Overview RPS Release 1 and 2 Iteration 1

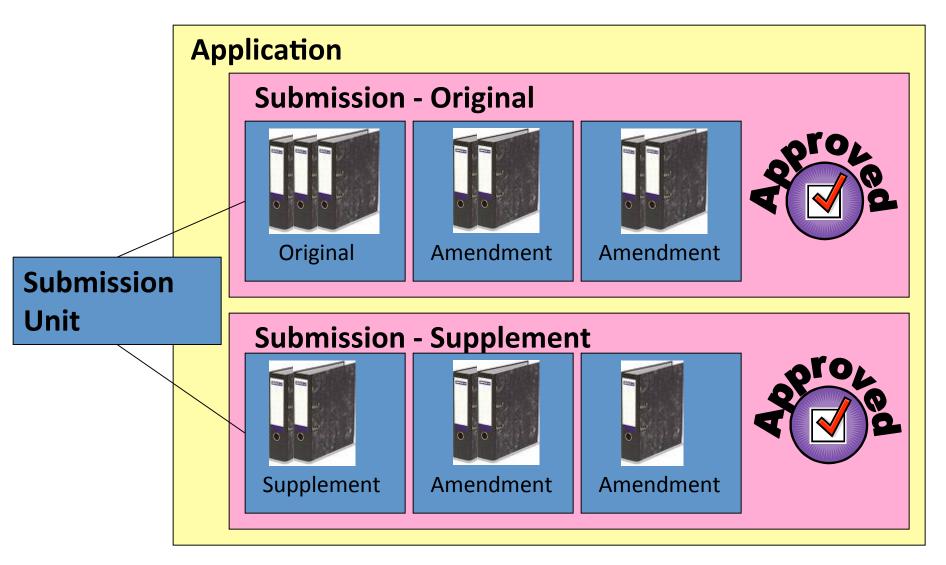
Jason Rock 215-253-7474

Contents

- Release 1
- Release 2 Iteration 1
- RPS Model

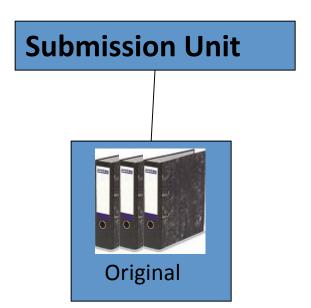
Release 1

Submission Hierarchy



Context of Use

Context of Use



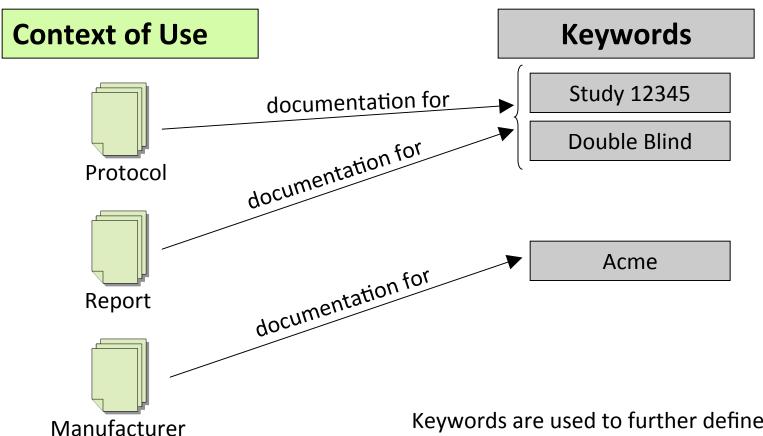
The collection of files provided to the Regulatory Authority at one time







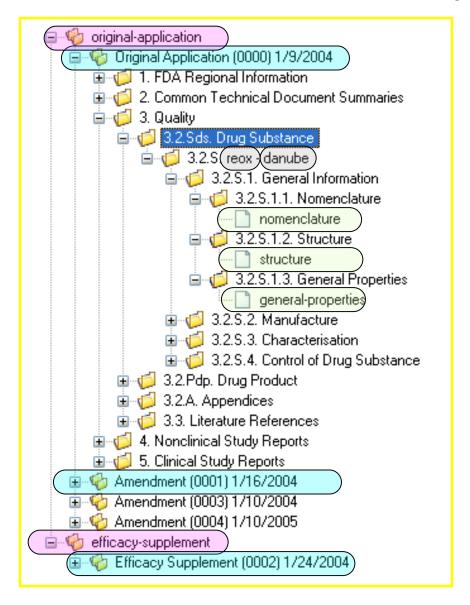
Keywords



Documentation submitted to support a regulatory review

Keywords are used to further define the context of documentation. Types defined by regulatory authority (e.g. manufacturer, study), value define by business (e.g. Acme, Study 12345)

View (2)



Application

Submission

Submission Unit

Keyword

Context of Use

Reviewable Units are not shown

Release 2 Iteration 1

Two-way communication

- Status of regulatory activity
- Organization of Submissions
 - e.g.; amendment is a supplement
- Other content
 - e.g.; meeting request, questions, letters, etc.

Mechanics

Submisson Message (PORP_RM000001UV)

Description

Regulator send RPS to Sponsor

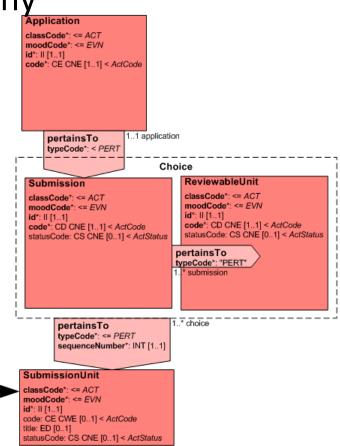
Can update submission hierarchy

Can update status

Can provide content

• e.g. letters, questions

New: title to submission unit



Status of Regulatory Activity

- Status code attribute
 - Withdrawn
 - Complete (approved)
 - Held (clinical hold)
 - etc.

Submission

classCode*: <= ACT
moodCode*: <= EVN
id*: II [1..1]
code*: CD CNE [1..1] < ActCode
statusCode: CS CNE [0..1] < ActStatus</pre>

ReviewableUnit classCode*: <= ACT

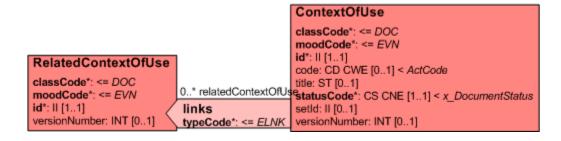
moodCode*: <= EVN id*: II [1..1] code*: CD CNE [1..1] < ActCode statusCode: CS CNE [0..1] < ActStatus

Context of Use

- Pointer to a file (FileReference)
 - e.g.; like a hyperlink to a file
- Link to table of contents (code)
- Create versions of a document (setId)
- SubmissionUnit Many in a submission unit classCode*: <= ACT moodCode*: <= EVN id*: II [1..1] code: CE CWE [0..1] < ActCode title: ED [0..1] statusCode: CS CNE [0..1] < ActStatus component FileReference typeCode*: <= COMP classCode*: <= ACT priorityNumber: REAL [0..1] moodCode*: <= EVN 0..* contextOfUse id*: || [1..1] referencedBy1 ContextOfUse typeCode*: <= REFR classCode*: <= DOC 0..1 fileReference moodCode*: <= EVN id*: || [1..1] code: CD CWE [0..1] < ActCode title: ST [0..1] statusCode*: CS CNE [1..1] < x_DocumentStatus setId: II [0..1] versionNumber: INT [0..1]

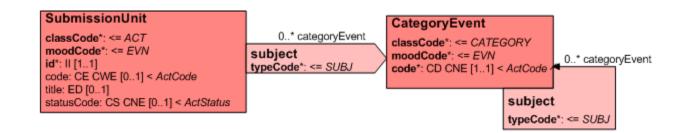
Other content

- If it walks and talks like a context of use....
 - Many in a submission
 - Has a title
 - Has a type
 - Points to a file
- New: Can be linked



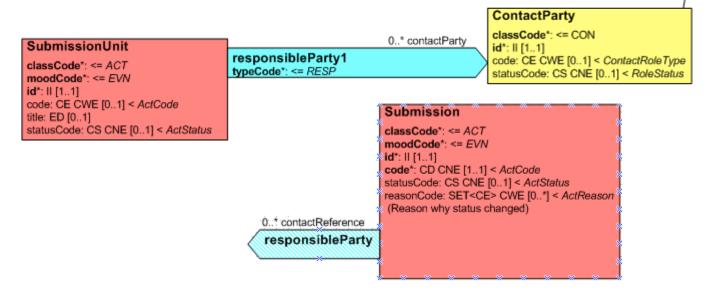
New: Category

- Submission unit code
 - If initial, amendment, etc
- Category event
 - Type of content in a submission
 - E.g.; IND Acknowledgement/Grant 30-Day Waiver



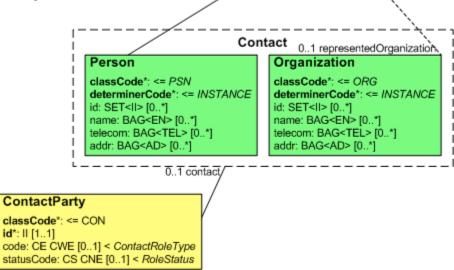
New: Contact Information

- Submission and Submission Unit
- "Role"
- Different Types of Contents (code)
- Contacts change over time (statusCode)



Person or Organization

- Contact "Role" plays Person or Organization
- Contact entity can be reused (Id)
- Complex attributes
 - (e.g.; telcom is fax, work phone, etc.)
- A person is an Agent



Agent

classCode*: <= AGNT

0.14 asAgent

RPS Model

