Using Vault to Manage and Report on Submission Status

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October 21, 2014

Intercept

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

Authoring Configurations

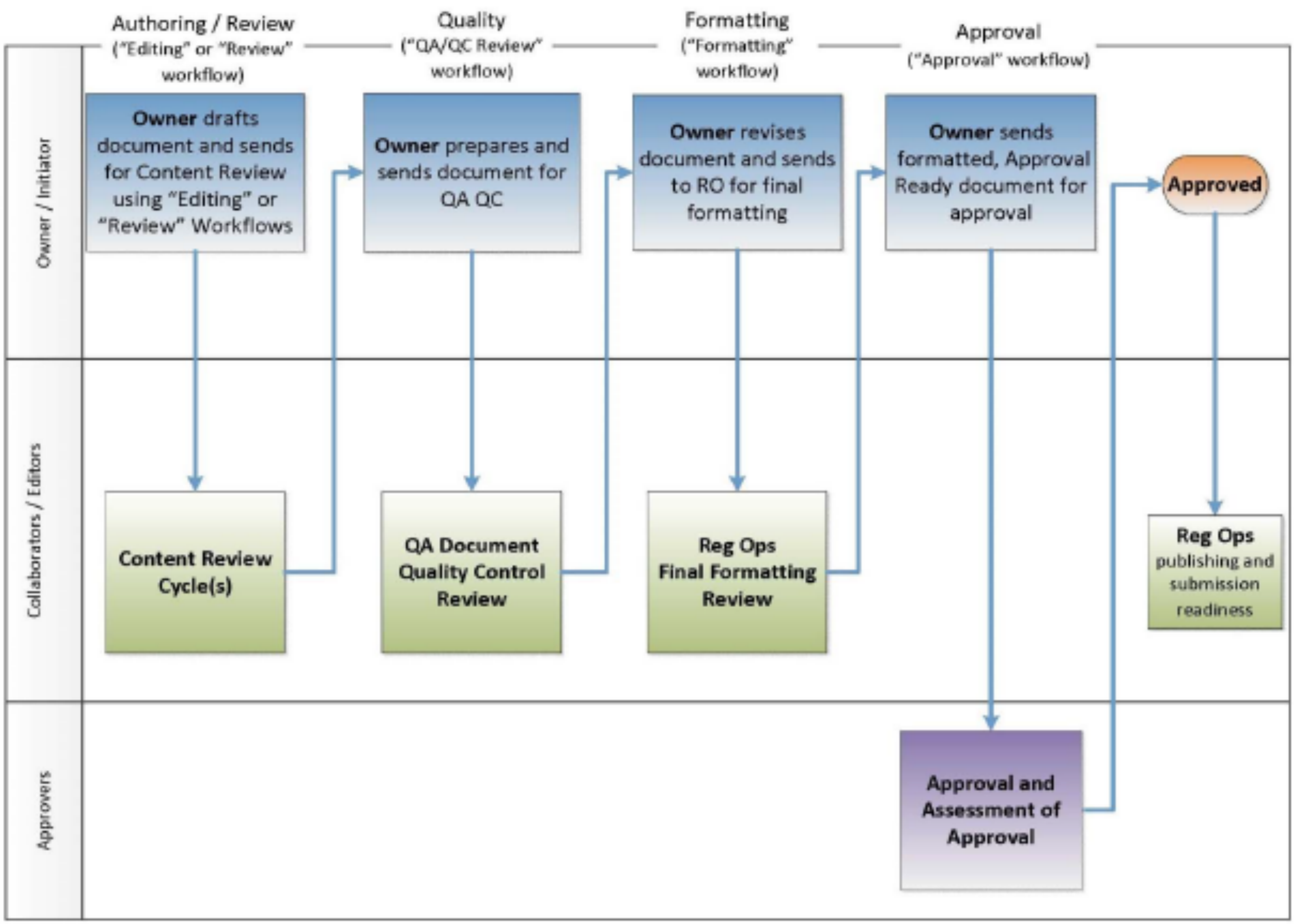
- To match business processes, created custom workflows in addition to authoring:
  - Created QA/QC workflow separate from Editing or Review workflows
    - Select QA/QC group (one person from the group accepts) or an individual of the QA/QC group
    - Select the QA/QC Review Focus
      - Editorial
      - 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)

Authoring Configurations (continued)

- 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

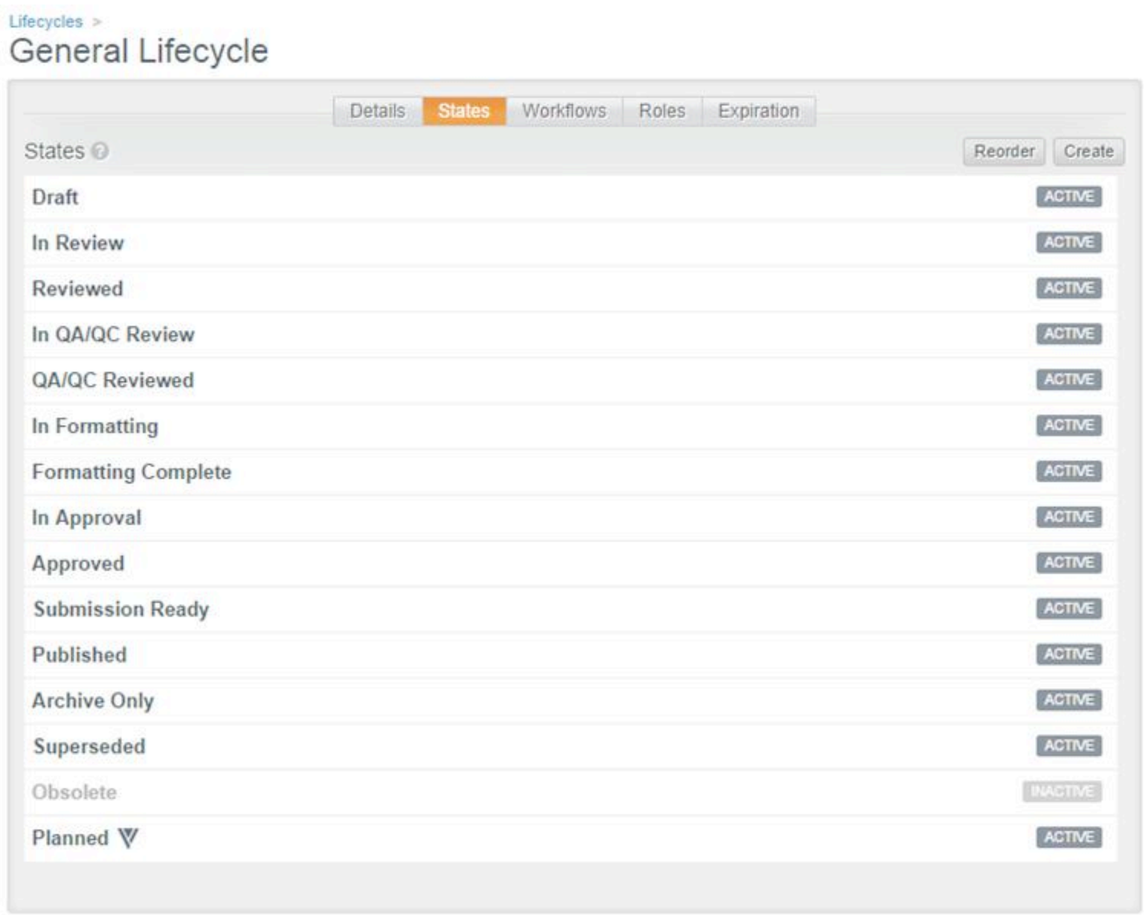
Authoring Configurations (continued)

Document Lifecycle Flow Chart



Authoring Configurations (continued)

- Lifecycle States



Binder Configurations

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 the1571 Form, Cover Letter, ESG Acknowledgement
    - Does not include the full CTD structure

Submission Structure (local templates only)

EU eCTD
Defined In: Submissions › Submission Structure

EU eCTD Template with Section Numbers
Defined In: Submissions › Submission Structure

Submission Binder EU
Defined In: Submissions › Submission Structure

Submission Binder IND
Defined In: Submissions › Submission Structure

Submission Binder IND
Defined In: Submissions › Submission Structure

Submission Binder IND
Defined In: Submissions › Submission Structure

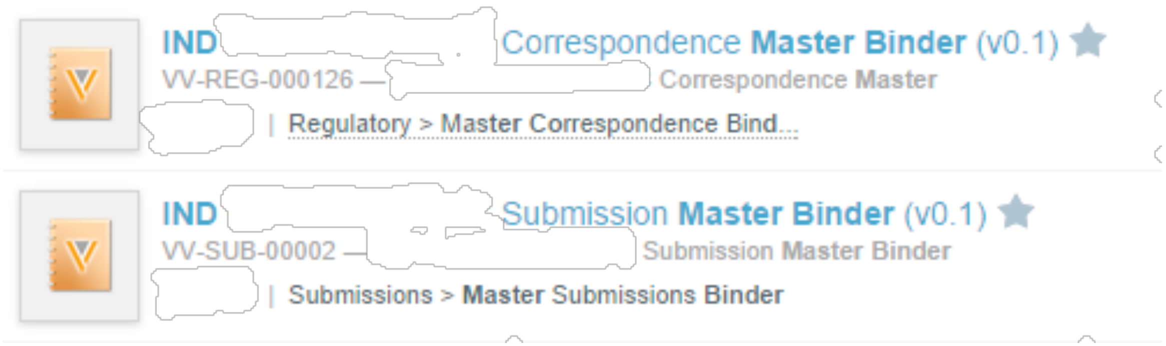
US IND eCTD Structure w/ Templates-Placeholders
Defined In: Submissions › Submission Structure

US eCTD
Defined In: Submissions › Submission Structure

US eCTD Template with Section Numbers
Defined In: Submissions › Submission Structure

Binder Configurations (continued)

- “Master” Binders
  - Organization of submissions and correspondence at the Application level
    - Supplements searching
    - Enables quick navigation

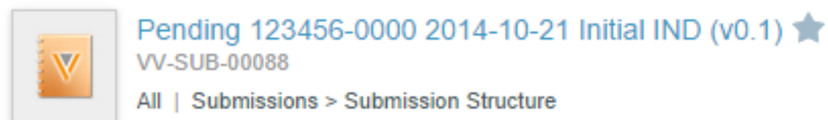


Binder Configurations (continued)

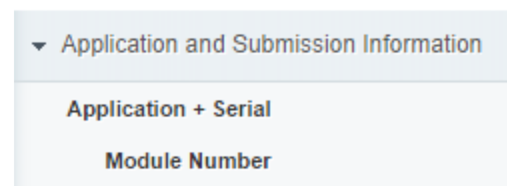
- Additional “Master” Binder Usage
  - Familiar structure for authors to both upload and navigate their documents
  - Examples
    - **Clinical Study** binders for medical writers
    - **Pharmacovigilence** binder for organization of safety information
    - **Literature References** binder for organization 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

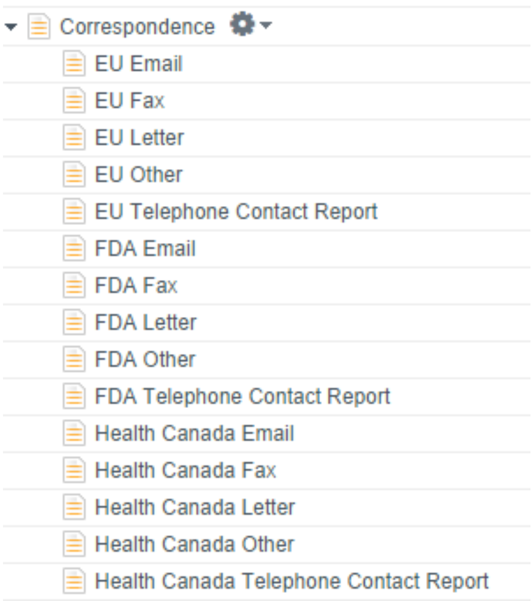


    - Metadata
      - Add "application + serial number"
      - Useful for reporting



Binder Configurations (continued)

- 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

NDA - Module Dashboard
Created by Janine Segich - *June 17*

NDA-0000 M1 Status
Document report
Created by Janine Segich - *June 17*

NDA-0000 M2 Status
Document report
Created by Janine Segich - *June 17*

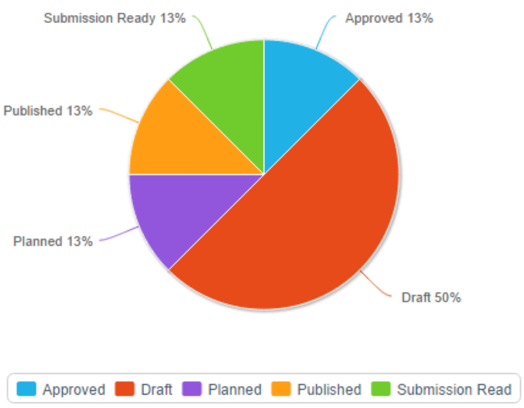
NDA-0000 M3 Status
Document report
Created by Janine Segich - *June 17*

NDA-0000 M4 Status
Document report
Created by Janine Segich - *June 17*

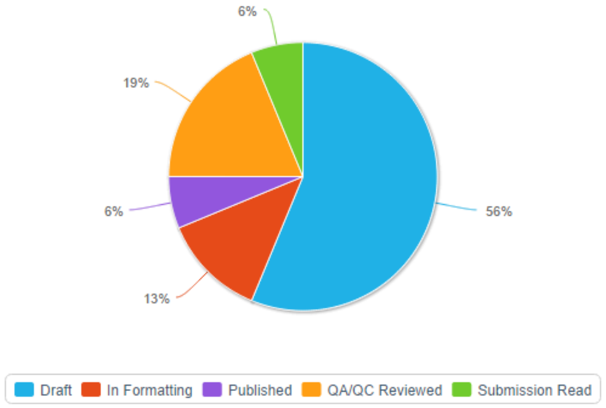
NDA-0000 M5 Status
Document report
Created by Janine Segich - *June 17*

Dashboard & Reporting Examples (continued)

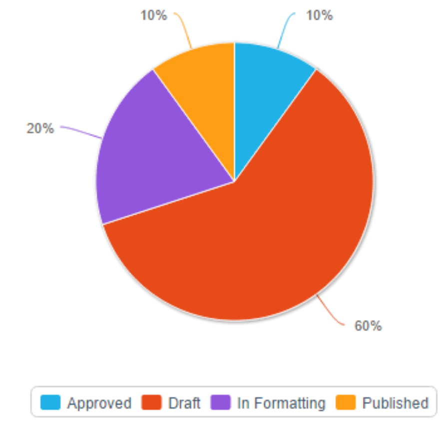
Module 1



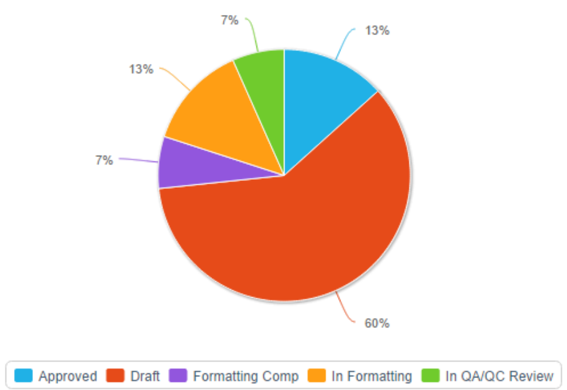
Module 2



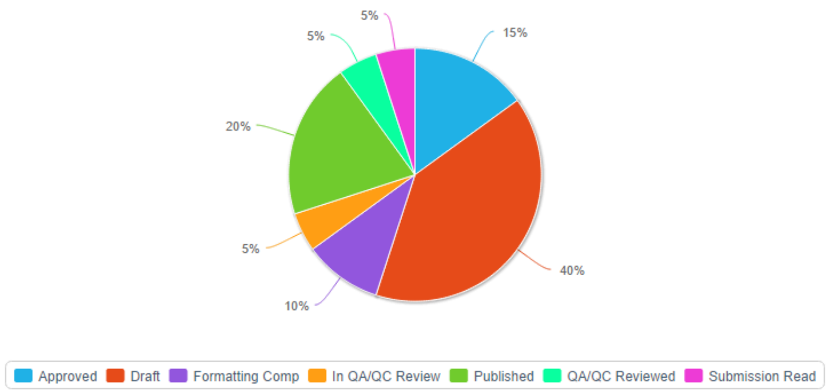
Module 3



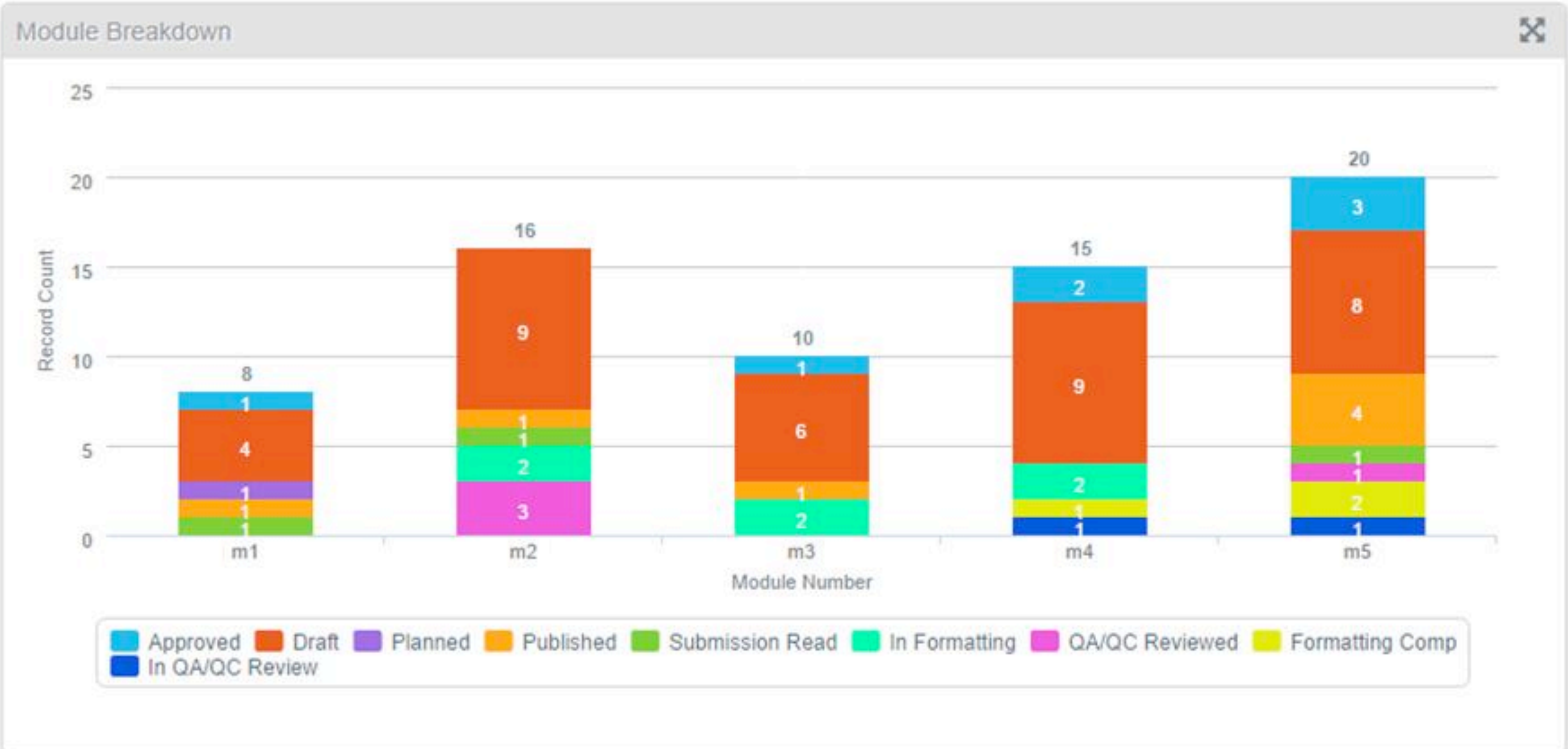
Module 4



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

Document Name	Document Number
0000 2007-01-27 Initial IND (v0.1)	VV-SUB-00105
0001 2007-09-29 Protocol, NII (v0.1)	VV-SUB-00128
0002 2007-09-29 Protocol Amendment 1 (v0.1)	VV-SUB-00150
0003 2007-12-15 Request for Meeting (v0.1)	VV-SUB-00149
0004 2007-12-20 Protocol Amendment 2 (v0.1)	VV-SUB-00148
0005 2008-01-22 Information Package (v0.1)	VV-SUB-00147

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