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Strategic Roadmap for Content Document Management

August 31, 2017

AGENDA

1. Project Overview
2. Findings & Recommendations
3. Strategic Roadmap
4. Appendix

01

Project Overview

Project Overview

GOALS

- Identify top-priority issues in consumer regulatory document management; focus on activities relating to planning, authoring, publishing, and archiving Health Authority (HA) submissions

- Outline a roadmap for solving those issues

METHODS

- Review existing research relating to regulatory document management

- Interview 15 participants (see Appendix) in Regulatory Affairs, Regulatory Operations, and other functional groups in NA, EMEA and APAC on:
  - Document Search & Platform Navigation
  - Data Sharing
  - Planning
  - Authoring Documents
  - Building CTD and eCTD Submissions
  - Reviews and Approvals
  - HA Submissions, including Validation
  - Tracking
  - Archiving

02

Findings & Recommendations

Datacentricity
Searchability
Systems Optimization
Source of Truth
Tracking & Collaboration

The Document Management Process guided analysis

PLAN

- Gather submission information from functional groups
- Update & review trackers

PREPARE

- Upload documents into Connect
- Author or format documents using HA templates

BUILD

- Create submission based on dossier plan

MAKE AVAILABLE

- Publish and validate submission
- Review before submission to HA

ARCHIVE

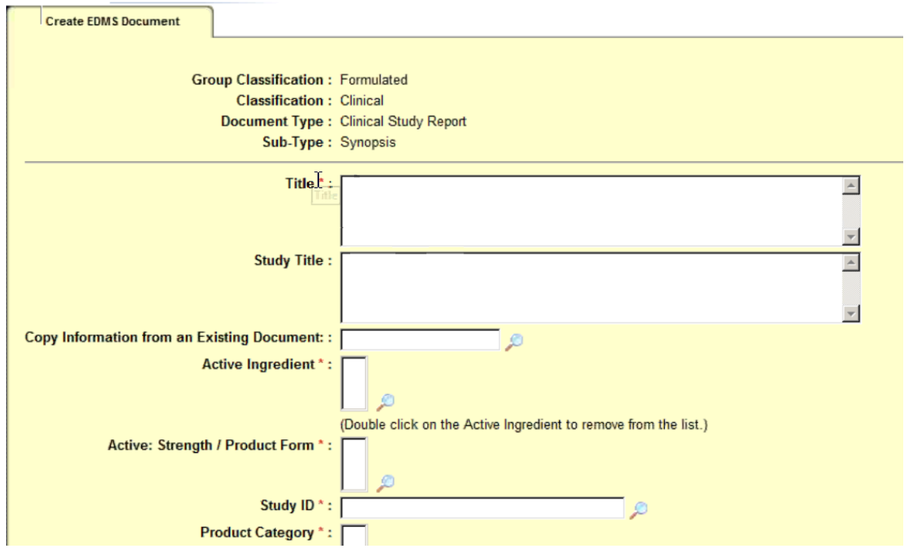
- Upload submission or approval into Connect
- Lifecycle management
- Update trackers
- Search

FINDINGS & RECOMMENDATIONS

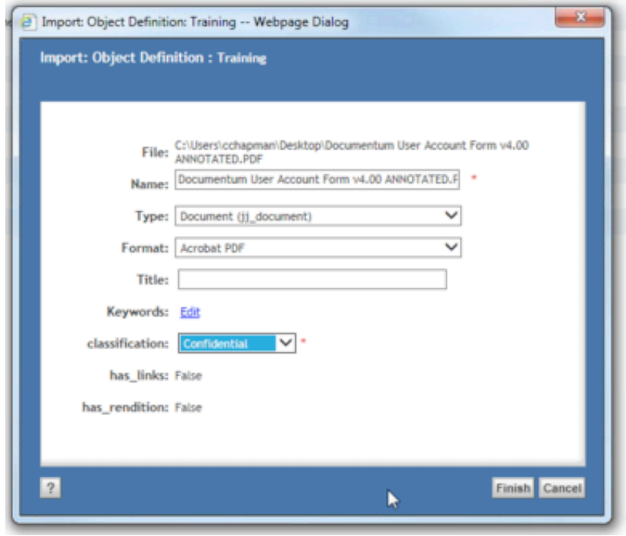
Datacentricity

Uploading documents in Connect requires too much manual input

- RAs too busy to take time to manually fill out many required free-text fields
- Multiple free-text fields increases potential for input error and reduces data quality
- RAs avoid uploading documents to Connect when possible
- EMEA RAs prefer Documentum which has drag-and-drop uploading and fewer fields, which prefill certain data



New document upload in Connect



New document upload in Documentum (EMEA)

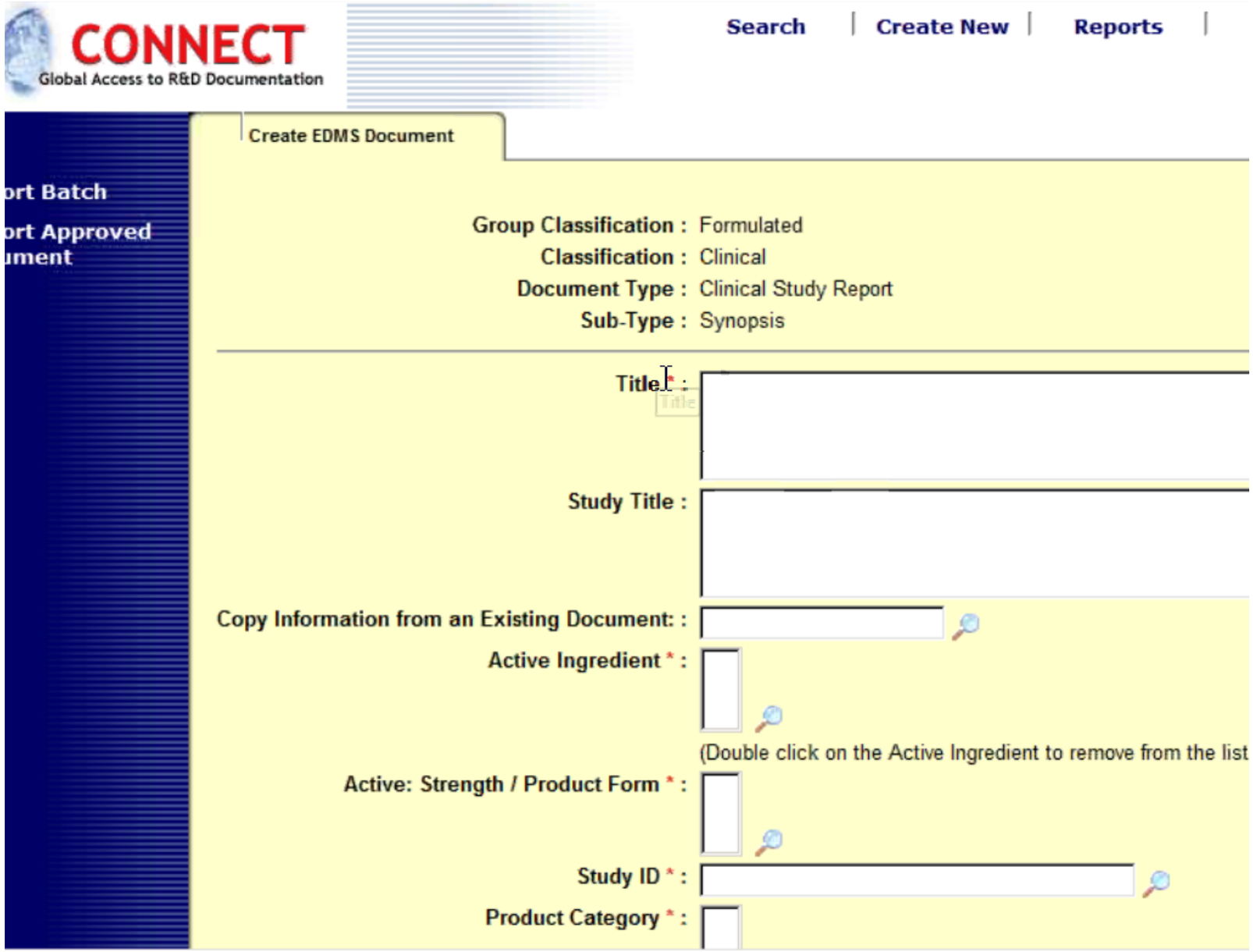
Ease uploading burden in Connect

- Change free-text fields to dropdowns in Connect
- Pull relevant metadata from uploaded documents to prefill Connect fields
- Add drag-and-drop uploading to Connect

“We need to get everyone on the same page.”

Lack of data and file naming standards leads to poor organization and findability

- Local markets have their own standards or none at all
- Poor understanding of what fields in Connect mean or how to fill them out
- Documentum (EMEA) relies on folder structure to associate metadata but no metadata is attached to the document itself



New document upload in Connect

RECOMMENDATIONS

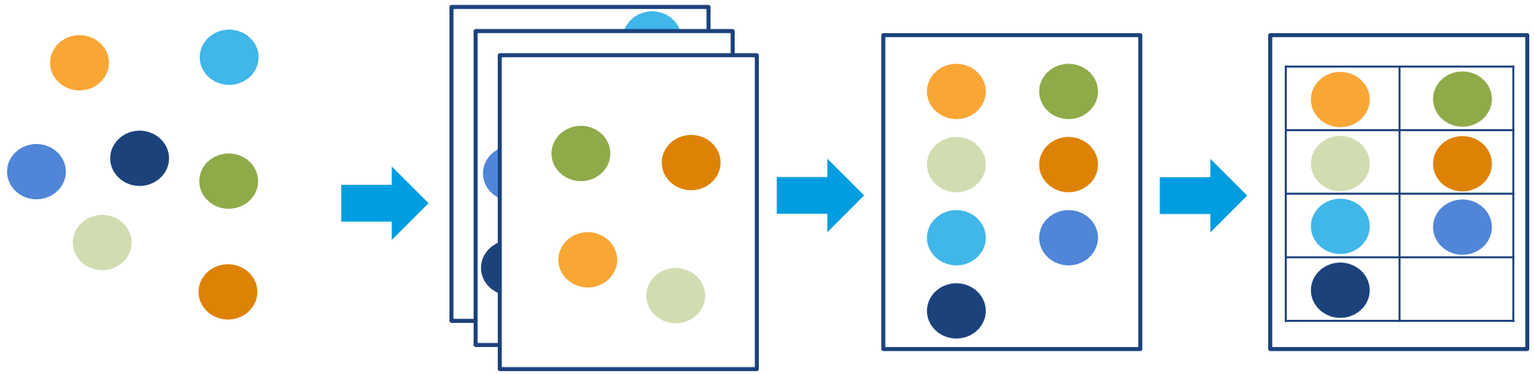
Establish consistent data standards

- Clean up metadata in Connect by locating missing values, removing duplicate values, and standardizing keywords
- Establish global standard for folder structure
- Establish global metadata standards and file-naming conventions for uploading documents in Connect and future CDM

"We need alignment on minimum metadata structure and to make sure we can leverage this for future migration into a true global repository system."

Data is translated into documents multiple times over submission process

- Functional groups create documents from data, which RAs reformat based on HA requirements, so Publishing can finally create an eCTD document



Data from various company systems

Authors in different functional groups create documents from data

RAs format documents based on HA templates

Publishing formats document into eCTD structure

Manage data not documents

- Interconnect systems (such as Product Development, Toxicology, Clinical Safety, etc.) so users can pull relevant submission or dossier content from any company system
- Develop a global data-centric model for authoring, saving, accessing, and reusing content: documents are collections of content, and content has a lifecycle that requires management

"We need a process that lends itself to normal regulatory compilation and authoring but also allow the system to extract data."

Focus on documents over data means information is locked

- Data stored in static PDFs cannot be searched or used
- Stymies efforts to standardize data collection and comply with future regulatory reporting requirements (i.e., IDMP)

"IDMP only works with a central data repository…we need to find a way to extract the data from all our documents."

Build processes for turning documents into data

- Require OCR for all PDFs added to system
- Implement semi-structured authoring (e.g., SPL document-structure templates) to bridge gap between documents and data

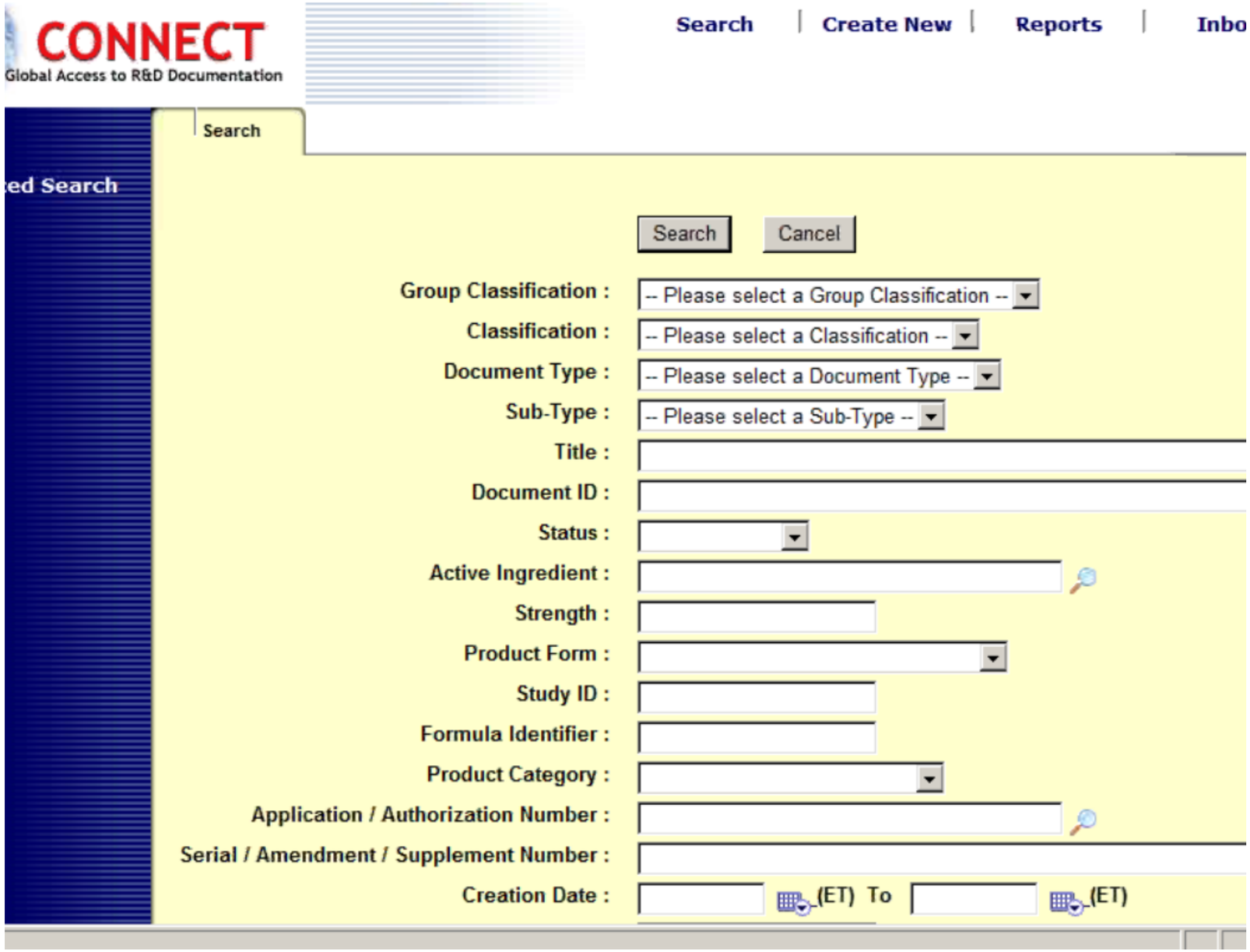
"Rules and processes around a system are just as important as the system itself for success."

FINDINGS & RECOMMENDATIONS

Searchability

Finding documents in Connect is difficult

- Users do not realize that Connect has multiple search functions that search only certain fields, and get frustrated when they cannot find what they need
- Search results not filterable
- RAs prefer to navigate via an organized folder structure, but Connect's is hidden
- RAs rely on lists of J#s to find documents they need



Search in Connect

Revise Connect to match user expectations

- Expose folder structure in Connect for easy browsing
- Add sortable and filterable search results in Connect
- Collapse multiple search functions in Connect into a single faceted search

“If it’s easier to use, more people will be inclined to use it.”

FINDINGS & RECOMMENDATIONS

Systems Optimization

System limitations frustrate users

- Cannot view multiple documents (e.g., submission checklist, status tracker, etc.) simultaneously within document systems, so must download them to desktop
- Cannot handle certain document types (e.g., datasets) or very large files
- Word version in Connect different than desktop version
- eCTD templates in Docubridge not current because of budgeting reasons

“Nothing. Works. Ever.”

Revise systems to meet users' needs

- Update Word in Connect to current desktop version
- Update eCTD templates in Docubridge
- Expand sizes and types of files Connect and Documentum (EMEA) can handle
- Add functionality to Connect and Documentum (EMEA) to simultaneously view multiple documents

"Need a system that people will actually want to use."

Poor system performance adds roadblocks to work processes

- Systems kick users out without warning
- Extremely slow speeds in Connect and other global systems
- Bugs in Connect make users lose faith in the system and they avoid using it

“Connect is SO SLOW.”

Restore faith by fixing system pain points

- Review Connect IT tickets and fix bugs
- Add logout warning to Connect and Documentum (EMEA)
- Improve speed and reliability of Connect and other company systems

“We need fast performance.”

FINDINGS & RECOMMENDATIONS

Source of Truth

FINDINGS

There is no one system to access all needed documents and information

- RAs expect to find entire HA communication and submission history of a product in one place, but must look in multiple systems or physical records to find everything
- Templates required for regulatory documents not located in one place
- Multiple logins required for multiple systems

"You can't work centrally: if global person wants to find something out about a product, they will likely need to go to someone at the local market."

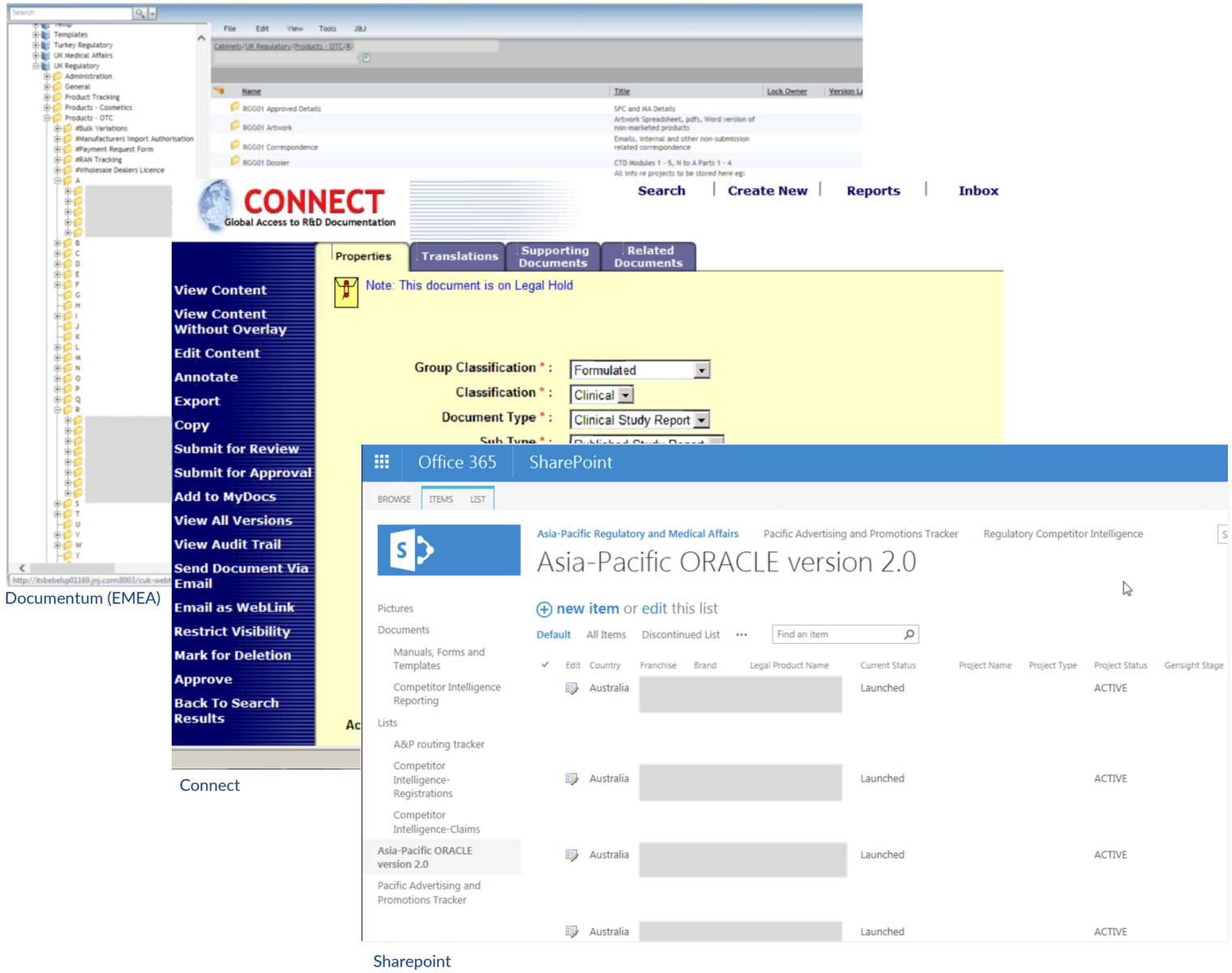
Create a single place to find regulatory information

- Add single sign-on for all company systems
- Collect all submission, document, and contact history on a product in a single place (e.g., Manage Products in RegPoint)
- Implement “pay as you go" migration of historical documents so they are added to the CDM as needed
- Incorporate all templates and SOPs into a single CDM

“Everyone needs to participate in the system for it to be a source of truth.”

Regional document repositories create siloed information

- Local markets use their own systems because global system does not account for their specific needs (e.g., requiring fields that are not relevant to their market)
- Documents remain in local repositories and cannot be accessed globally: only local markets know where and how documents are archived



Documentum (EMEA)

Connect

Sharepoint

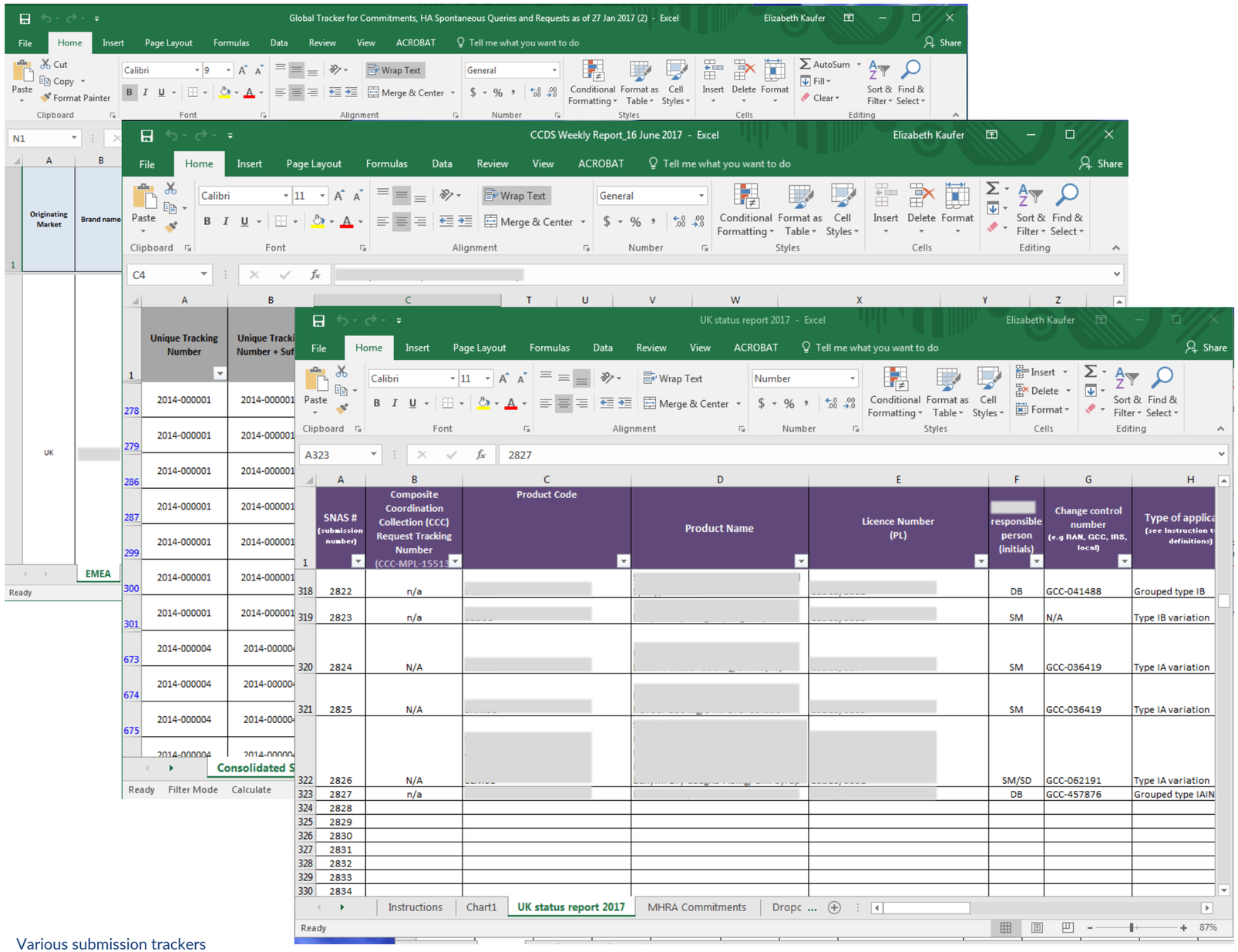
Ensure global CDM meets local needs

- Move to a single, global CDM
- Design CDM that can accommodate local variations by gathering local requirements from all markets
- Map global data fields to local terminology (e.g., “Registration Number” to “License Number”)

“Want to it to be easier to access any information on any product in the world.”

Unconnected systems add extra submission steps and increase potential for delay

- Must update multiple systems and trackers with the same submission and approval information
- Same data and documents moved among multiple systems during submission creation
- Systems are not linked (e.g., Docubridge does not link back to Connect, GCC does not link to Connect) so users must search multiple systems and upload same documents multiple times



Various submission trackers

Link company systems together

- Connect CDM to company systems to allow users to access needed documents in context (e.g., viewing a submission in Manage Products)
- Use CDM to pull relevant content from directly company systems into submission, dossier or other regulatory templates

"I want there to be one place I can find everything."

FINDINGS & RECOMMENDATIONS

Collaboration & Tracking

Current systems do not facilitate collaboration

- Track changes and commenting functionality do not work as expected in Connect
- Multiple users cannot be in a document at the same time; review process takes longer because users must spend time coordinating access
- Publishing lacks visibility into what work is upcoming and cannot adequately plan for resourcing needs

"Everything happens last minute in Publishing. We spend all our time fighting fires."

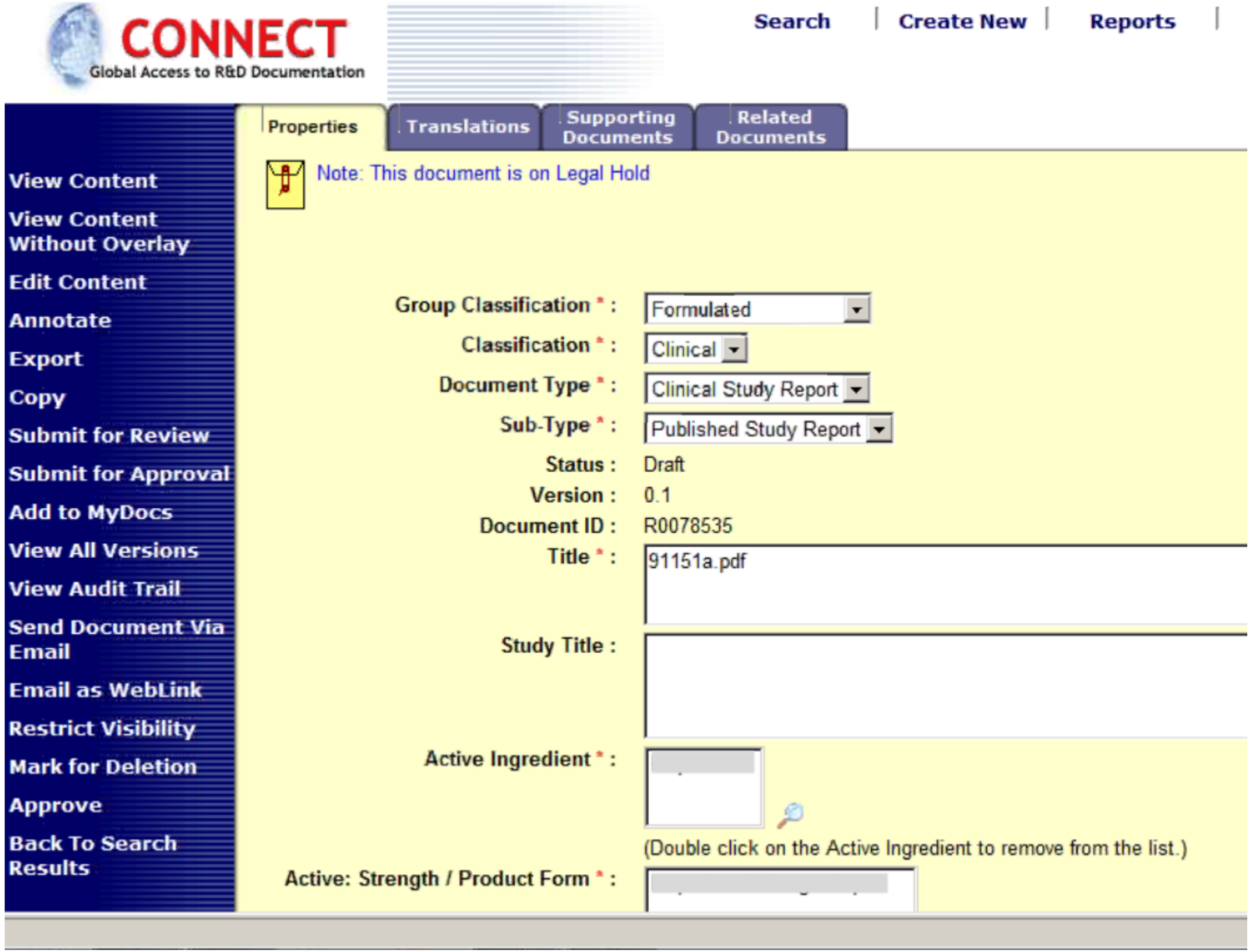
Simplify shared planning and reviewing

- Add “share via hyperlink” functionality to Connect and Documentum (EMEA)
- Create shared submissions tool for RA and RegOps (e.g., Submissions, HA Query Tracker in RegPoint) visibility into upcoming submissions

“I want one system that could do more of the process, like reviewing, validating, and publishing.”

Access to Connect is limited and time-intensive

- Reviewers who need to view documents do not have access to Connect
- Required training to get access to Connect takes a lot of time



Document properties in Connect

Make it easier for users to get access to CDM

- Ensure users can access CDM with minimal training
- Create a mechanism for external users to review documents (e.g., limited user permissions)

“Want something so easy to use you don't need to be trained on it.”

Current systems do not facilitate reporting

- Connect and Documentum (EMEA) cannot automatically create internal reports for tracking metrics and reconciling data
- Reports must be compiled manually, adding to workload
- Lack of insight into workload makes planning and resourcing more difficult
- Difficult to verify maintenance of data standards

"Metrics are really valuable for process improvement."

Use metrics for process improvement

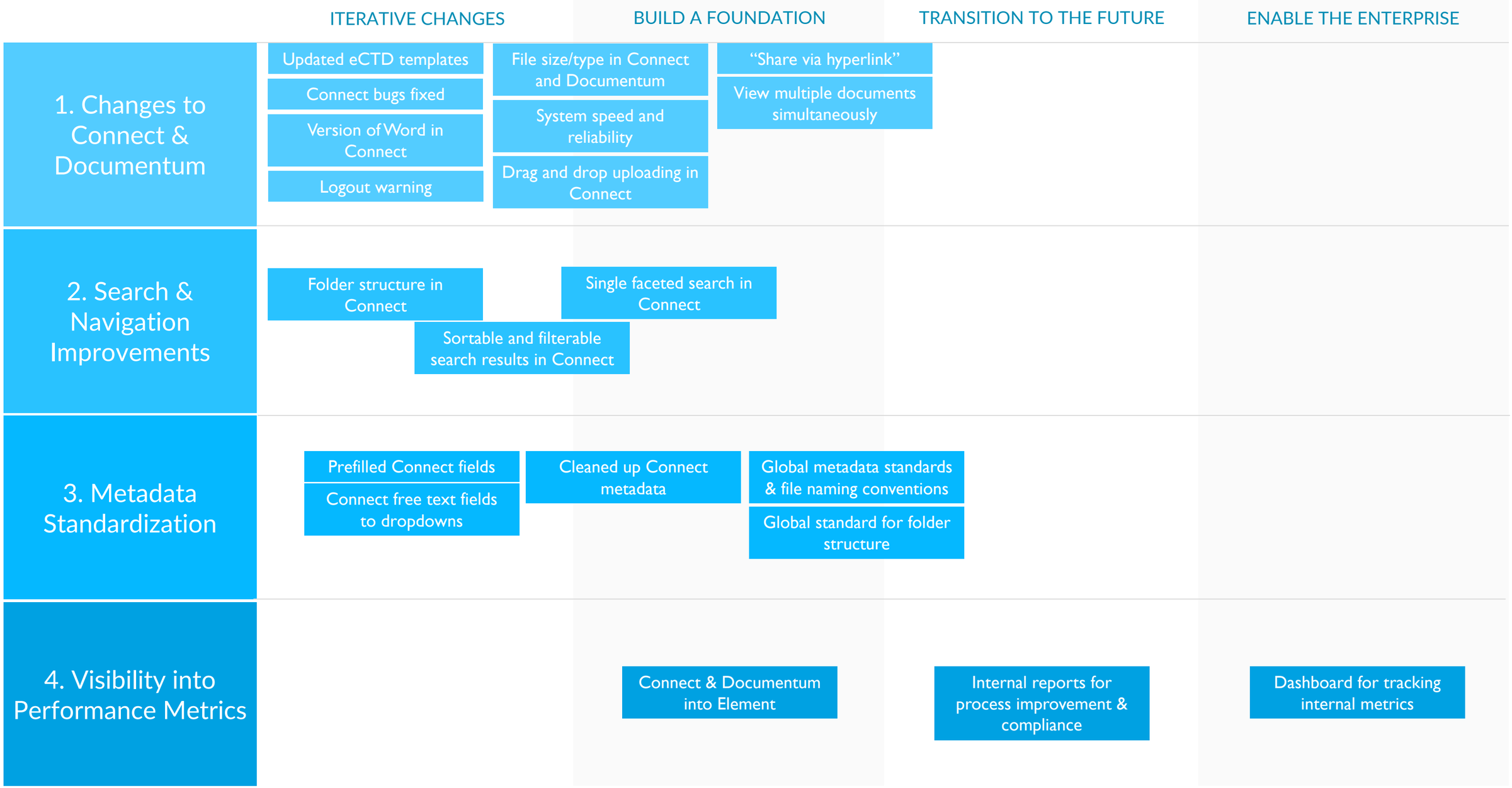
- Incorporate Connect and Documentum (EMEA) into Element for reporting and traceability
- Track compliance with metadata standards through internal reports
- Develop a dashboard for tracking internal metrics

"Anything a user does that's not core to the business should be automated."

03

Strategic Roadmap

STRATEGIC ROADMAP & TRANSITION PLAN



STRATEGIC ROADMAP & TRANSITION PLAN

	ITERATIVE CHANGES	BUILD A FOUNDATION	TRANSITION TO THE FUTURE	ENABLE THE ENTERPRISE
5. Link to Content Sources		Interconnect company systems	Connected CDM to access documents in-context	CDM pulls content directly from company systems
6. Centralized Submission Tools		All product documents & information in one place Single Sign-On	Shared submissions tool for RA and RegOps	
7. Global Data-Centric Model		Global data-centric model development "Pay as you go" document migration OCR for all PDFs	Semi-structured authoring	
8. Global CDM			Single, global CDM Templates and SOPs into a single CDM Access to CDM with minimal training	Local requirements for single CDM Global data fields to local terminology Review for external users to review documents

Projects to improve the Document Management process


PLAN | PREPARE | BUILD | MAKE AVAILABLE | ARCHIVE

1. Changes to Connect & Documentum

2. Search & Navigation Improvements

3. Metadata Standardization

4. Visibility into Performance Metrics

2. Search & Navigation Improvements

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4. Visibility into Performance Metrics

5. Link to Content Sources

6. Centralized Submission Tools

7. Global Data-Centric Model

7. Global Data-Centric Model

8. Global CDM

04

Appendix

APPENDIX

Participant Breakdown

Regulatory Affairs

Regulatory Operations

Other Functional Groups (e.g., CMC)

User Requirements for Future CDM

PLAN

- Change control
- Metrics for internal reports
- Shared planning tools between RA and RegOps
- Linked systems

PREPARE

- Versioning
- Semi-structured authoring
- Permission controls
- Track changes
- Check in/out
- User-friendly interface
- Extracting data directly from other systems (e.g., Capri)

BUILD

- Templates
- Working files
- Fast system speed
- Reliability

MAKE AVAILABLE

- Publishing tool
- Review and approval
- Share via hyperlink
- Commenting
- Multi-user collaboration
- Notifications with user-set preferences

ARCHIVE

- Global folder structure
- Easy upload/drag and drop
- Favorites
- RIM
- Single source for all data & documents on a product
- Prefilled metadata fields
- Map local fields to global
- Tagging
- Easy to search
- Metadata & file naming standards
- Exposed folder structure
- Easy to move documents & data between systems
- Single repository for documents & SOPs
- Copy metadata from existing files
- Data cleanup & reconciliation
- Customized for local markets
- View documents in context

CDM Best Practices

PLAN

- Defined KPIs for measuring system success
- Audit trail
- Integration with existing systems

PREPARE

- Semi-structured authoring
- Automated workflows where appropriate
- Integration with MS Office
- User-friendly interface
- Role-based view & edit permissions
- Version control and history

BUILD

- Document templates
- Folder templates

MAKE AVAILABLE

- Access for external parties
- Clear hierarchy for decision-making
- Customized alerts

ARCHIVE

- Easy, fast to access a document
- Consistent folder structure
- Consistent file naming
- Metadata standards
- Automatic data capture to minimize data entry
- Secure data
- Drag & drop uploading
- Store any file format
- Minimal number of data input fields to be useful
- OCR-scanned documents
- Tagging
- Document retention policy