

Building Integrated Clinical Ecosystem

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ABSTRACT

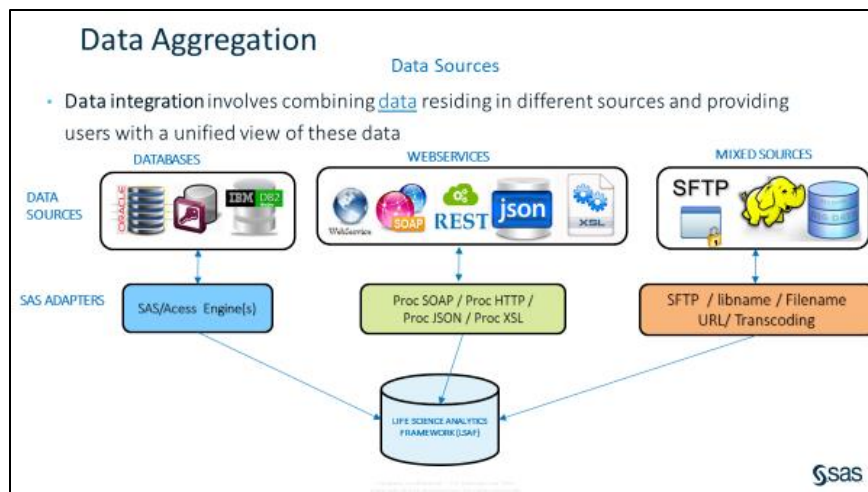
In today's world, there is a variety of niche vendors that have a 'best of breed' product within the Clinical space. The ability to take these various applications and create an integrated system is key for productivity and efficiency. When these applications are hosted in the Cloud connectivity it is facilitated and as an added benefit, system access is available from anywhere in world simply through a web browser.

This paper talks in general about variety of features and functionalities one should be mindful of when selecting applications that can be utilized in their Clinical Ecosystem. The question to ask is: can data be collected and stored into one centralized repository and yet can be distributed to remote applications to support different end users and their various use-cases.

DATA REPOSITORY: CLOUD VS IN-HOUSE

Identifying an application for a centralized data repository can be very challenging, potential requirements can include:

- Is it web-based or server based?
- Does it support version control?
- Is it a secure system for both internal and external 3rd party uses?
- Does it support audit history?
- Does it support E-signatures?
- Does it provide APIs for integration with other systems?
- Can it be scaled to support large number of users from different sites across globe
- Does it have secured backup and disaster recovery
- What kind of data sources aggregation does it support?



INTERGRATIONS - EDC, IVRS, CTMS, TMS SYSTEMS:

- Does it have web services for APIs?
- For EDC integrations, does it support Snapshot and incremental data pull?
- Does it support Industry standard like ODM data streaming or any other data format that can be easily consumable?
- Does it support data extract and data update?

STATISTICAL COMPUTING ENVIRONMENT:

While variety of languages and IDEs are available for Statistical Computing, only few can support validated results that are acceptable by regulatory agency.

- Is it server based, or web based?
- Is it open-source or proprietary?
- Is it a validated environment?
- Does it support impact analysis?
- Does it provide the ability to identify inputs and outputs of the programs?

DATA VISUALITION AND REPORTING SYSTEM:

While variety of visualization tools are available,

- Web-based or server based
- Can data be easily transferrable from SCE to Visualization and/or Reporting system
- Does it support on-demand reporting and standard reporting templates?
- Does it support standard graphing templates?
- Does it support security for access controls?
- Different output formats support
- Does it have APIs or Web-services for auto-updates to reports for new data
- Open Source vs proprietary

COLLABORATIVE SYSTEMS:

The purpose of Ecosystem should be ability to provide various partners, vendors, CROs and company sites to work into one Centralized system with appropriate access control to the data.

- Does it provide ability to control various functionalities user can perform in the system
- Does it provide ability to control access to data on need to know basis
- Does it have audit trail for various actions performed in the system
- Does it support functionalities like workflows or E-signatures to reduce paper trail
- Does it provide ability to have single authentication across applications?

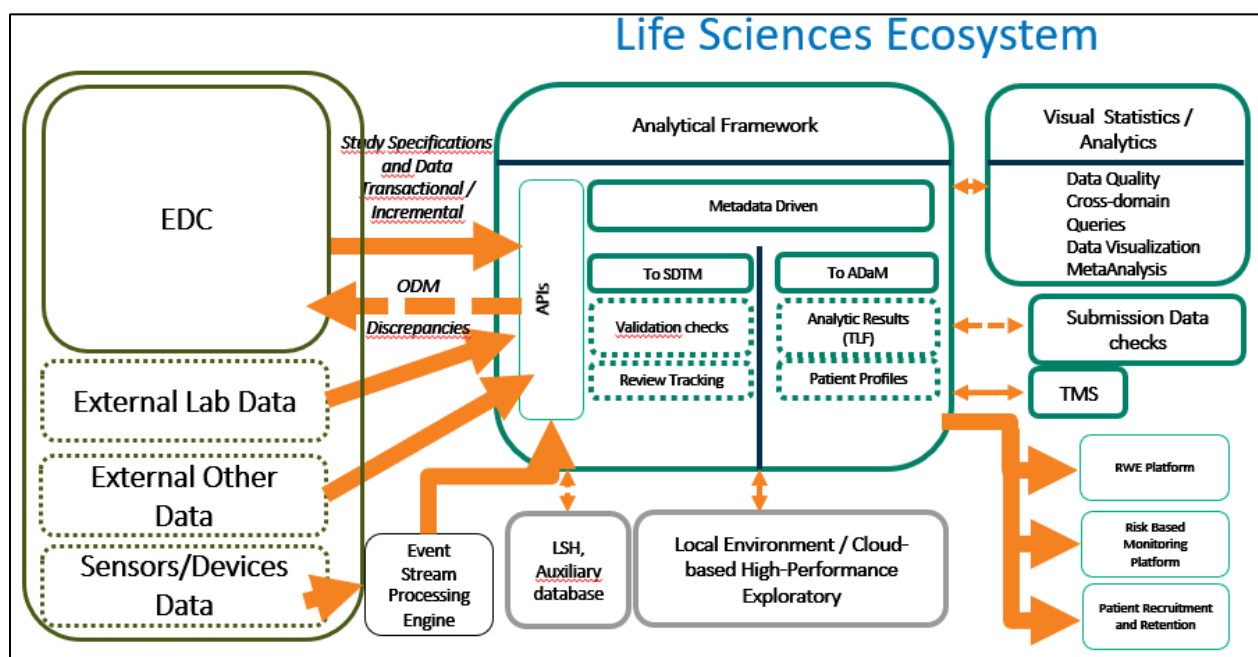
INTEGRATION MECHANISM:

While an individual can use any analytical tool or language for Clinical data analysis prominent among them are SAS, R and python. Some of the key features for these languages are

- Provide rich Statistical methods to analyze the data
- Provide mechanism to integrated using web-services or APIs
- Provide mechanism to use other programming languages like Java or .NET to integrate various applications.
- Provide mechanism to integrate various database systems
- Support designing and executing variety of Machine Learning models and data mining techniques

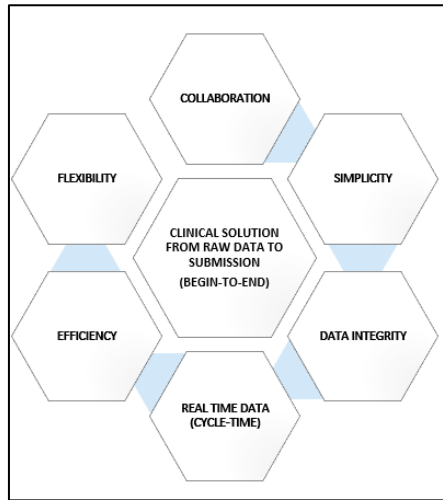
THE ECOSYSTEM BENEFITS:

An Ecosystem can be combination of multiple systems that allows data exchange and can answer analytical questions.



A properly designed Ecosystem can automate information exchange and sharing across various

stakeholders. It can enable true collaboration across various phases of the drug development by providing various benefits:



- Full transparency into trial activities, allowing greater oversight and better decision-making
- Automated information flow and reduction of manual tasks
- Provides real-time communication between all constituents for greater engagement, oversight, and problem-solving.

REFERENCES

Thies, Eric and Langston, Rick. 2008. *Introducing the SAS® Code Analyzer*. SAS® Global Forum 2008 Conference. Cary, NC: SAS Institute Inc.

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