Using Vault to Manage and Report on Submission Status

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About Intercept

- Focused on the development of therapies to treat chronic liver and intestinal diseases

- Rapidly growing
  - +200% headcount in the last year
  - Currently have > 100 Full Users
  - Two Sites (San Diego & New York)

- Headed towards first Marketing Applications
  - Managing two INDs (in-house)
  - Utilizing Submissions outsourcing partner for NDA and MAA

- Utilizing Veeva across a number of areas
  - Submissions, QualityDocs, PromoMats, MedComms, CRM
Agenda

1. Authoring and workflow-related configurations
2. Binder-related configurations
3. Dashboard and reporting examples
4. What’s Next
Authoring Lessons Learned

- “Out of the Box” was a good start, but…
  - Our processes were being built in parallel to implementation
  - Initial configurations did not ultimately match our business processes

- Heavily used groups (vs. individuals)
  - Across both internal and external contributors

- Timing of author training critical to ensure successful transition
  - Needed refresher training for “legacy” authors
  - New user training is completed during the first week;
  - Follow-up after initial training is helpful
To match business processes, created custom workflows in addition to authoring:

- Created QA/QC workflow separate from Editing or Review workflows
  - Select QA/QC group (one person from the group accepts) or an individual of the QA/QC group
  - Select the QA/QC Review Focus
    - Editorial
    - Internal Consistency (Content/Data)
    - External Consistency (Content/Data)
    - Data/Numbers Only
  - Select the QA/QC Review Type
    - Abbreviated (portion of the document)
    - Full (all of the document)
To match business processes, created custom workflows in addition to authoring (continued):

- Created Formatting workflow separate from Editing or Review workflows
  - Select Formatting group (one person from the group accepts)
  - Author has the ability to send to formatting at any time by noting Full or Partial Format
  - Regulatory Operations will select the appropriate completion of the formatting task
    - Formatting complete (document is locked and ready for approval workflow)
    - Formatting Partially Complete (document will stay at draft state and editing can continue)
    - Formatting Not Complete

- Regulatory Operations has the same permissions as Authors
  - Assist with workflows
Authoring Configurations (continued)

Document Lifecycle Flow Chart

- **Owner / Initiator**
  - **Authoring / Review** ("Editing" or "Review" workflow)
    - Owner drafts document and sends for Content Review using "Editing" or "Review" Workflows
  - **Quality** ("QA/QC Review" workflow)
    - Owner prepares and sends document for QA QC
  - **Formatting** ("Formatting" workflow)
    - Owner revises document and sends to RO for final formatting
  - **Approval** ("Approval" workflow)
    - Owner sends formatted, Approval Ready document for approval

- **Collaborators / Editors**
  - **Content Review Cycle(s)**
  - **QA Document Quality Control Review**
  - **Reg Ops Final Formatting Review**

- **Approvers**
  - **Approval and Assessment of Approval**
  - Reg Ops publishing and submission readiness

Approved
Authoring Configurations (continued)

- Lifecycle States
Binder Configurations
Submission Binder Templates

- Initial Applications
  - eCTD submission binder templates include all eCTD sections with document templates or placeholders

- Amendments to an Application
  - IND submission binder templates include templates for the 1571 Form, Cover Letter, ESG Acknowledgement
  - Does not include the full CTD structure
“Master” Binders
- Organization of submissions and correspondence at the Application level
  - Supplements searching
  - Enables quick navigation
Additional “Master” Binder Usage

- Familiar structure for authors to both upload and navigate their documents

- Examples
  - Clinical Study binders for medical writers
  - Pharmacovigilence binder for organization of safety information
  - Literature References binder for organization of safety information
  - Program Management binder for team-related documents including agendas, minutes, and presentations
Binder Configurations (continued)

- **Binder Metadata**
  - Submission binders:
    - **Naming Conventions**
      - Name includes application number, serial number, date and short description
      - Use “Pending” in name until submission is filed
        - Useful for search
    - **Metadata**
      - Add “application + serial number”
      - Useful for reporting
Correspondence

- Added region-specific correspondence types at the Classification level to enable downstream searching and reporting
Dashboards and Reports
Dashboard & Reporting Examples

- Reporting for Initial IND or NDA/MAA
  - Created a report for each Module
  - Reports were easily configurable
  - Exported to excel (includes hyperlinks)
  - Distributed to the team lead
Dashboard & Reporting Examples (continued)

Module 1

Module 2

Module 3

Module 4

Module 5
Dashboard & Reporting Examples (continued)
Dashboard & Reporting Examples (continued)

- Reporting on Submission Information
  - Reports for submissions
    - Submission log by application
    - Based on the binder metadata
  - Reports for correspondences
    - Correspondence log by application
    - Based on application + classification

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What’s Next
In Closing...

- Looking forward to
  - Binder reporting
  - Having approval workflow cancel when someone “rejects”
  - More bulk update features
  - Ability to configure dashboard graphic output
  - Share documents across multiple vaults (example: references)

- Acquiring PleaseReview to support collaborate authoring and early-stage document reviews

- Looking to integrate submission publishing system with Vault

- Exploring use of Objects to track agency commitments and registration details