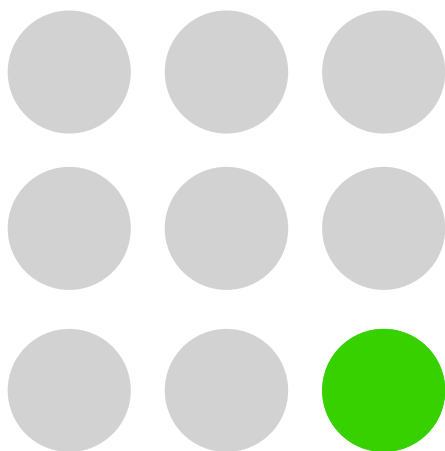

New Approaches to Validation for SaaS-based Clinical Computing Solutions in the Cloud



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Optimizing Clinical Trials:
Concept to Conclusion™

Agenda

- **Key concepts**
- **What does 'CSV in the Cloud' mean to us?**
 - Working with the Cloud
 - Multi Instance (MIST) /Single Instance (SIMT) – Software as a Service (SaaS)
 - Agile software development
 - Computerized system validation (CSV)
- **What does 'CSV in the Cloud' mean ...**
 - ... re. regulatory compliance of product and of supplier services and operations
 - ... to Customer User Acceptance Testing (UAT)
 - ... audits of us as a SaaS provider?

Paradigm Changes

Key Concepts

- **Cloud Computing**

- Infrastructure as a Service (IaaS) - Hardware, servers, storage space etc provided “as a service”
- Platform as a Service (PaaS) - Computing platform (operating system, database, web server) provided “as a service”
- Software as a Service (SaaS) - Application software and data provided as a service

- **Agile software development** – iterative & collaborative

- Build the right thing -> Business value
- Build the thing right -> Quality built in from the start
- Eliminate waste

- **Validation**

- Computerized System Validation (CSV) - Providing documented evidence that the *system consistently* does what it is supposed to do
- User Acceptance Testing (UAT) - Testing conducted by the users to ensure that the *system* meets their needs



Working with the Cloud

“The Cloud” means software that is always available, online, on-demand, and with a user experience that creates increased productivity, at lower cost, and allows for iterative changes over time.

Features include:

- Greater scalability
- Greater availability
- Higher reliability
- Better security
- Self-service
- Configured, not customized
- Continually up-versioned
- Standards-based
- Greater interoperability
- For development efficiency
- Better user experience
- Lower risk

Better and newer techniques around:

- Software development
- Software testing
- Computerized system validation
- Ensuring security and privacy
- Deployment

MIST/SIMT – SaaS - example

Multi Instance

Features

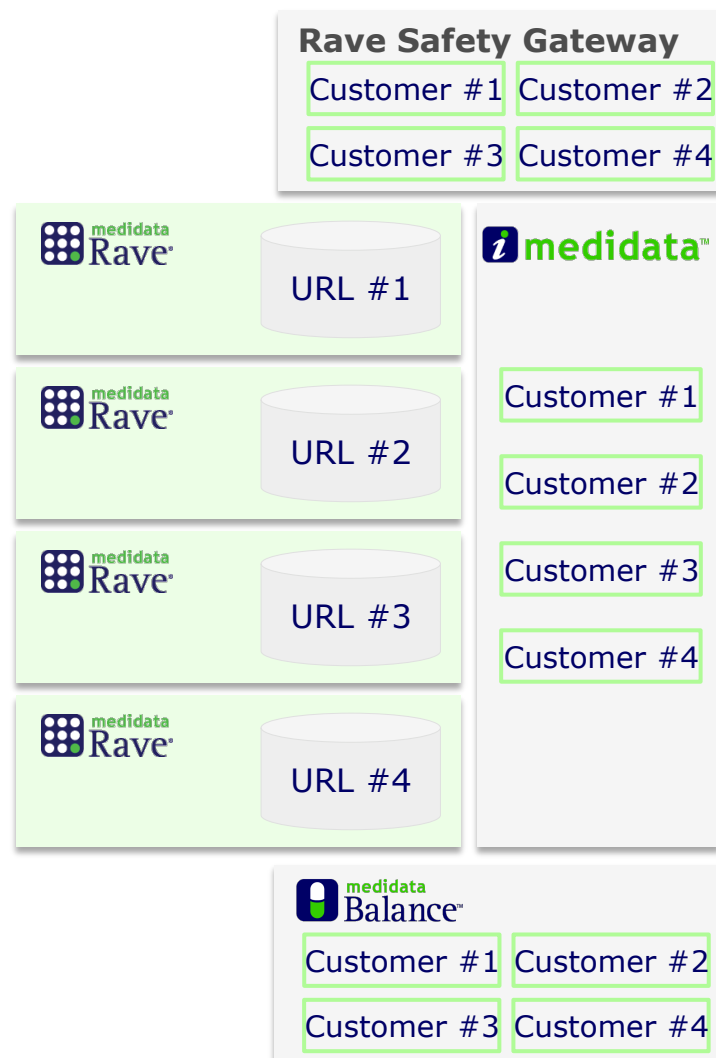
- Each “customer URL” hosted as separate software instance
- Each customer can run different version of software
- Each URL upgraded and supported separately

Benefits

- Better support for complex integrations
- More control on timing upgrades – “study sensitive”

Products

- Rave, CTMS



Single Instance

Features

- Application hosted as single software instance
- Customer data separately partitioned
- All customers use and updated to latest software version

Benefits

- Better “innovate:maintain” development ratio
- Superior operational management
- Less involved upgrade planning

Products

- Balance, Coder, Grants Manager, iMedidata, Safety Gateway



Agile Software Development

- Focused teams represent all areas
- Iterative process
- Frequent verification checkpoints
- Leverages test driven development and automated testing
- Customer value and experience
- Bring features to market quickly



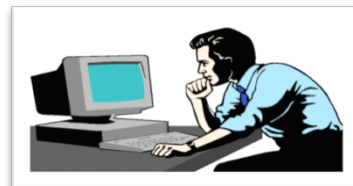
Customers



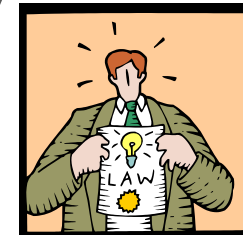
Hosting



Product
Management



Development

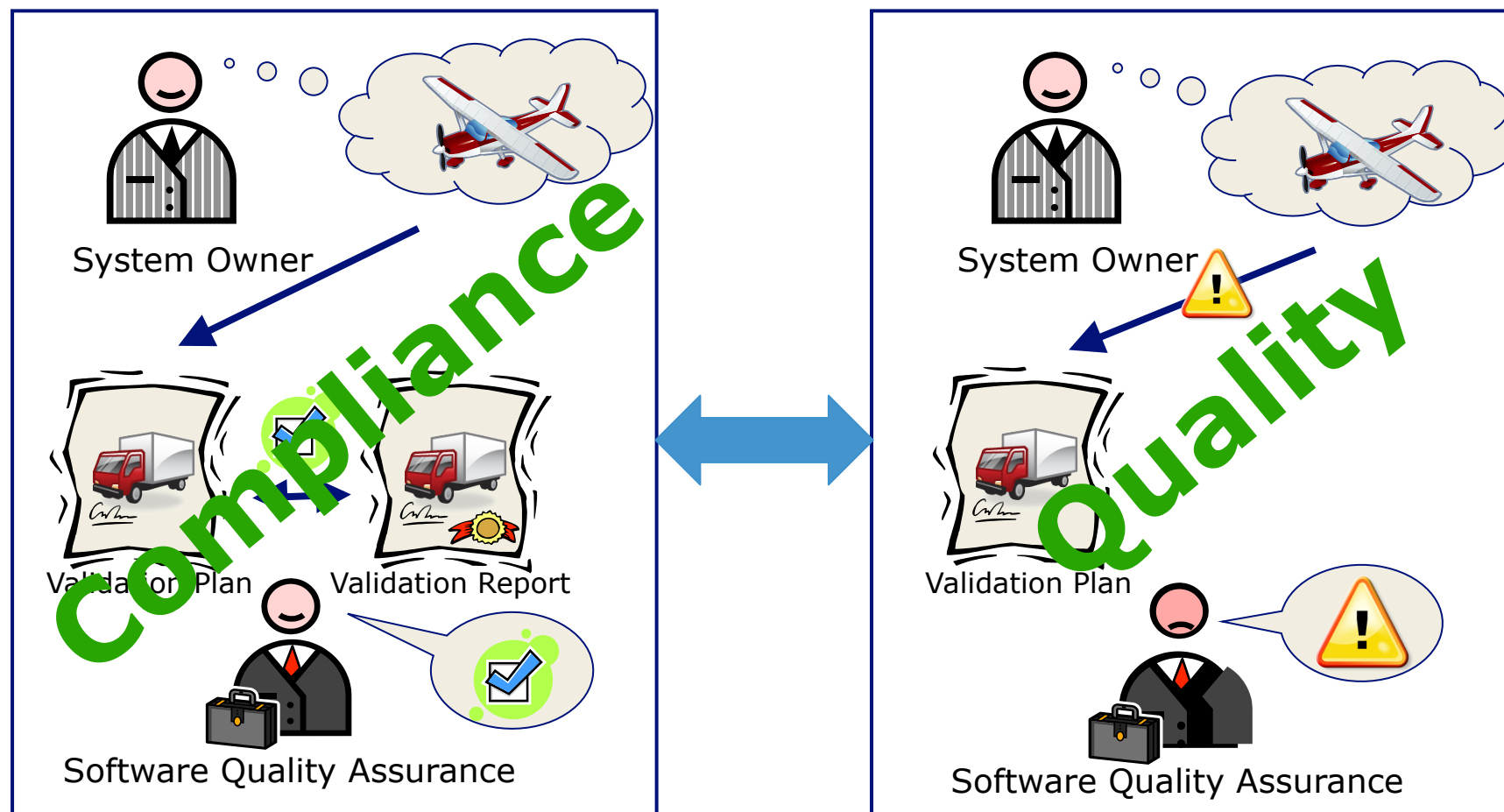


Regulatory



Testing

CSV – Compliance “vs” Quality



SaaS Provider CSV and Customer UAT

It's not just about producing a pretty validation package....



What does this mean for [our] customers?

- **Regulatory compliance of product**

- Does the *functionality* comply with appropriate national and international regulatory requirements?
 - Good Clinical Practice (GCP)
 - Data Protection/Data Privacy
 - Electronic Record/Electronic Signature (audit trail, electronic signature)

- **Regulatory compliance of SaaS provider's operations and services**

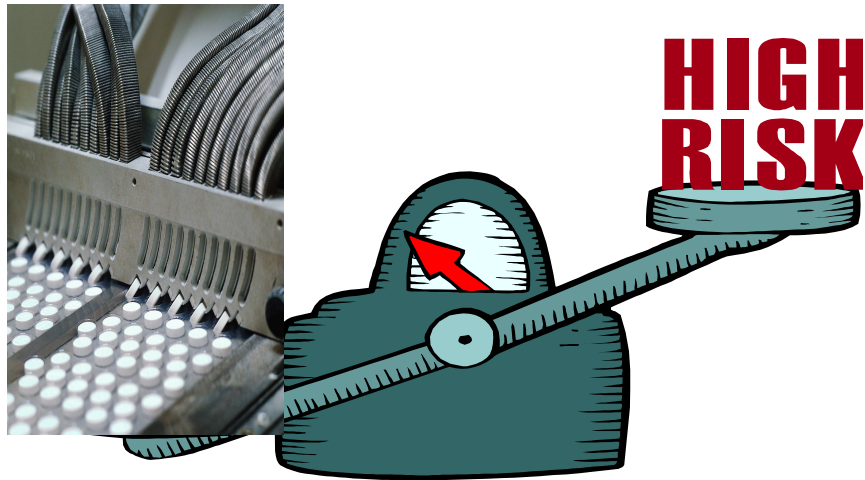
- Is the provider knowledgeable of (and in compliance with) current and evolving regulatory requirements (for product; for operations)?
- Has the provider clearly identified the roles and responsibilities of all parties?

What does this mean for [our] customers?

- **Sensible level of customer CSV/UAT based on the 'risk' of the system**



Preparation of monitoring trip reports



Drug manufacturing

- Consider how widespread the use of the system is within the industry
- Recognize that risk-based approach is accepted and promoted by regulatory authorities (GAMP, ICH, US FDA)

What does this mean for [our] customers?

- **More flexible/innovative CSV (UAT)**
 - Focus UAT on customer use of the system
 - “Customer configuration” of the system
 - Integration with other customer applications
 - Assess the adequacy of the CSV performed by the SaaS provider
 - Leverage the testing performed by the SaaS provider
 - Actively participate in pre-release testing of Single Instance Multi Tenant (SIMT) products
 - Don’t attempt to validate (retest) the entire functional set and code base of the system

What does this mean for [our] customers?

- **More effective/efficient supplier audits – focus on**

- Cloud performance, reliability, scalability, security, privacy
 - How does SaaS provider assess IaaS and PaaS providers?
 - Are there 3rd party certifications (SOC 2 (SAS 70), ISO, CMMI)?
 - How are Disaster Recovery and Business Continuity defined and tested?
 - How is security and privacy of data and software ensured?
- Robustness of development methodology
 - How does development approach improve quality of product (and not just quality of CSV package)?
 - What is the breadth and depth of automated testing?
- Change management
 - Are changes clearly defined? controlled? documented?

- **Reconsider the Audit Method?**

What does this mean for [our] customers?

- **All that said... the “traditional” audit focus still has a place**
 - Quality system
 - Compliance with procedures
 - Training records

Summary – Activities

Customer activities	Our activities
• Define/submit requirements (and enhancement requests) • Participate in pre-release testing (of SIMT products) • Perform UAT (risk-based approach; focus on configuration/integration; leverage supplier testing) • Audit supplier	• Stay current on/help define regulatory positions and industry best practices • Assess requirements (customers, internal, regulatory changes, standards) • Develop system • Maintain/support system • Conduct and document CSV of system, including testing of core functionality • Facilitate hosting of apps and data • Facilitate customer audits (documentation provided electronically; audit webinars/group audits)

Both Customers and us benefit from adoption of more innovative development, implementation, and deployment approaches.

Summary – Benefits

- **Cloud SaaS solutions** – customer can focus on their core business (drug, biologic, device development; contract research services)
- **Cloud PaaS and IaaS solutions** – SaaS provider can focus on their core business (innovative software development)
- **Single Instance Multi Tenant (SIMT)** – more timely adoption/implementation of software updates
- **Agile software development** – improved product quality, introduction of enhanced features in a more timely manner
- **Customer UAT** – focused on unique aspects of customer's implementation (configurations, integrations)
- **Audit models** – customer can take advantage of alternative audit options (audit webinars; group audits)

