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

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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
CSV – Compliance “vs” Quality

System Owner

Validation Plan

Validation Report

Software Quality Assurance

System Owner

Validation Plan

Software Quality Assurance

Compliance

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

• 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

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