

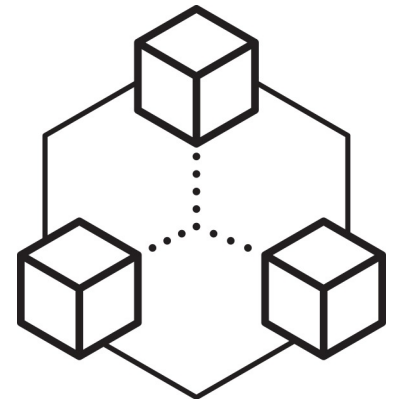
d-wise™

An Instem Company

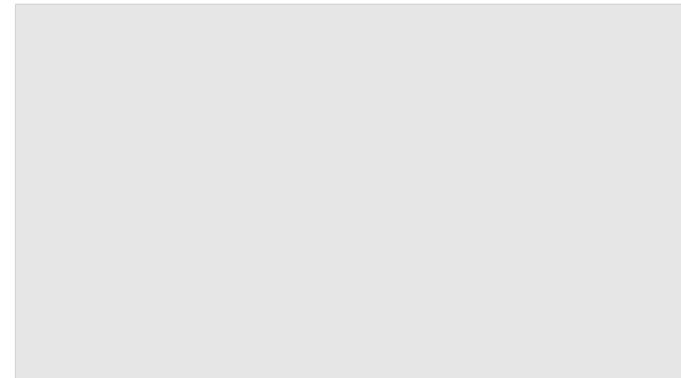
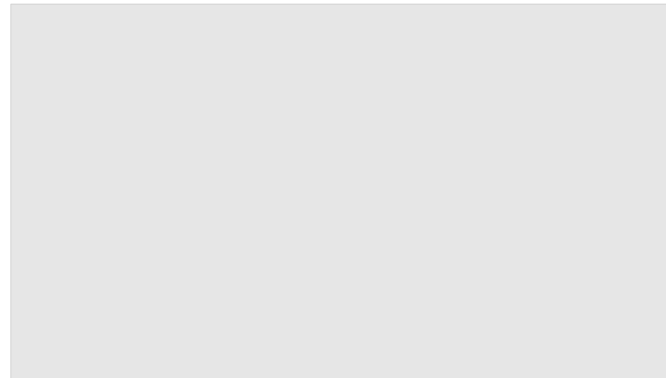


Aspire Demo PHUSE EU Connect 2021

Andy Ratcliffe
Solution Owner, Aspire



Agenda



A person wearing glasses and holding a camera up to their eye, with a blue overlay.

Industry Overview



What can cloud-native SCE mean for my business?



An SCE meeting these principles would deliver **quality, improve decision making and accelerate time to the approval and delivery of new medicines to patients across the globe.**

- ✓ Be an application that is intuitive and easy to use application
- ✓ Involve modern and scalable forward focused technology
- ✓ Adopt technology that is reliably used for big data
- ✓ Facilitate multiple programming languages
- ✓ Effectively integrate with a variety of systems and tools to allow seamless access to data
- ✓ Successfully manage programming workflow e.g. version control, traceability, reproducibility
- ✓ Allow effective outsourcing and collaboration
- ✓ Include automated functionality to replace repetitive and manual-heavy tasks
- ✓ Enable high performance computing for complex statistical methods to be run in minutes



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



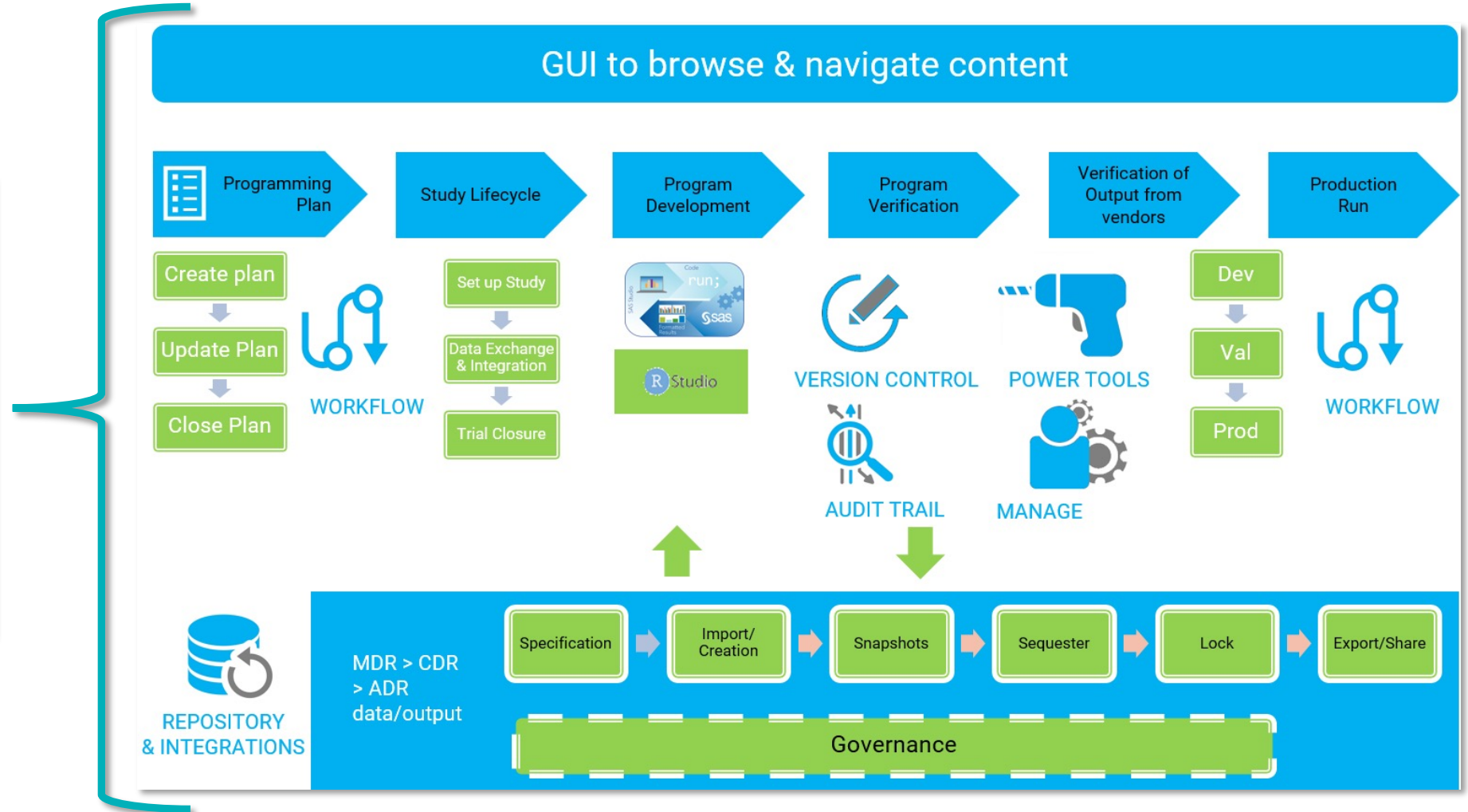
- Lack of robust end to end lineage
- Challenges reproducing results

Traceability



Features of SCE Solutions

	WORKFLOW	Workflow & File Management
	VERSION CONTROL	Programming Support
	POWER TOOLS	Control of Program Execution
	AUDIT TRAIL	Integrations
	REPOSITORY	Compliance
	MANAGE	System Support



Aspire is...

a **clinical analytics framework** of **flexible** and **configurable** clinical components allowing data scientists to focus on the **meaning** of the data by **automating** the mundane tasks, providing a fit for purpose **experience** workflow and enabling the **right tool** for the right task built on an **extendable** cloud architecture to rapidly add **new capabilities** while maintaining **data integrity** and **traceability** throughout the clinical data lifecycle



Aspire Concepts adopted from 20 years of Client Experience

- ✓ Compliance is critical but must not get in the way
- ✓ User Experience should be at the core of the solution
- ✓ Enable people to use their tools instead of forcing them to adopt new tools that don't meet their needs
- ✓ Embrace and leverage the cloud native capabilities
- ✓ Single monolithic solutions do not work
- ✓ Solutions must provide access to the wide array of current and future programming languages



Aspire Projects

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

Produce Statistical Analyses
with control & efficiency

1	COTS	3	Third Way	2	Custom build
 Assumed quick build	 Limited configuration	 Pre-built core components	 Quick build	 Unlimited customization	 Slow build
 Shared cost	 Limited control of roadmap	 Efficient & economic	 Fit-for-purpose & adoptable	 Control of roadmap	 Expensive costs: build/own

ASPIRE: THE THIRD WAY

We prioritized the following themes:

- **Consistency of user experience**, focusing on the user and an intuitive workflow easy to adopt
- Use of **best-in-class** Integrated Development Environments (IDEs) and tools for developing code and performing analytics
- **Adaptable** and forward-looking architecture, to facilitate the addition of additional tools, data sources and capabilities without being constrained by integration limits
- **Scalable**, allowing our clients' user population and range of use cases to grow without being stymied by architectural boundaries making full use of the inherent scaling available in today's cloud environments

We partnered to move away from customized solutions based on proprietary technology. With too many static solutions, we recognized the need to connect open tools across the enterprise and purchase smaller proprietary pieces that are both configurable and replaceable.

- Global Pharma, Head Data Analytics & Data Science

Aspire Products



Aspire Software Products

Foundation

Aspire Compute

Languages of your choice and seamless scalability you need

Aspire Versions

Task based versions based on business rules seamless to the user

Aspire Store

High performance data without high complexity

Aspire Search

Intelligent and intuitive searching for key business needs

Compliance

Aspire Audit

Who, what, when...ensuring end to end compliance

Aspire Secure

Protect your key data assets

Aspire Trace

Traceability and automation made easy

Aspire Snapshot

One click archive and restore of key study milestones

Workflow

Aspire Plan

Integrated and intuitive planning and guided execution

Aspire Exchange

Managed and intelligent data transfer

Aspire Flow

The system aligns to your way of working

Aspire Integrate

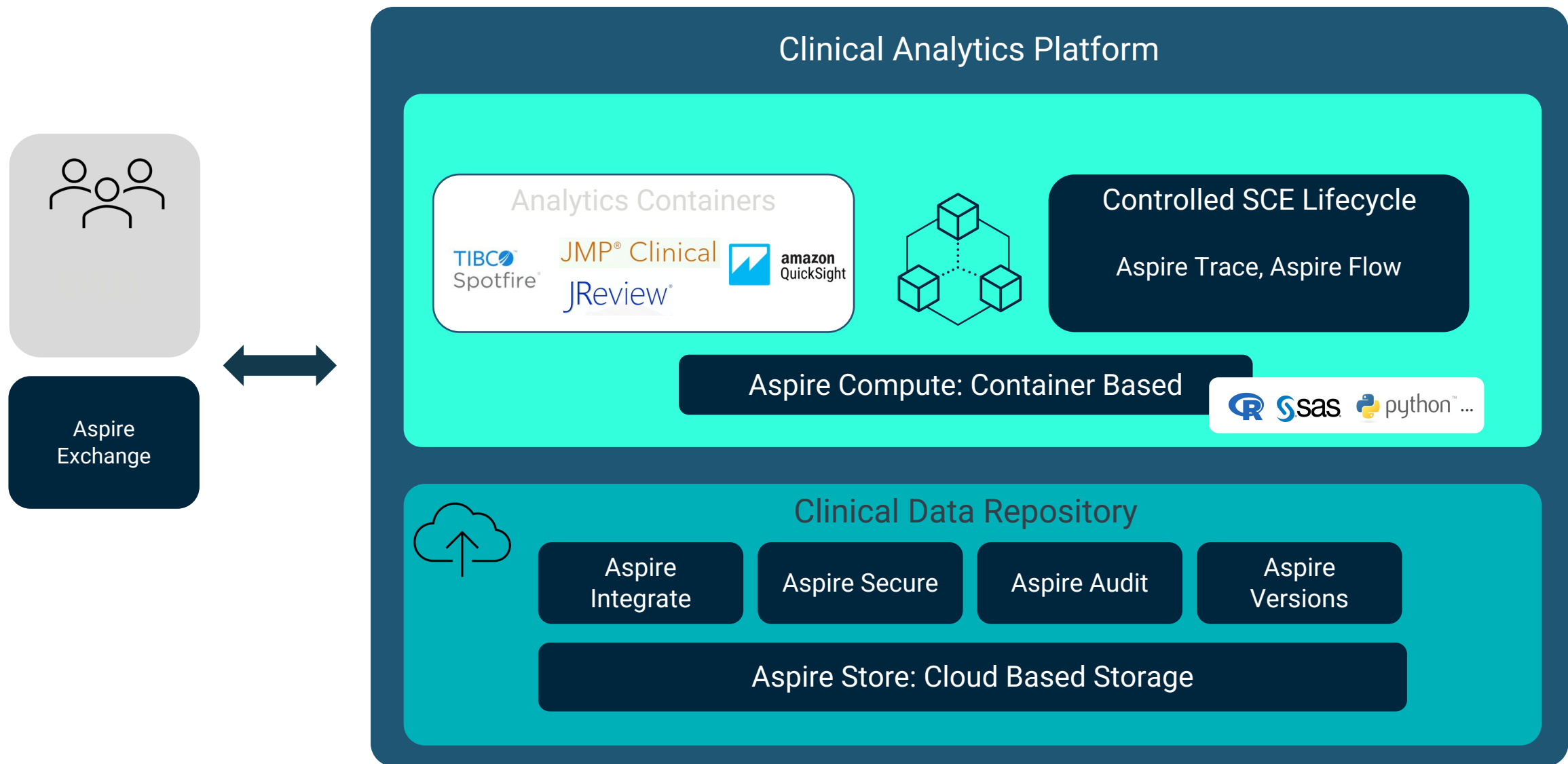
Plug-n-play for existing and future transformation and analytical tools

Other Aspire Products:

- Notifications
- Scheduling
- Collaboration
- Design
- Metrics
- Standards



Foundational Clinical Analytics Platform





Aspire Audit

Aspire Audit

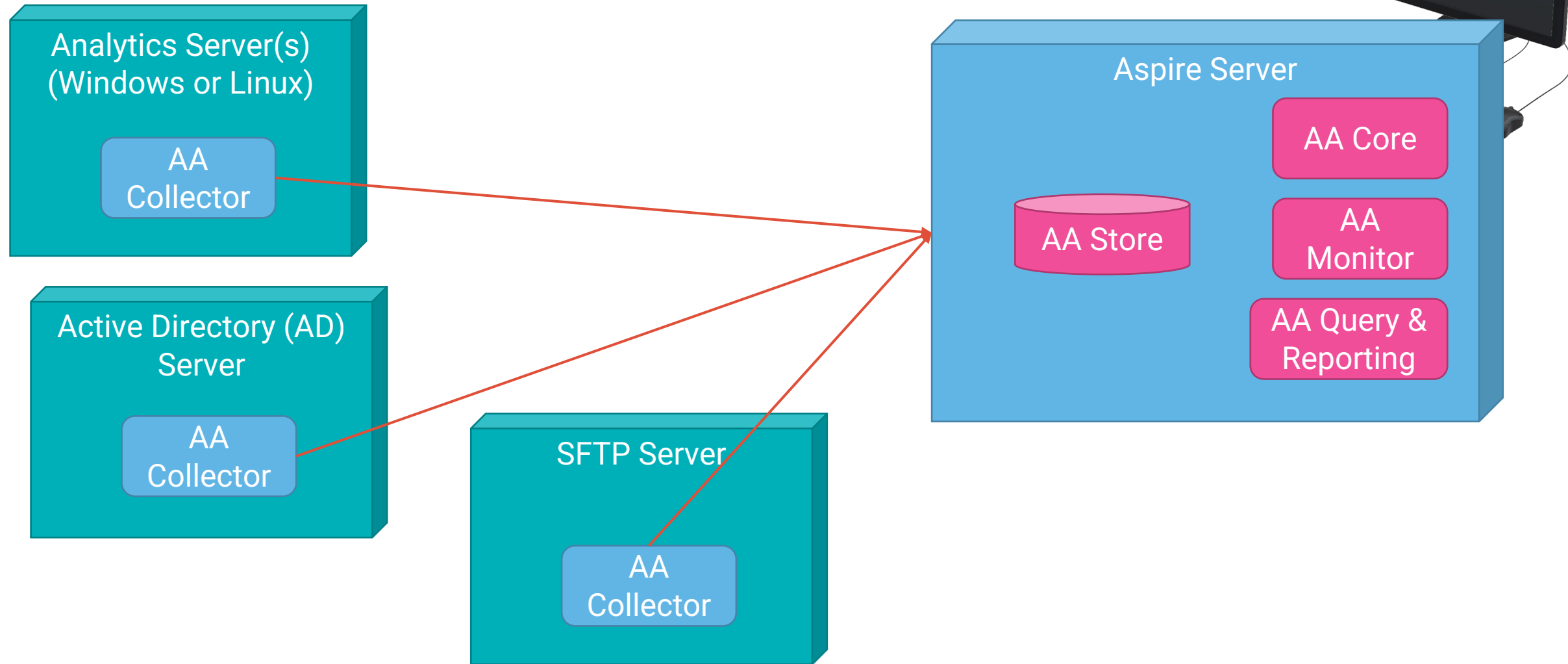
Key Features

- Total audit trail of permissions and file events
 - Create, update, delete, changed ownership, changed permissions
- Total audit trail of AD group membership changes
- Powerful and user-friendly interface for reports and dashboards
- 24x7 automated monitoring of user activities
- Resilient architecture with built-in self-monitoring
- For Windows and Linux
- Compatible with other Aspire products

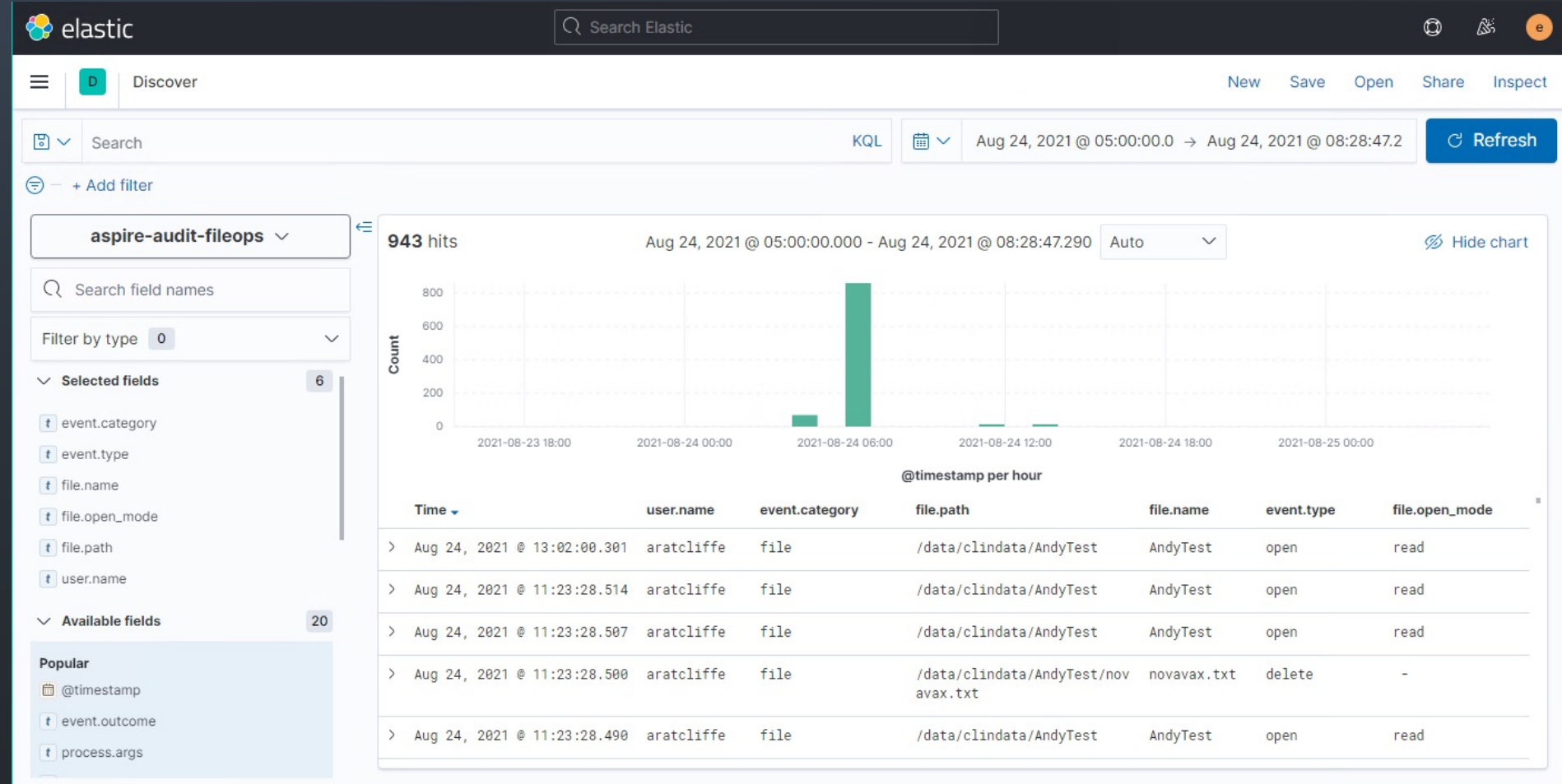
Business Benefits

- Automated solution to the need for an audit trail, requiring no IT or business intervention
- Ability to retrospectively understand who has been accessing which file(s), and when they did so
- Ability to retrospectively understand who changed security permissions, and when

Outline Architecture – Aspire Audit (AA)

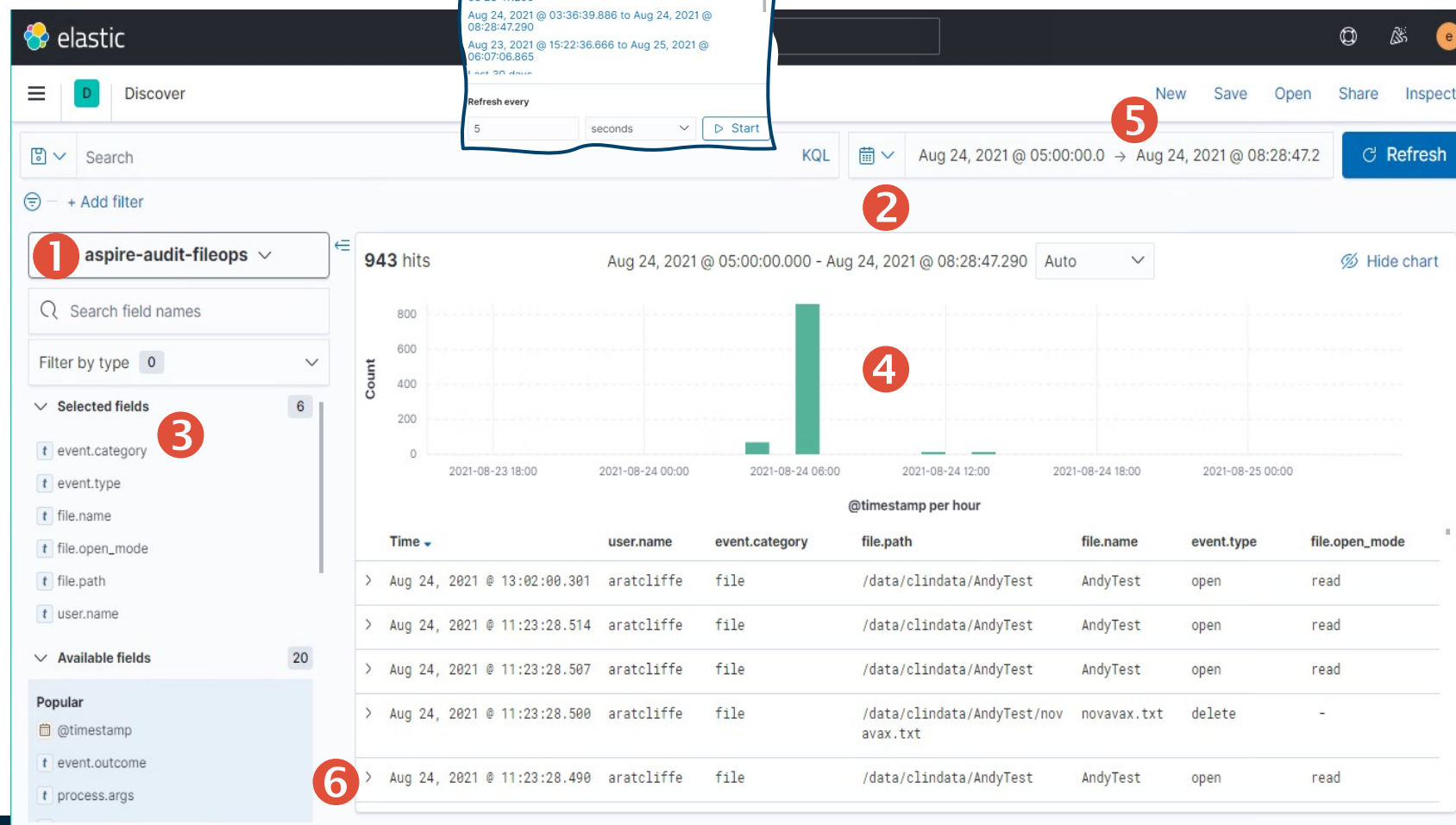


Aspire Audit - Discover



Aspire Audit - Discover

1. Select one or more collector sources
2. Search with date/time ranges, Kibana Query Language (KQL), or Filters (wizards)
 - Apply commonly-used ranges
 - Auto-refresh
3. Choose which fields to show from each record
4. Chart shows distribution of records over selected time range
5. Create, save, share reports
6. Expand individual records to see all fields



The screenshot shows the Elastic Discover interface. A callout box (2) highlights the 'Quick select' menu with options like 'Last 15 minutes' and 'Commonly used' ranges. The main interface shows a search for 'aspire-audit-fileops' (1) with a time range of 'Aug 24, 2021 @ 05:00:00.000 to Aug 24, 2021 @ 08:28:47.290' (5). A bar chart (4) shows the distribution of records over time. The left sidebar shows 'Selected fields' (3) including '@timestamp', 'event.category', 'event.type', 'file.name', 'file.open_mode', 'file.path', and 'user.name'. The bottom table (6) shows individual records with columns: Time, user.name, event.category, file.path, file.name, event.type, and file.open_mode.

Time	user.name	event.category	file.path	file.name	event.type	file.open_mode
> Aug 24, 2021 @ 13:02:00.301	aratcliffe	file	/data/clindata/AndyTest	AndyTest	open	read
> Aug 24, 2021 @ 11:23:28.514	aratcliffe	file	/data/clindata/AndyTest	AndyTest	open	read
> Aug 24, 2021 @ 11:23:28.507	aratcliffe	file	/data/clindata/AndyTest	AndyTest	open	read
> Aug 24, 2021 @ 11:23:28.500	aratcliffe	file	/data/clindata/AndyTest/novavax.txt	novavax.txt	delete	-
> Aug 24, 2021 @ 11:23:28.490	aratcliffe	file	/data/clindata/AndyTest	AndyTest	open	read

Aspire Archive



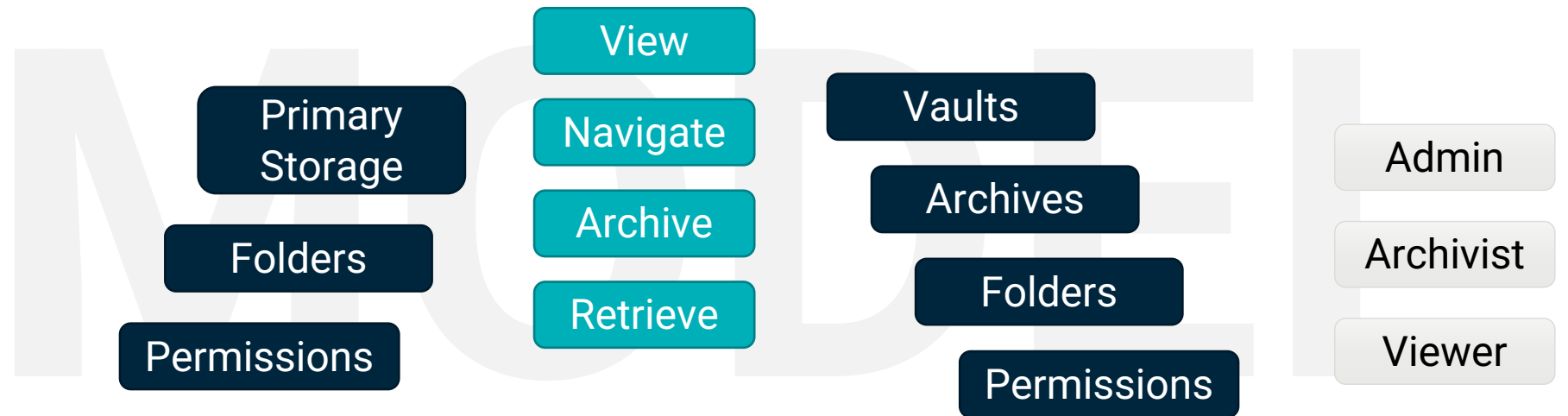
Business Concepts

- **Issue:** All clinical studies on one storage volume
 - Studies are submitted, closed, and not used anymore
 - Can be accidentally updated (or deleted)
 - Closed studies take up space, and cause distraction when navigating through folders
- **Solution:** Move closed studies to a different location (“an archive *vault*”)
 - Perhaps cheaper storage
 - Somewhere that is not visible when navigating folders for open studies
 - Can be retrieved, if required
- A *vault* could be created
 - Remotely on cloud storage, or
 - Locally
 - In a different folder on the same disk as the clinical studies
 - e.g. s:\clindata is where all my studies are stored, whilst I have a vault at s:\AndyVault where I move (“archive”) my closed studies
 - This is very useful for testing



Approach

- Aspire Archive allows *Admins* to create one or more "Vaults"
- Vaults contain 0, 1 or more archives, e.g. studies
- Projects/studies can be "Archived" to a Vault by an *Archivist*
- Archives can be "Retrieved" from a Vault by an *Archivist*
- Archives can be viewed within a Vault by a *Viewer*



Aspire Audit Qualities

- Robust and reliable
 - Never lose a study!
- Flexible upon Retrieve
 - The world doesn't stand still
- Support for cloud and on-prem / local
- Compatible with other Aspire products
 - Driven by some
 - Using Aspire Audit



Aspire Compute & Store

Challenges

- Difficult to add extra storage in a granular fashion
 - Typically added in large amounts
- Difficult to adopt new storage technology
 - Needs a big bang approach
- Increasing number of users & studies results in need for increasingly complex (parallel) storage solutions
 - Complex and expensive
- Difficult to add extra languages & tools
 - Often results in creation of a new “silo” for the new language/tool
 - Especially true when language is “experimental”
- Difficult to upgrade version of languages
 - Often results in a big bang upgrade for all projects – requiring extensive & expensive regression testing
 - Difficult to retain ability to re-run code on older versions of languages & tools
- Difficult to add extra capacity that is available to all languages & tools (and versions thereof)

Aspire Compute & Store Benefits

- Language-agnostic solution
- Scalable in a granular fashion (data & compute)
 - No need to acquire more than you need
 - No complexity or exponential expense associated with growth
- Multiple versions of tools easily co-exist
 - Confidence in ability to re-run old code with old versions of languages & tools
- Efficient use made of compute resources
 - Shared amongst all languages and tools
 - No ring-fencing; all resources are available to all languages & tools
- Able to add new storage technology in an evolutionary fashion
- Simplified security model

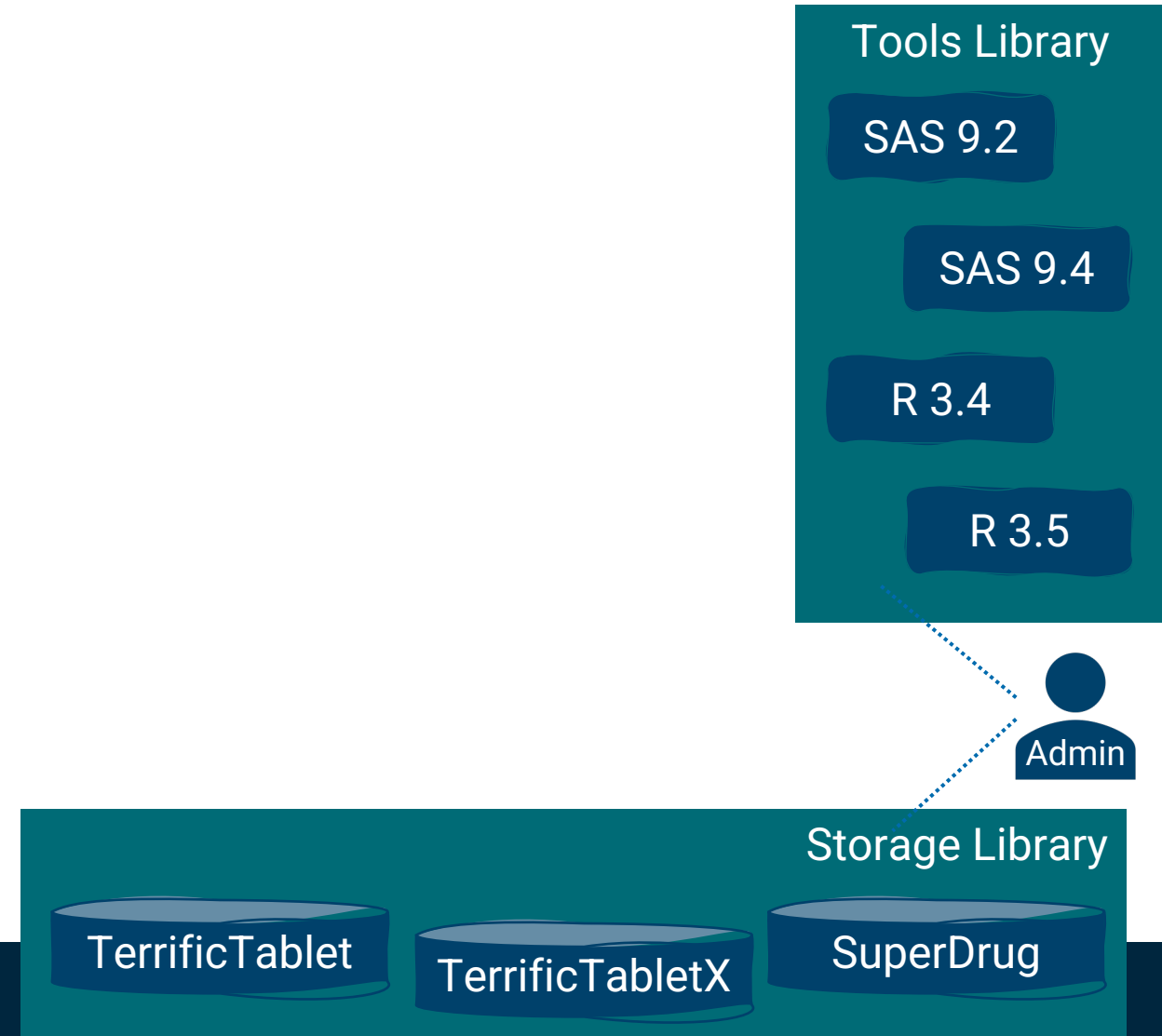
Concepts

- **Tools:** analytical languages
 - And associated IDEs, e.g. SAS Studio



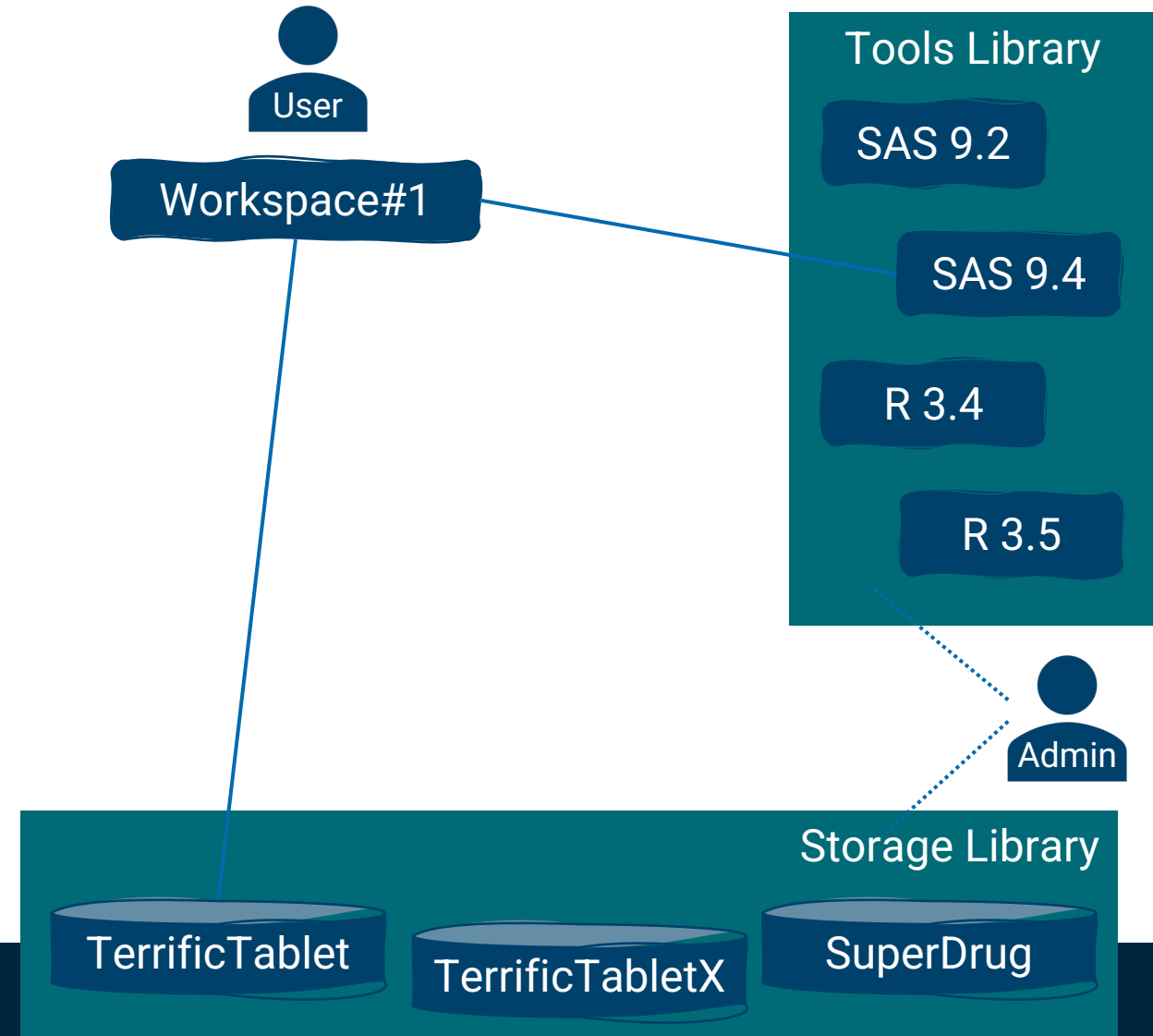
Concepts

- **Tools:** analytical languages
 - And associated IDEs, e.g. SAS Studio
- **Data storage:** location where study-specific artefacts are stored
 - e.g. input data, code, output data and TLFs
 - Multiple data storage areas
 - Specific to studies, or shared
 - Flagged, if appropriate, as containing qualified content



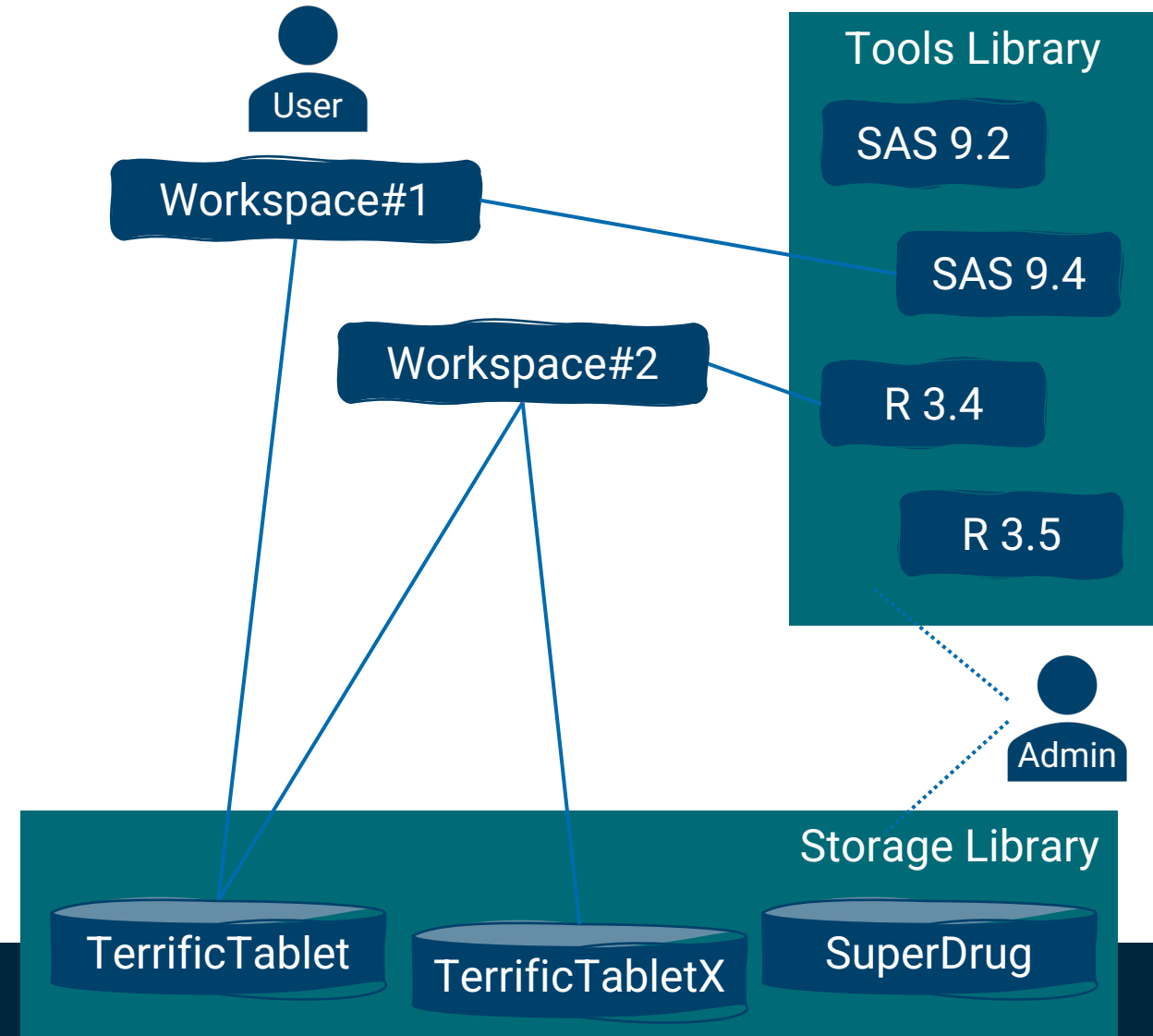
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 - “Personal server”



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Use Cases

- As an Admin, I can
 - Create a Study
 - Create a StatsPgmr
 - Assign user to a study

Admin

StatsPgmr

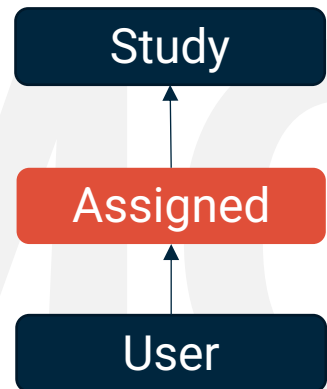
Create

Read

Update

Delete

List



Create a study

Create a user

Assign user to study



Use Cases

- As an Admin, I can
 - Create a Study
 - Create a StatsPgmr
 - Assign user to a study
 - Create a Storage Volume
 - Flag a storage volume as Qualified or Non-Qualified
 - Assign a storage volume to a study

Admin

StatsPgmr

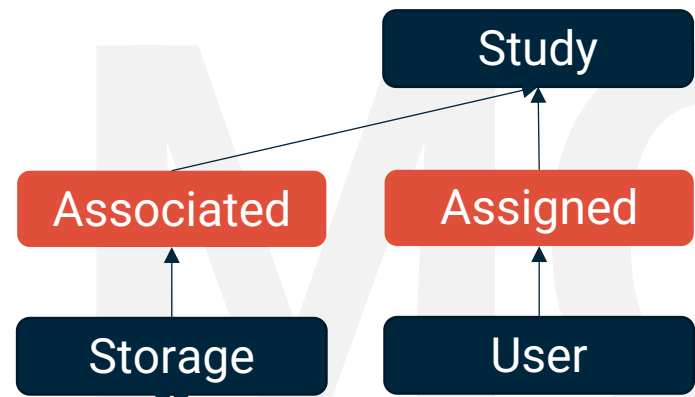
Create

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Create a study

Create a user

Assign user to study

Create storage

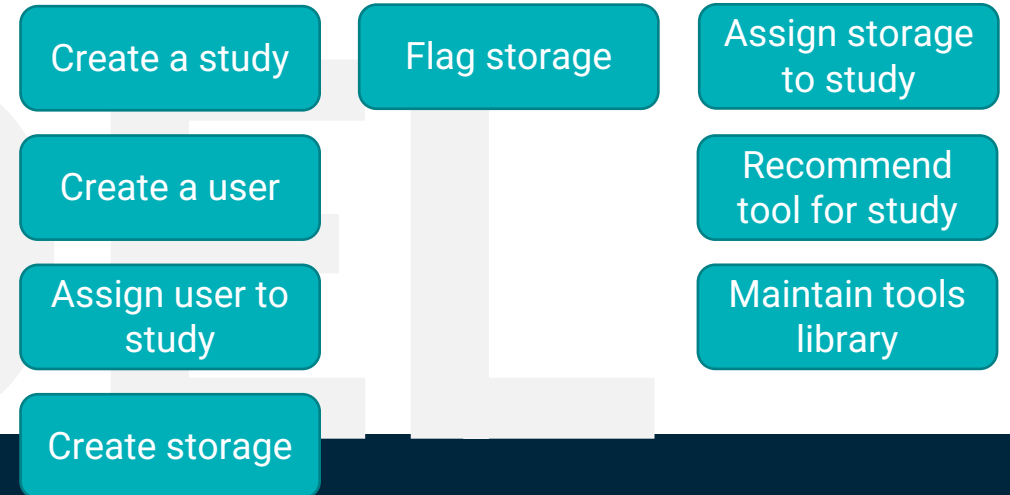
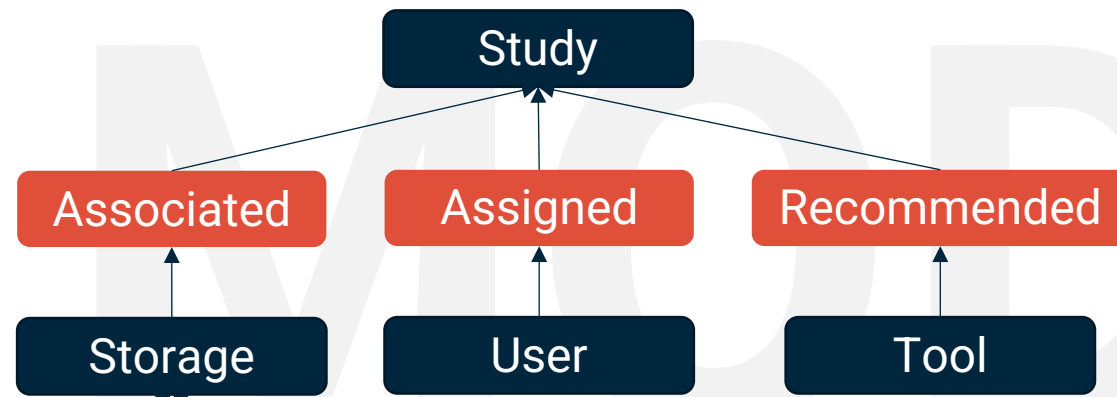
Flag storage

Assign storage to study

Use Cases

- As an Admin, I can
 - Create a Study
 - Create a StatsPgmr
 - Assign user to a study
 - Create a Storage Volume
 - Flag a storage volume as Qualified or Non-Qualified
 - Assign a storage volume to a study
 - Maintain the library of Tools
 - Assign a Tool to a Study ("recommended tool")

Admin	Create
	Read
StatsPgmr	Update
	Delete
	List



Use Cases

Admin

Create

Read

Update

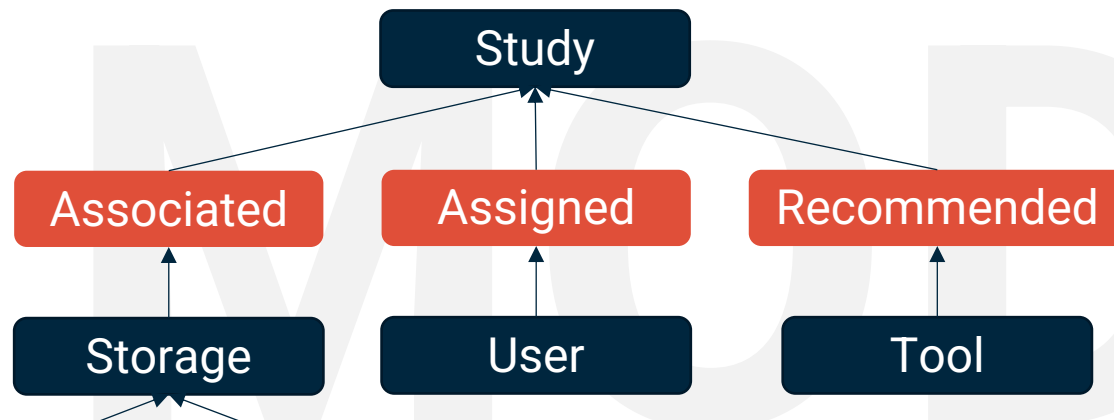
Delete

List

StatsPgmr

- As an Admin, I can
 - Create a Study
 - Create a StatsPgmr
 - Assign user to a study
 - Create a Storage Volume
 - Flag a storage volume as Qualified or Non-Qualified
 - Assign a storage volume to a study
 - Maintain the library of Tools
 - Assign a Tool to a Study ("recommended tool")

- As a StatsPgmr, I can
 - View a list of studies I am assigned to
- As a StatsPgmr, for a study I am assigned to, I can
 - Navigate the associated storage volumes
 - Launch a tool in interactive mode
 - Study's assigned storage volumes are automatically mounted
 - Thereby creating a workspace from which I gain access to the IDE
- As a StatsPgmr, for a specific file for a study I am assigned to, I can
 - Browse the file
 - If the file is of a type that pertains to a tool, launch a tool in batch mode
 - Study's assigned storage volumes are automatically mounted
 - File is executed; log file is created



Create a study

Flag storage

Assign storage to study

Create a user

Launch interactive

Recommend tool for study

Assign user to study

Run in background

Maintain tools library

Create storage

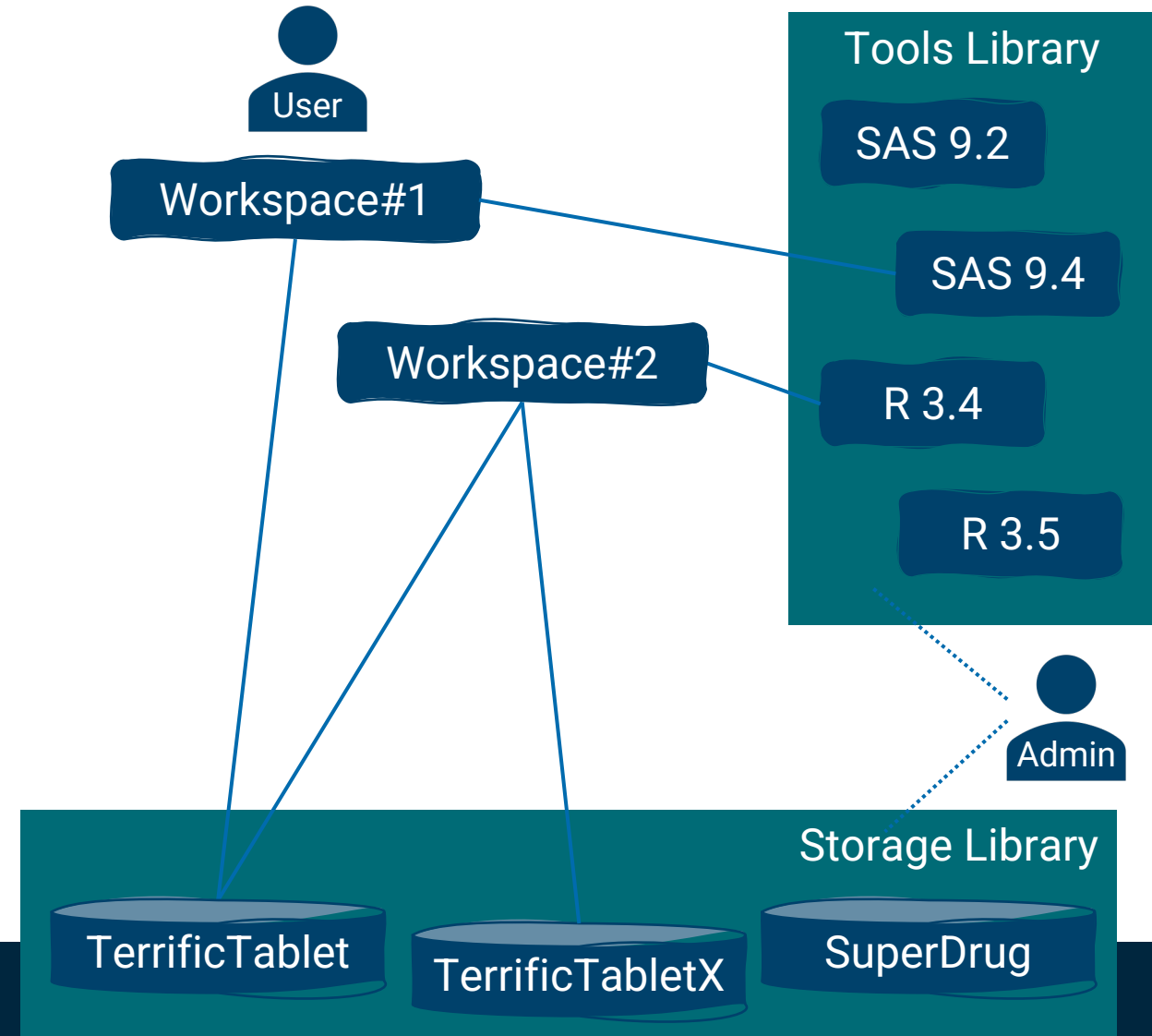
View File

Aspire Demonstration



Concepts

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Future Feature Highlights

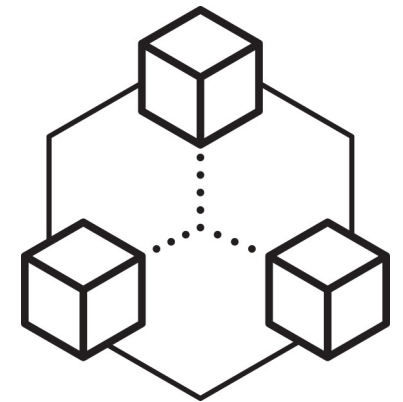
- Assign multiple storage volumes to a workspace, mounted as different folders
 - Supporting common macros and functions in addition to study-specific work
- Rules ensure no “unqualified artefacts” get written to the qualified storage volumes
- Lifecycle for tools, to retire old versions
 - Retaining availability for use by old projects
- Windows companion facilitates drives mapped and made available to Windows-based tools

Backlog Highlights

- Program Execution
 - Save program execution return code
 - As a User, I can see the programs I executed and their return codes (execution history)
 - As a User, I can see the programs that are running
 - As an Admin, I can kill a program that is running from any user
- Collaboration
 - As a User, I can invite users into my container in order to collaborate on content that I've stored inside it
 - As a user, I can tag content
 - As a user, I can invite conversation and resolution on tagged content
- Search
 - All content is meta-tagged
 - As a user, I can search, find and re-use
- Automation
 - As a User, I want to see a dependency graph of inputs, intermediary outputs and final outputs of an executed program
 - I can understand dependencies between programs
 - I can automate execution of data pipelines

Summary

- Designed and built for Life Sciences use cases and needs
 - Compliance features are built-in
- Forward-thinking
 - Minimal barriers to adoption of new technology
- Granular, scalable, language-agnostic solution
- Low cost of ownership
- Maintainable
 - Minimal scheduled down-time
- Simple and explainable security model



Questions



Aspire Roadmap

AUDIT

V1.0 May 2021

- Linux

V1.2 October 2021

- Linux & Windows

V1.x

- Installation enhancements
- Additional collectors, e.g. FTP
- Remote collectors

V2.x

- Interpretation of raw audit records

ARCHIVE

V1.0 December 2021

- Linux
- xFS
- Isilon

V2.0 2022

- Windows
- AWS S3

ASPIRE

Exchange
Compute, Store, Version,
Trace

***Rate and order of
development is driven by
Aspire projects***



Questions?



