

MEDICAL RESEARCH O365/SHAREPOINT ONLINE UPGRADE

OVERVIEW

1. Description

This upgrade will transfer all on-premises SharePoint 2010 content to a Microsoft-hosted, cloud-based, multitenant O365/SharePoint Online environment. After a short grace period, the on-premises SharePoint 2010 environment and all ancillary support technologies (e.g. the [REDACTED]) will be retired.

2. Infrastructure Scope

These items are considered part of the core infrastructure required to support the Clinical Research upgrade:

- The O365/SharePoint Online environment
- Site Collections (i.e. projects)
- Sites (i.e. Studies)
- Document Libraries/Lists (all versions)
- Permissions
- Audit Event Logging
- Content Types
- Managed Metadata Services (i.e. tagging service)
- Remote Access
- Managed Metadata Sync from [REDACTED]
- [REDACTED] (* if required)
- QA documentation for the creation of qualified infrastructure items
- Data transfer from the on-premises environment to SharePoint Online

3. Application Scope

These items are considered applications or customizations:

- InfoPath Forms
- SharePoint Workflows
- JavaScript menus
- Custom Search Query Web Parts
- Alterations to page layout via SharePoint Designer

4. QA Scope

O365/SharePoint Online is hosted as a cloud service, negating the need for IQ/OQ testing (i.e. software installation, patch management, hardware changes, etc. are outside the purview of ████████ I.T.). The following PQ testing will be required:

- Successful data transfer
- 21 CFR Part 11 core functionality testing (controlled document management, audit/permission testing, data recovery, etc.)
- User interface testing (views, web parts, JavaScript menus, etc.)
- Form/Application testing
- Workflow testing
- Batch Process testing (e.g. ████████)
- QA documentation creation and execution for all tasks

5. R.A.C.I. Matrix of Roles and Responsibilities

The upgrade will primarily involve four teams: Clinical Systems, R&D Systems, SharePoint Infrastructure and SharePoint Applications. Using the R.A.C.I. matrix, the roles and responsibilities are:

Scope	Clinical Systems	R&D Systems	SharePoint Infrastructure	SharePoint Applications
Infrastructure – environment creation, content transfer	C	C	R,A	I
Application – upgrade/reconfiguration	R,A	A	I	R,C
QA – PQ generation and testing	C	R,A	I	I

R	Responsible — Person doing the work on the activity
A	Accountable — Person with decision authority
C	Consulted — Key stakeholder who should be included in the decision or work activity
I	Informed — Needs to know of the decision or action

6. Governance

The new environment will operate with these policies except where there is a defined exception for a business reason:

- All pages will display a “VALIDATED” watermark in the background to inform the end user they are in a controlled SharePoint area.
- Content Types will be hosted globally and will not be permitted to be created locally.
- Lists will have versioning enforced.
- All change events will be audited.
- View events will not be audited.
- Creation of new infrastructure items, e.g. sites, document libraries, etc., will be done manually or via templates.
- Large batch copies of items, e.g. site collections, etc., will be done via the ████████ tool.

7. Out of Scope

The following items will not be addressed as part of the upgrade and will be retired as appropriate:

- [REDACTED]
- On-premises Audit log data
- [REDACTED] (retired EOY)
- Controlled test environments
- [REDACTED]
- [REDACTED] ([REDACTED])
- [REDACTED]

8. Upgrade Plan

The upgrade will require this preparatory work:

- SharePoint Infrastructure will develop and test upgrade processes for all items in the infrastructure scope.
- SharePoint Infrastructure will implement all necessary infrastructure required for integration with on-premises systems (e.g. [REDACTED]).
- Clinical Systems will perform a comprehensive inventory and analysis of all content, determining what content, infrastructure and application components will require upgrading.
- SharePoint Applications will review all forms and workflows and create an upgrade plan (if required).
- R&D Systems and Clinical Systems will work with [REDACTED] to develop comprehensive QA processes to test whether an upgrade has been successful.

Once the underlying infrastructure is in place, a typical upgrade would work as follows:

- SharePoint Infrastructure will file a change control (CC) for the targeted project upgrade (e.g. [REDACTED], [REDACTED], etc.). The team will then provision the O365/SharePoint Online site collection.
- Clinical Systems will perform a full inventory of the site collection and will work with SharePoint Infrastructure to develop the appropriate mappings from the on-premises environment to SharePoint Online.
- SharePoint Infrastructure will do a first-pass copy of data.
- Clinical Systems will review the site and make any customizations necessary to achieve the desired look and feel, etc. If required, SharePoint Applications will implement any necessary application changes.
- At the scheduled time on the upgrade day, SharePoint Infrastructure will disable access to the on-premises site. An incremental/delta copy of the on-premises environment will be made to SharePoint Online. Once this copy is complete, SharePoint Infrastructure will notify the team via email.
- Clinical Systems and R&D Systems will perform a final QA of the site collection, which will include execution of the PQ test. Upon successful completion of these tests, they will notify the team via email.
- SharePoint Infrastructure will redirect all users to the SharePoint Online site. SharePoint Applications will assist by changing links in any affiliated portal sites (e.g. the root-level [REDACTED] site).