Eisai エーザイ hhc ヒューマン・ヘルスケア

The Trials and Tribulations of Implementing a Global Analysis Environment

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PhUSE Single Day Event

Current SAS environment

- Eisai has SAS in three Regions
  - US
    - Unix, PC SAS, Windows Server (32 bit)
    - Unix file server using global directory structure
    - Legacy windows and Unix file systems
    - TLG Reporting system on Unix
  - UK
    - (some) PC SAS, Windows Server (64 bit)
    - Windows shared drive using global directory structure
    - Legacy file shares
  - Japan
    - Migration from SAS Drug Development
    - (some) PC SAS, Windows Server (32 bit)
    - Windows shared drive
      - Starting to implement global directory structure
    - Legacy file shares

Project Overview

- Global SAS Environment Scope:
  - SAS itself and relevant IT system operating SAS (application server, data server, connector) as first priority
  - Software related SAS (eg. JMP clinical, JMP genomics) as lower priority

- General issues in the current global SAS environment
  - Harmonize with regulatory requirements (eg. 21 CFR part 11)
  - Inefficient work globally by different production systems in each region
  - Alignment with other operational systems challenging
  - Difficult to manage outsourced resource
  - SAS license cost is high (about $700K/year)
  - Many versions of SAS (Version 8.2, version 9.13, version 9.2)
  - Difficult to manage upgrade process and associated validation process
  - Operational model has too many hand-offs and manual processes

Project Overview (cont.)

- Benefits (Goals) :
  - – Establish optimal SAS environment in Biostatistics and other related functions.
  - ❑ Improve quality and speed of analysis, moving candidates more quickly through the pipeline
    - ✓ Transform the current Regional working model to a more global one (US/UK/JP/India)
    - ✓ Relevant application systems interactions improved
    - ✓ Consistent working environment (CRO, work at home, outside usage, etc.)
  - ❑ Reduce cost through a global and more efficient license structure

- Scope for organization
  - ❑ Relevant organizations using SAS
    - ✓ Biostatistics,
    - ✓ Clinical Programming (including Accenture in India),
    - ✓ Data Management (including Accenture in India),
    - ✓ Clinical Pharmacology,
    - ✓ Medical Affairs (activities under ‘GCP’)

Goals

2011

- Standardize the global SAS environment to reduce license costs and to increase performance efficiency of running SAS based systems (FY2011)

2012

- Implement Global SAS Environment (2nd QTR) and subsequently modify the Reporting System to run on GAE (3rd QTR)
- Develop a migration plan (1st QTR)
- Complete migration for ongoing studies for Global SAS environment (3rd QTR)

Project Team

- Business Project Manager
- Business Representative
  - PCU Representatives
  - Data Management
  - Medical Affairs
  - Regional Technical leads
- IT Project Manager
- IT Regional Lead
  - UK, US, JP
  - Work stream Members
- Business Owner
- Project Review Committee members

Requirements

- Several Global Meetings
- Review between meetings

1. 21 CFR Part 11, etc	*2. System*	*3. Governance*
1.1 21 CFR Part 11, Annex 11 and Japan guidance	2.1 Data	3.1 Governance
1.2 Global Availability	2.2 CRO	
1.3 Secure Access	2.3 Software	
1.4 Versioning	2.4 audit	
1.5 Archiving	2.5 Governance	
1.6 Audit Trial	2.6 Disaster Recovery	
1.7 Electronic signature	2.7 System Support	

Review Criteria

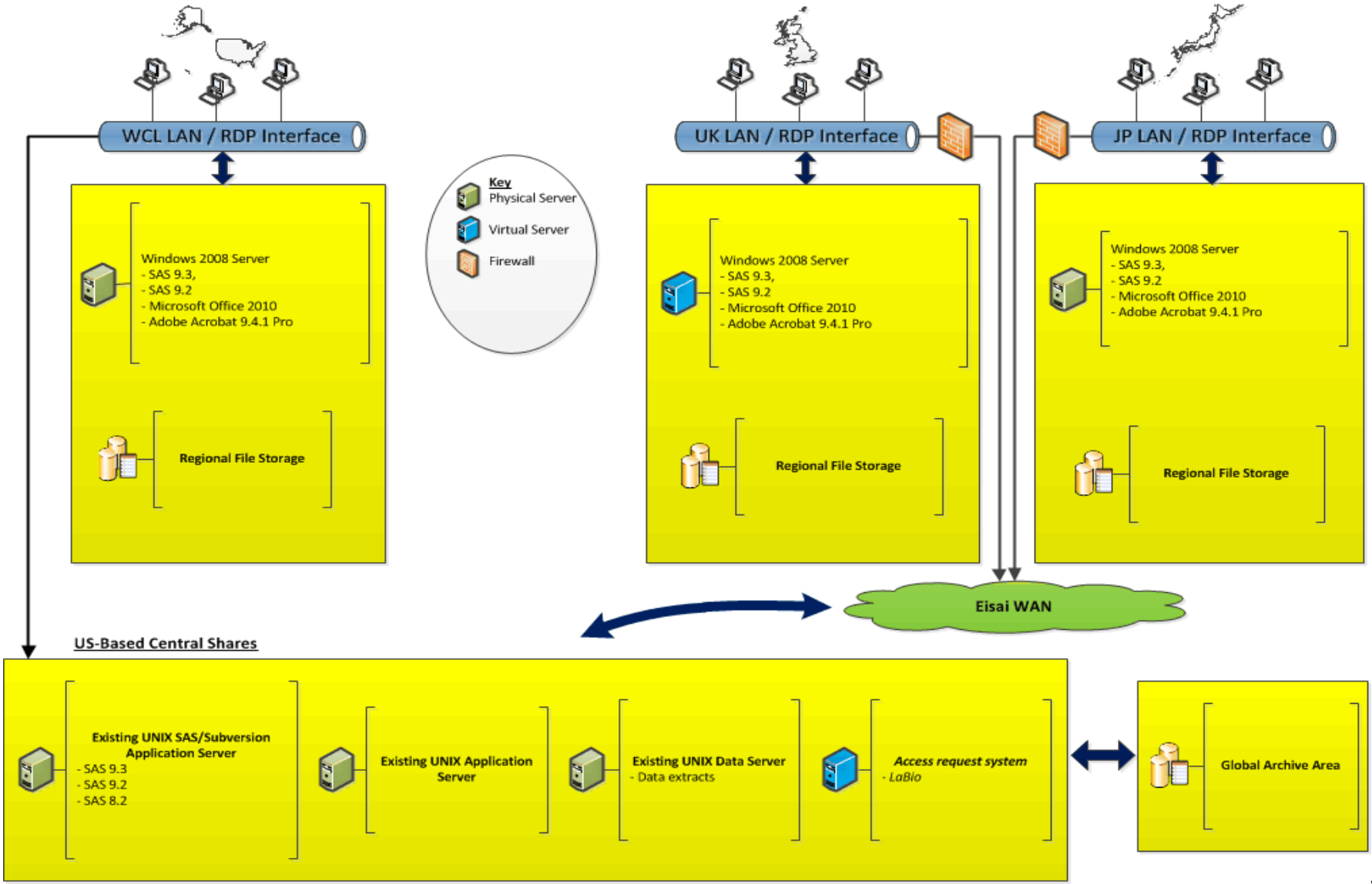
- Priority Categorization:
  - H - Requirement to be met in Release 1
  - M - Requirement to be met in Release 2 or Release 3
  - L - Requirements to be met in Release 3

The criteria used to assess the design is as follows

- Meets or satisfies 100% of our Requirements ranked with a High priority.
- Meets or satisfies at least 50% of our Requirements ranked with a Medium priority
- Meets as many of the Low priority as possible.
- Implemented within our project budget.
- Completed within the timescales for the project
- Conforms to all Eisai Technical Standards.

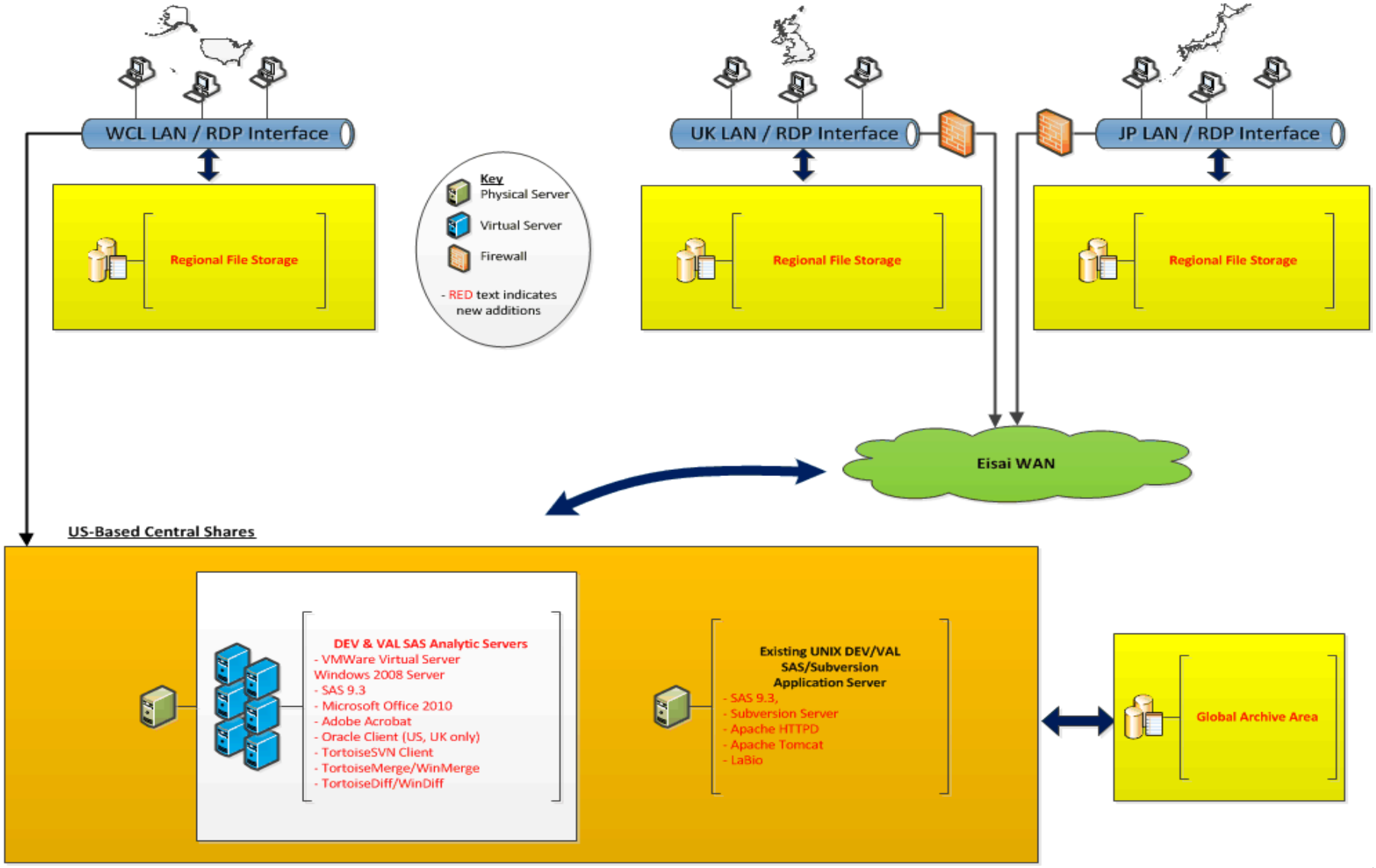
Production Design

***Figure 1*: PRODUCTION ENVIRONMENT**



Development & Validation Design

***Figure 2:* DEVELOPMENT & VALIDATION ENVIRONMENTS**



Proposed Design Review

Criteria	Criteria met by design?	Comments
High	41 / 51 7 n/a 2 no 1 unknown	7 n/a are governance 2 no – Disaster Recovery (separate Policy) & Electronic Signatures (discussion with CQA) 1 unknown – IT policy
Medium	13/ 19 2 partial 3 n/a 1 unknown	2 partial – technically possible, managed by process. Using previous versions & different versions 1 unknown – external use by CRO members; separate project 3 n/a are governance
Low	3 / 9 4 n/a 1 no 1 possible	1 No – upstream audit capability 1 possible – promote and demote grouped items

Additional Requirements

- Data Access Control
  - System available for Unix and US Legacy system
  - No global system available for Windows
  - Manual use in UK and JP

- Data Transfer Utility
  - Data Transfer to regions
  - Archiving
  - Restore Archived Files

- Version Control
  - Business defines the usage
    - What is to version controlled
    - What wont be version controlled
    - When to start

Version control - Business

- What is to be version controlled
  - Annotated CRFs
  - SDTM/ADaM specifications
  - SDTM (Update) programs
  - ADaM Programs
  - TFL Programs

- What won't be version controlled
  - Data will not be version controlled
    - Data transfer utility used to copy and audit trail movement
    - Recreate data by rerunning programs

  - TLF outputs
    - Recreated by running programs

When will VC Start - Outsourced to CRO

- DRAFT delivery
  - TLGs

- FINAL delivery
  - SDTM & ADaM
  - TLGs
  - All programming
  - QC
  - Documentation

- Version Control
  - Just Archive
  - Restore and start VC if amendment needed in the future

When will VC Start - In-House Programming

- SDLC
  - Development
  - Validation
  - Production
  - DRAFT delivery
  - FINAL delivery

- Version Control
  - Start when passes QC

12 months in…where are we?

- Requirements complete (September 2011)
- High level design (November 2011)
- Business process complete (March 2012)
- Technical Architecture Document (TAD) complete
  - Multiple versions
- Validation Plan complete
- Sandbox servers built (operating system)
  - Sandbox for Japan may need to be reinstalled
- Vendor Chosen for SAS install
  - Should start 2nd July.
- Data migration plan in review

Why the delays?

- Changes in IT personnel
  - Complex TAD
  - Revisited three times
  - Two rounds of Validation Plan review and update
- Regional IT
- Business Member availability
  - May cause future delays
- Split into Sub projects
  - Migration plan
  - Servers and SAS Install
  - Access Control
  - DTU & Subversion

Questions?