SAS → R / Python)
- Architecture (M&S, RWE, Clinical programming separate?)
  - On-premise vs Cloud
  - Licensing
  - Containerisation

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Automated
Non-Clinical
Renewed
exploratory
desire
Focus
Potentially
in-house
promotion
Traceability
out-sourced
labelling
Software
partners
delivery
SDLC
Python
open
Enhanced
Continuous
Re-focus
Study
applications
tagging
clinical
reduced
approach
virtualisation
CDR
Plan
code
Data
products
metadata
updated
reduce
Increasing
custom
reproducibility
Cloud
DevOps
Security
static
capture
Reproducibility
SCE
needs
control
Elasticity
Application
Shiny
human
e.g
LSAF
statistical
Continued
use
Agility
Platform
TLFs
SAS
scientists
Re-balancing
COTS
tools
new
CSR
interest
Built
Workflow
cost
sharing
quality
Groups
increase
happened
data
effort
Auditability
investment
Flat
security
lifecycle
Sycamore
development
testing
Recognition
regulatory
consistency
super-set
structure
automate
Sub-set
languages
programmers
source
improved
requirements
could/might
Demonstrably
Findability
Non-unary
versions
Searchability
improvement

Direction of travel

- Digital Data Flow (Transcelerate)
  - Automate beyond the protocol
  - Definition from protocol
- Trends
  - Lightweight Clinical Trial Platform – implemented in ~ 6 months
  - Enterprise Clinical Trial Platform – developed with microservices, AWS, containers
  - Enterprise Clinical Trial Platform – Grid computing with workflow tools

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Future

The Future

Automation

eProtocol

Linked Data

Machine Learning

Open Source Tools

Tools supporting data flow

Enter data

Instant analysis

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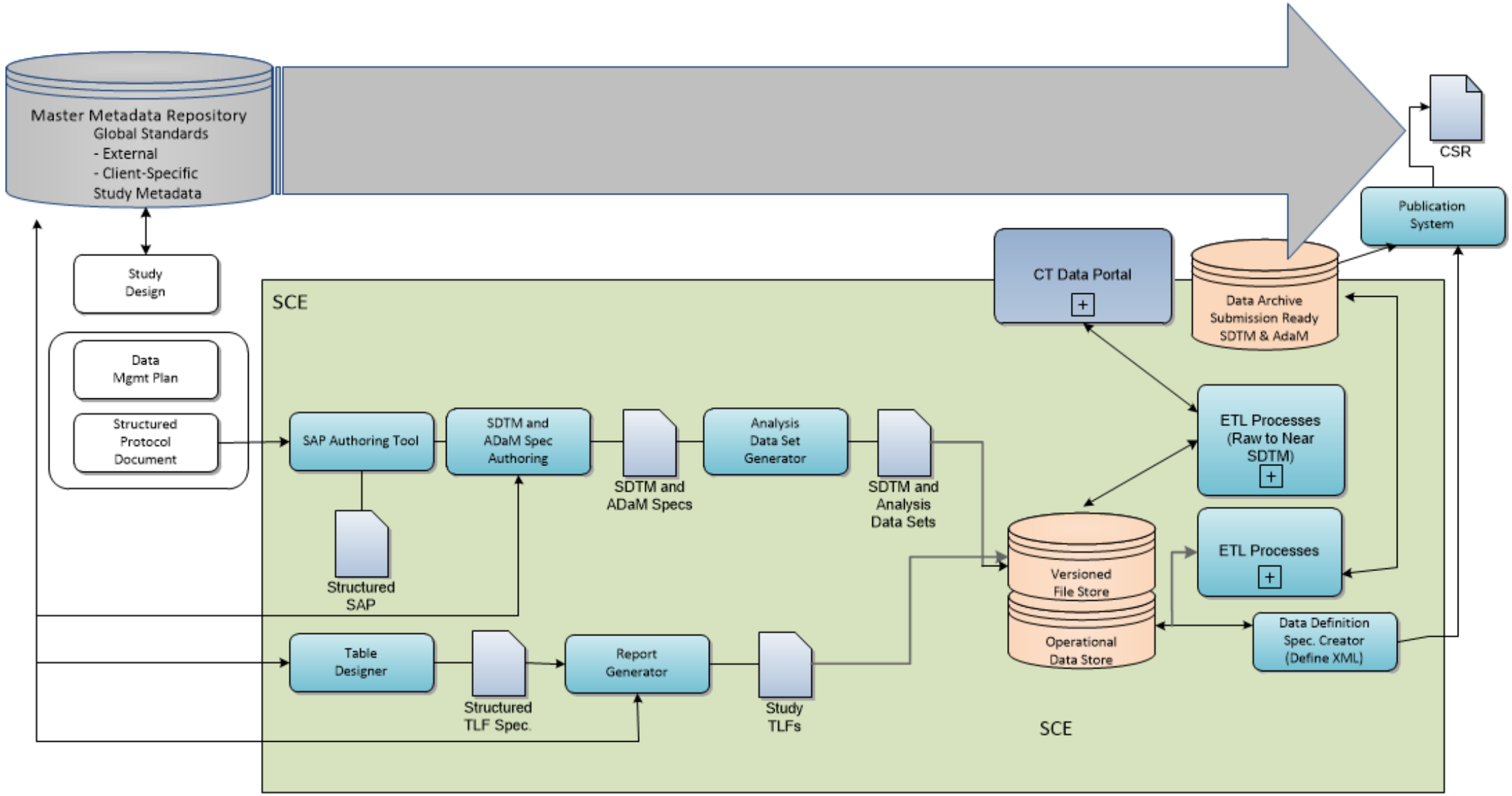
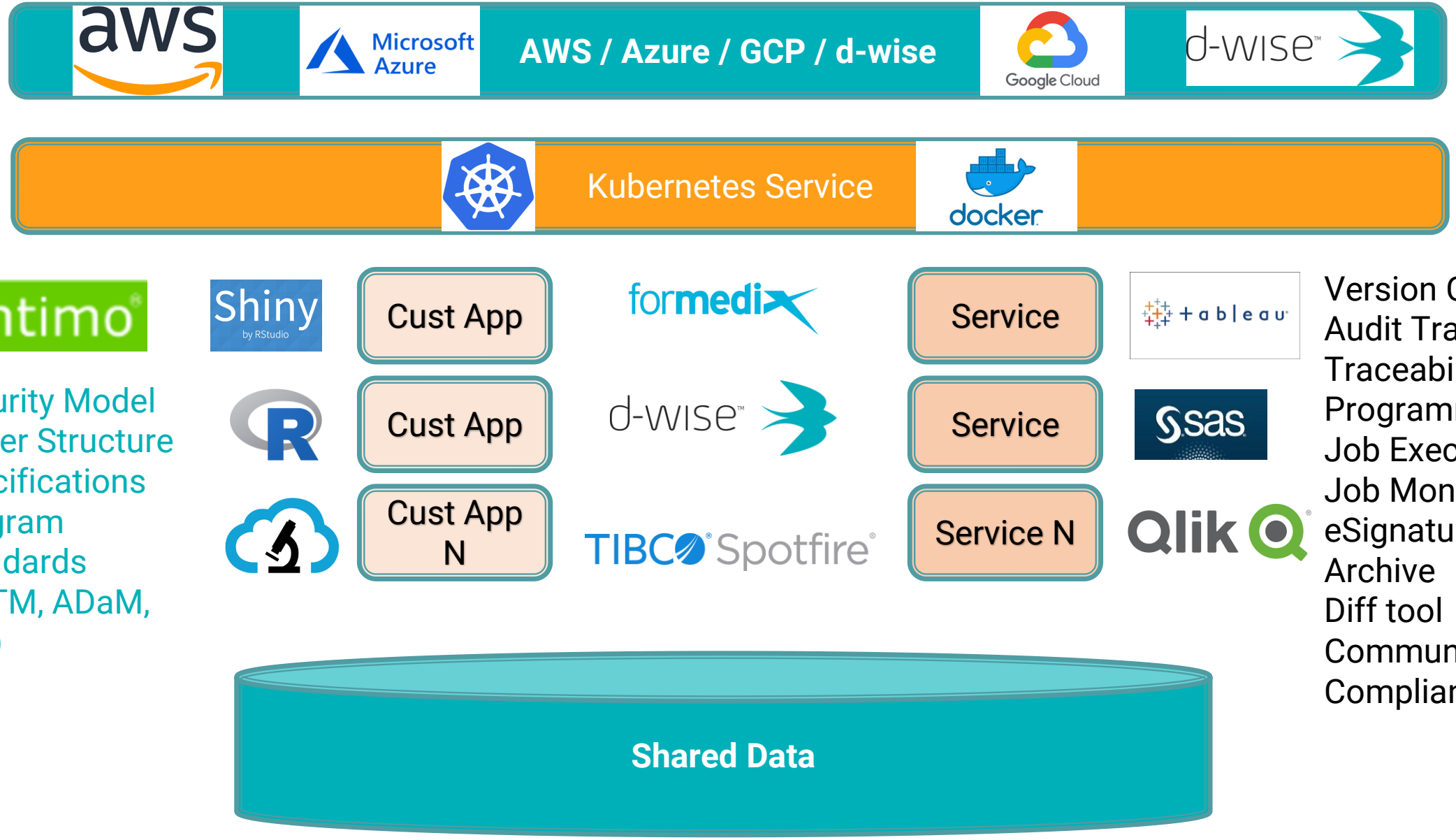
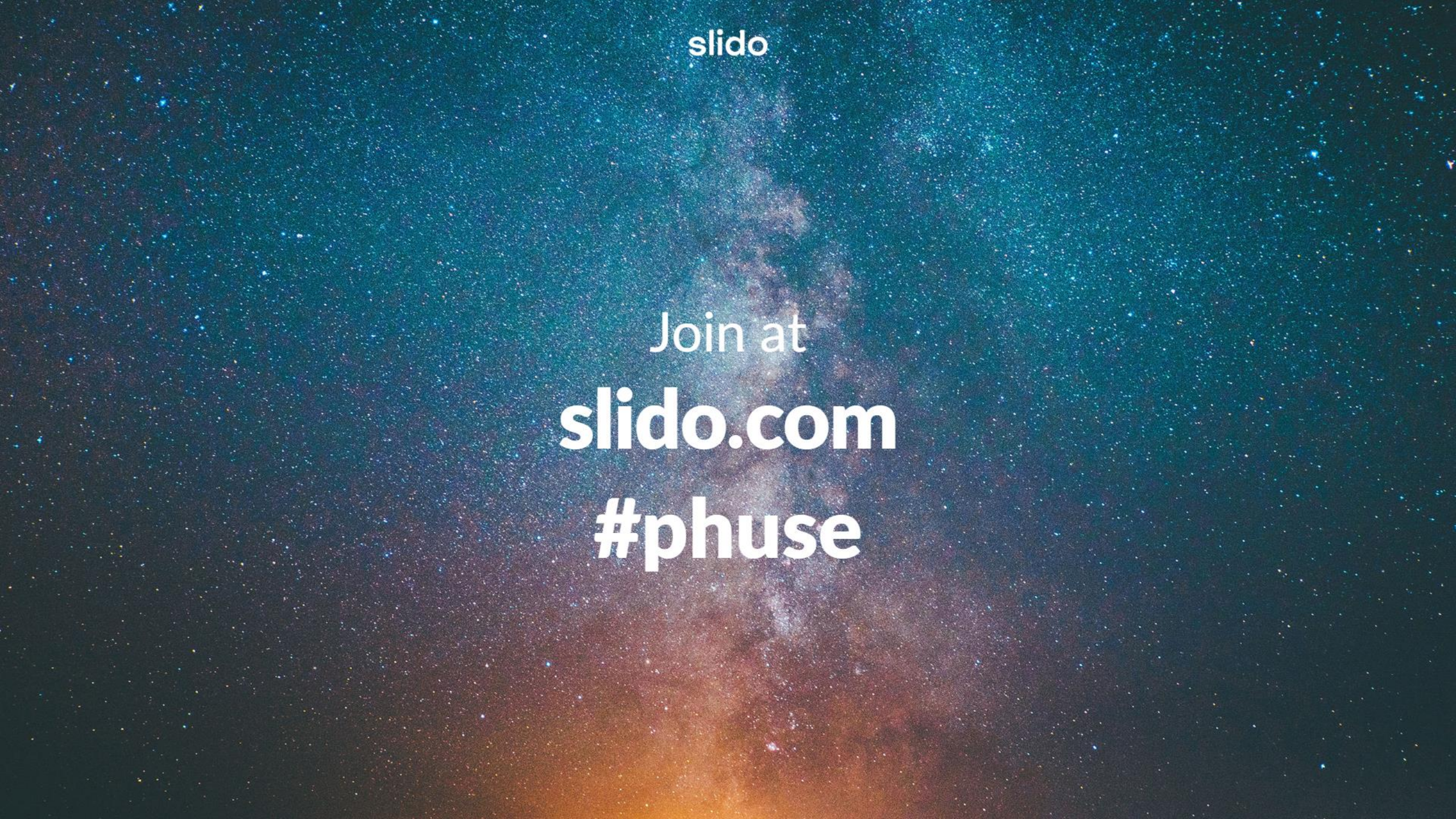

Master Metadata Repository
Global Standards
- External
- Client-Specific
Study Metadata
Study Design
Data Mgmt Plan
Structured Protocol Document
SCE
SAP Authoring Tool
SDTM and ADaM Spec Authoring
SDTM and ADaM Specs
Analysis Data Set Generator
SDTM and Analysis Data Sets
Structured SAP
Table Designer
Structured TLF Spec.
Report Generator
Study TLFs
SCE
CT Data Portal
Data Archive Submission Ready SDTM & AdaM
Publication System
CSR
ETL Processes (Raw to Near SDTM)
ETL Processes
Versioned File Store
Operational Data Store
Data Definition Spec. Creator (Define XML)


aws
Microsoft Azure
AWS / Azure / GCP / d-wise
Google Cloud
d-wise
Kubernetes Service
docker
entimo
Security Model
Folder Structure
Specifications
Program
Standards
(SDTM, ADaM,
TFL)
Shiny
by RStudio
Cust App
Cust App
Cust App
N
formedix
d-wise
TIBCO Spotfire
Service
Service
Service N
+ableau
sas
Qlik
Version Control
Audit Trail
Traceability
Programme plan
Job Execution
Job Monitor
eSignatures
Archive
Diff tool
Communication
Compliance
Shared Data

Questions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