

d-wise

Empowering innovation for a healthier world



STRATEGY



DATA



CLOUD



PRIVACY



ANALYTICS

Navigating Cloud Computing in the fast-growing Clinical Research Landscape

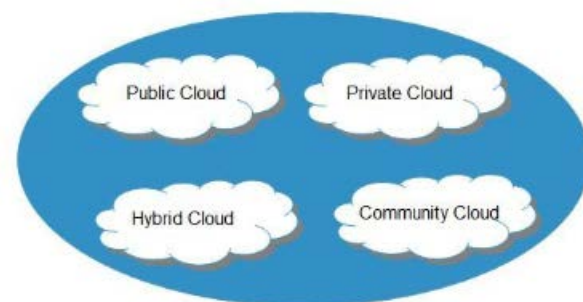
Sam Warden, BSc, MBA, CMgr

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What do we mean by the Cloud?

- “Cloud computing is a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (e.g., networks, servers, storage, applications, and services)”
- Rapid provisioning with minimal management effort or service provider interaction for release
- This cloud model is composed of:
 - 5 essential characteristics,
 - 3 service models, IaaS, SaaS and PaaS
 - and 4 deployment models
 - See this link: <https://www.linkedin.com/pulse/3-service-4-deployment-models-cloud-computing-sankar-somepalle>



From the NIST (National Institute of Standards and Technology)

**I want to buy a fog machine
and put it in a data center**

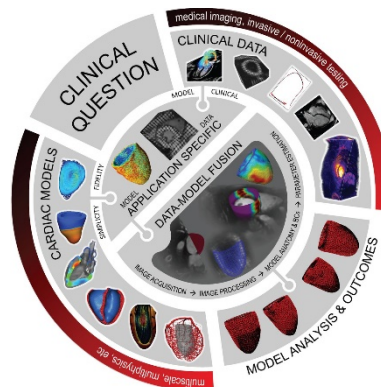
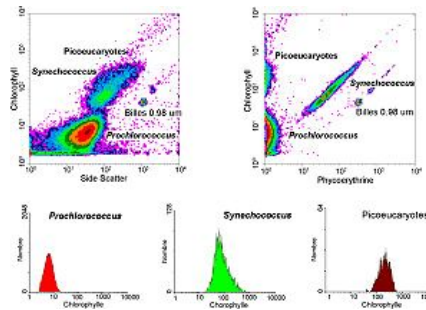
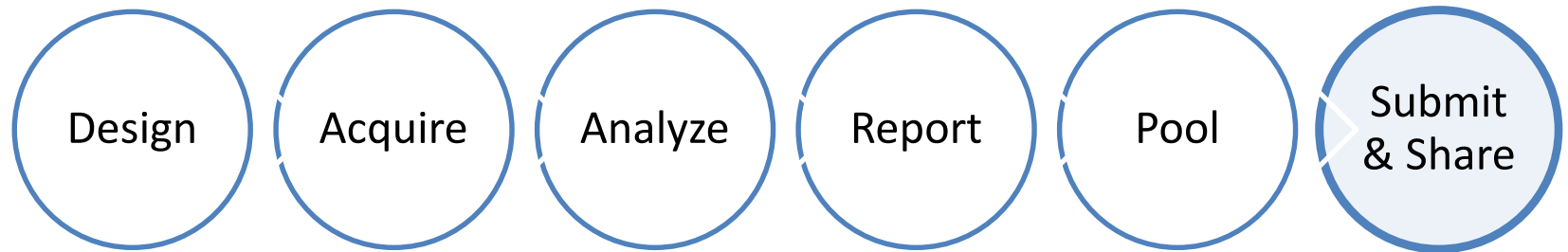


**So when i open the door,
fog spills out, I can say
"Welcome to THE CLOUD!"**

Essential Characteristics

- On Demand Self-service
- Available Everywhere
- Dynamic Computing Resources
- Rapid Elasticity & Scalability
- Measured Service

What is “special” about the clinical research landscape?





So What are the Options?

■ In house

- Proprietary in nature – creates encumbrance for future action (restricts ability to choose different paths in the future)

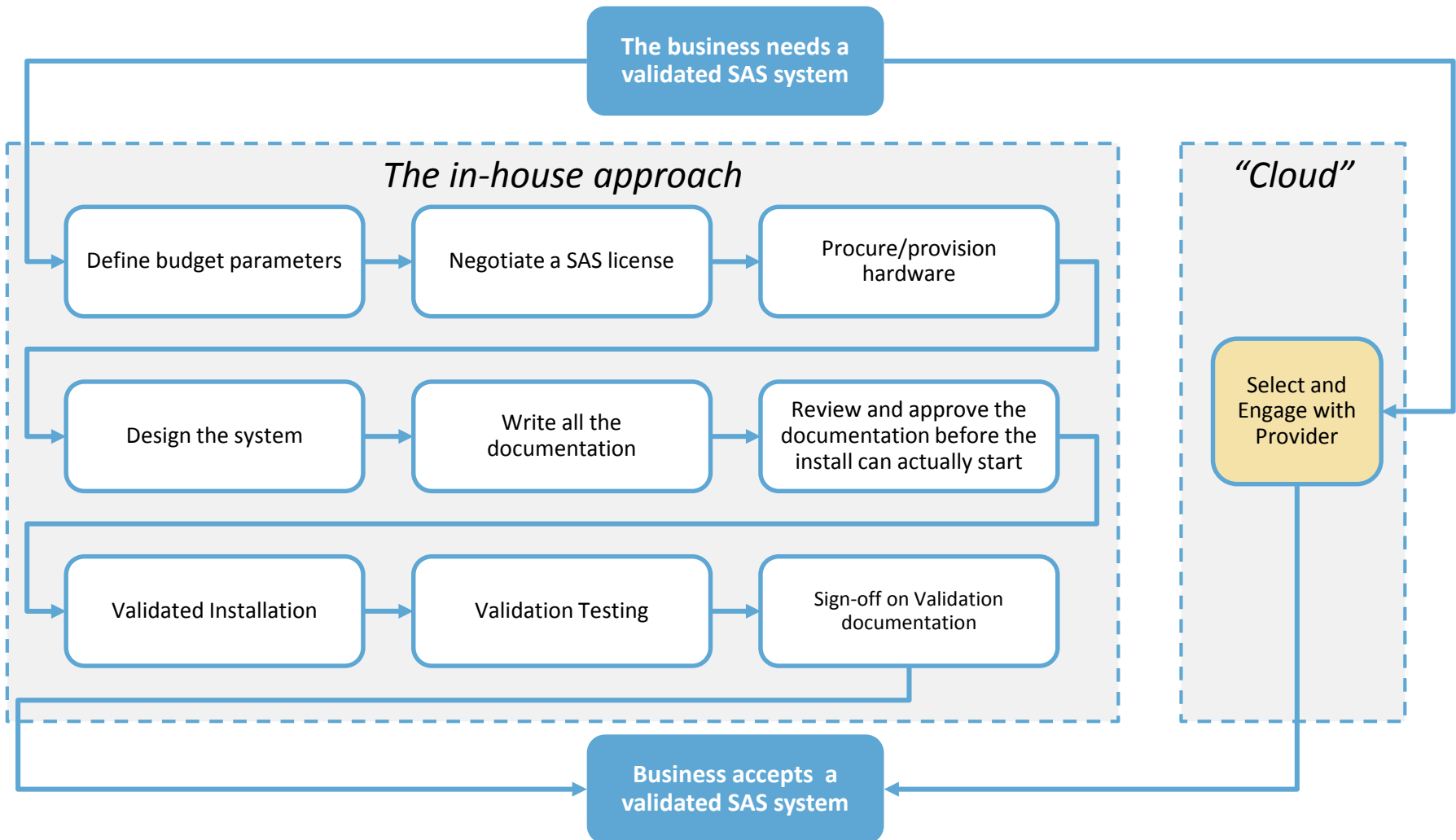
■ “Cloud”

- People remain highly efficient when switching companies (due to the use of same provider across companies)
- Best solution will win in the long run (market dynamics)

■ Outsource...

- To a CRO who may also have in-house or cloud solutions

Comparison



What do you see?



Cloud Computing *for eClinical solutions*

Enables:

- Response to variable workload
- Expand workforce quickly
- Focus on research and development while vendor improves the toolset

Special needs:

- Functions as a collaboration space for joint research projects with partners



Cloud Computing *for eClinical solutions*

Access Data from Any Device:

- As long as the device has reliable access to the internet, all data can be accessed

Modern Business Model:

- Shift from capital expenditure (punctual spend) to operational expenditure (monthly spend when needed) – more predictable profitability
- Earn economies of scale, as the provider has already negotiated these low costs
- The software is always up-to-date, ready to respond





Key to Success: Data Security

- Audit before investment to ensure your requirements are met
- Pay attention to legal requirements across your business geographies
- Enterprise Class Security supports current standards including PCI DSS, HIPAA, HITECH and SCO2
- Disaster recovery and business continuity plans must also be in place, including the use of redundant sites, hardware and networks with a verified business continuity plan provided to you by your eClinical partner. Look for redundant sites that vary in location and geography and outline time requirements to activate stored data

Key to Success: A Service Level Agreement

Allows you to manage the cloud-based vendor appropriately.



- **Verify System Availability Definition**
 - Your eClinical provider should define the system availability of the application in the cloud
- **Service Level Credits**
 - Ensuring that from the beginning the SLA defines what credits you receive when the eClinical vendor does not meet the SLA is very important
- **Support Services Agreements**
 - Available resources to provide assistance when issues arise within a cloud-based application are as important as system availability
 - Consider local language support and define off hours where relevant
- **Response Time Requirements**
 - Define the expected response times when support issues do arise (global where relevant)



Key to Success: Well Defined Roles & Responsibilities

	Customer has a contractual relationship with the provider and/or broker. Consumes services	Provider makes service available to customer	Auditor qualified party able to conduct assessments of services provided
SDLC Policies & Procedures	Accountable, Responsible	Responsible	
Supplier Management & Assessment	Accountable, Responsible	Contribute	Contribute
Information Risk, Privacy & Data Assessment	Accountable, Responsible	Contribute	Contribute
IT Security Evaluation	Accountable, Responsible	Contribute	Contribute
Operational System Control	Informed	Accountable, Responsible	
Validation & Quality Plan (including configuration management, change management, IQ/OQ etc)	Informed	Accountable, Responsible	
Acceptance (User acceptance/Report)	Accountable	Responsible	
SOPs governing infrastructure/platform processes	Informed	Accountable, Responsible	
Identity & Access Management	Informed	Accountable, Responsible	
Back-up & Restore	Informed	Accountable, Responsible	
Business Continuity & Disaster Recovery	Informed	Accountable, Responsible	
Service Level Agreements (SLA/OLA)	Accountable	Accountable, Responsible	



Hat Tip: PhUSE activity

- Cloud phuse working group white paper
- <https://s3-us-west-2.amazonaws.com/phuse/public/PhUSE+Cloud+Doc+18-Nov-2016.pdf>
- Contact Anders Vistrup (avid@nnit.com) or Tony Hewer (thewer@mdsol.com)

CASE STUDY:

A Cloud-based SAS Environment for Growing Pharma Company

Client Scope

- Anticipating a submission cycle with the FDA, this growing pharma urgently needed an analysis environment that would satisfy regulatory scrutiny.
- A legacy desktop SAS model with limited controls was clearly not going to satisfy a regulator, and timing was of the essence, as submission dates were already established.
- The client needed a validated environment, and they needed it now – all without causing undue interruption to business.

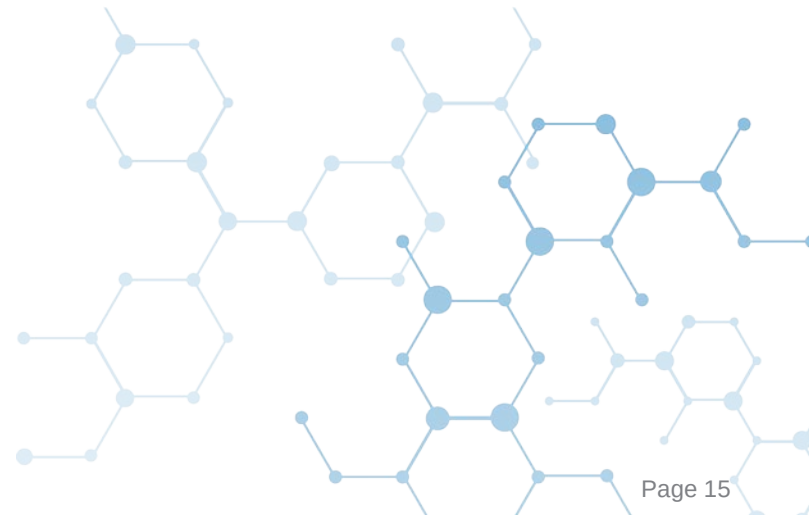
Challenges

- The client needed to be able to start running code in a validated environment ASAP.
- They didn't have time to build an environment internally, and had they been given more time, they lacked the expertise in SAS and validation of SAS to do it right.
- The biostats group, under intense timelines and working long hours, was anxious about any changes that might slow down productivity and put more risk on already tight deadlines.

Adding complexity to a challenging situation, the client had no experience licensing SAS for server use, (prior use was all desktop based), and needed coaching on how to select the right SAS license.

Solution

We had the client online in a validated SAS system in days, and our services team provided adoption support to accelerate the end-user transition. Our team worked with the client to finalize a license transaction with SAS that would be turnkey with our hosted platform.



BACK UP

Platform as a Service (PaaS)



Scalability

Easily increase or decrease your hosting footprint, or leverage the cloud.



Reliability

High-performance, high-availability and security you can depend on.



Systems Experts

Implementation and validation of complex clinical applications for resource-challenged companies.



Life Science Expertise

We understand how life science companies deliver and utilize technology.



Security

Our private cloud hosting facility provides confidence that your clinical trial data is secure and compliant.



24/7 Support

Full-service, help desk and global access to clinical trial data around-the-clock.



Validated Environment

Extensive experience maintaining validated clinical systems.



Rapid Deployment

Bring infrastructure online in days instead of months.

Fully Managed



Tech Support Concierge

Our tech experts will facilitate communications with your software vendors to ensure any support needs are addressed in a timely manner.



Administrative Support

Our team will assist your admins to ensure smooth processes in management, configuration, troubleshooting, analyzing performance, and more.



Business User Support

We'll field any user questions pertaining to the new SAS environment, and ensure they are understanding, using, and navigating it correctly.

**Support
Suite**