

Overview RPS

Release 1 and 2 Iteration 1

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Contents

- Release 1
- Release 2 Iteration 1
- RPS Model

Release 1

Submission Hierarchy

Application

Submission - Original



Original



Amendment



Amendment



Submission Unit

Submission - Supplement



Supplement



Amendment



Amendment



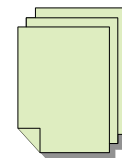
Context of Use

Submission Unit

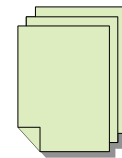


The collection of files provided to the Regulatory Authority at one time

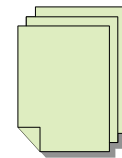
Context of Use



Protocol

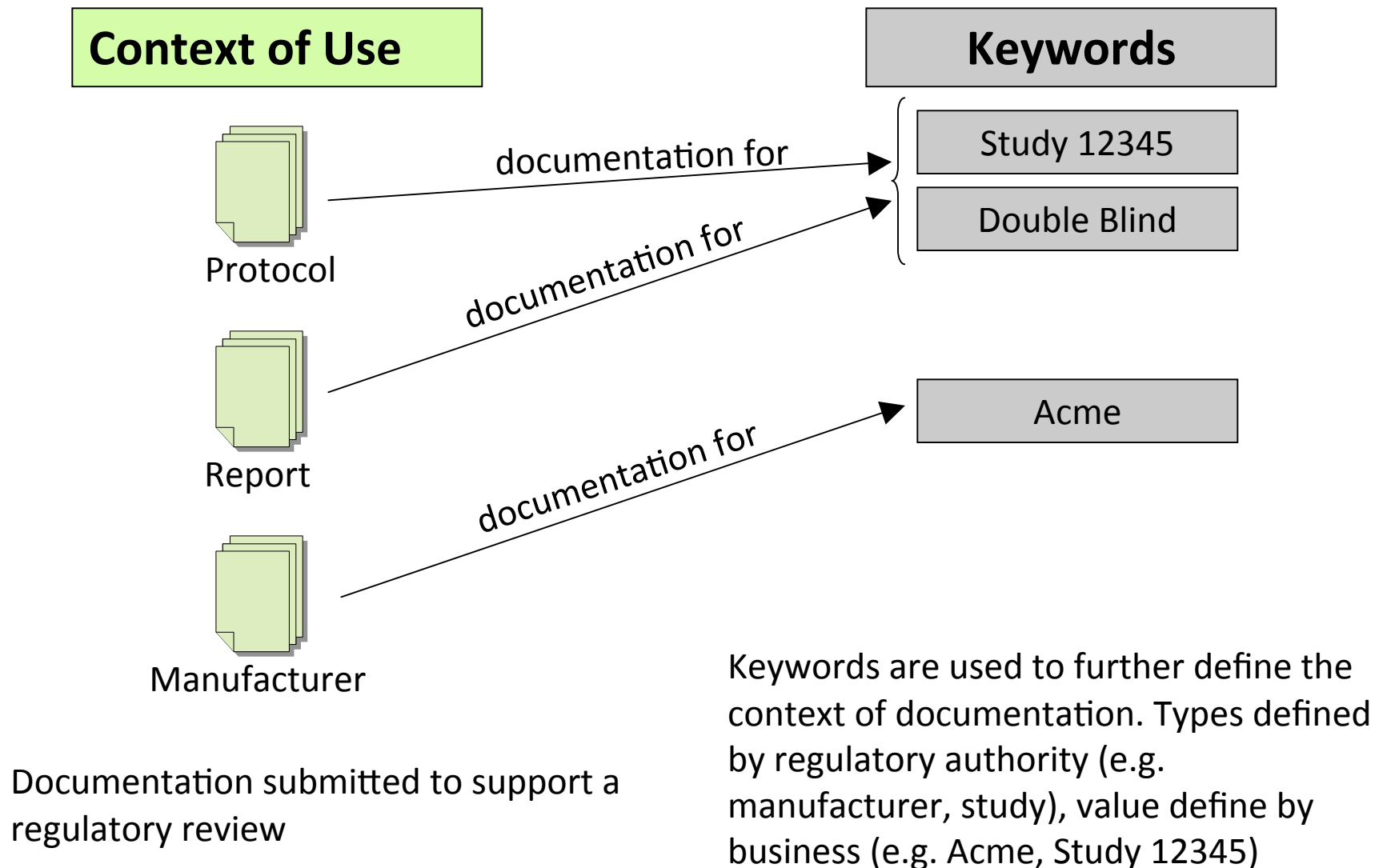


Intro

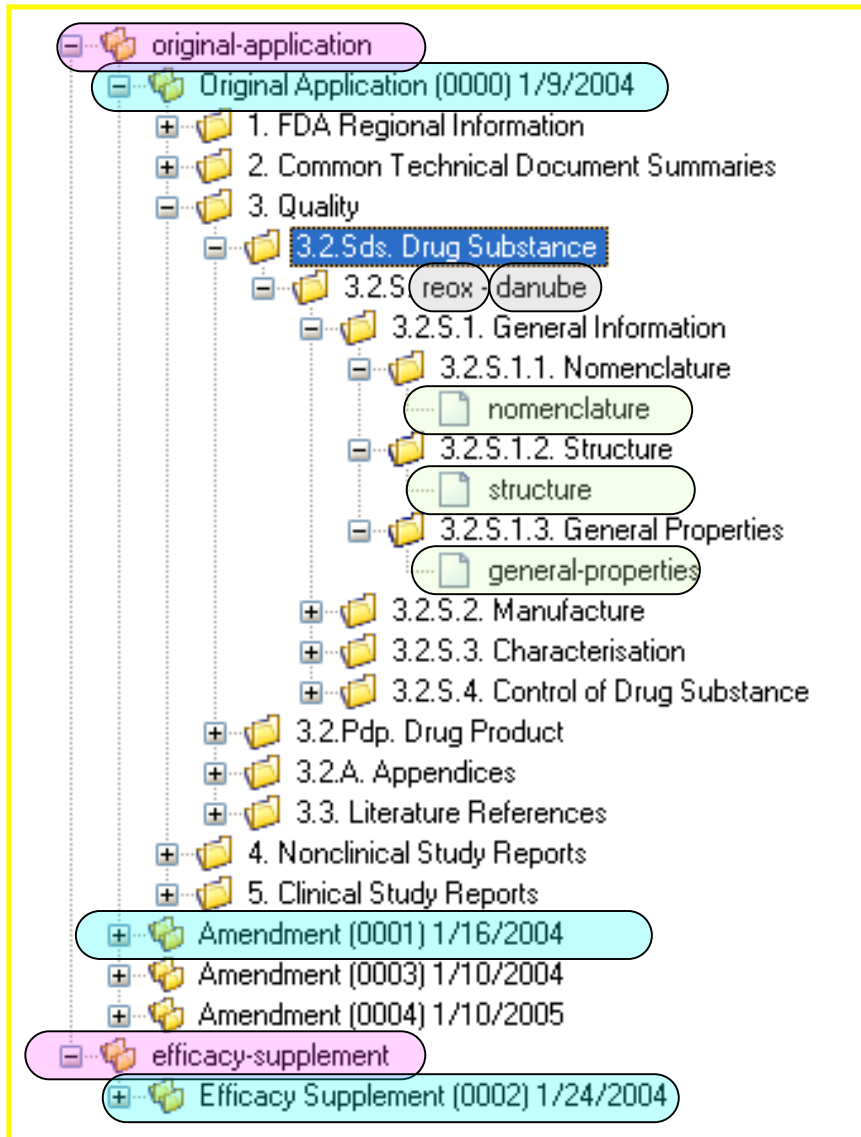


Report

Keywords



View (2)



Application

Submission

Submission Unit

Keyword

Context of Use

Reviewable Units are
not shown

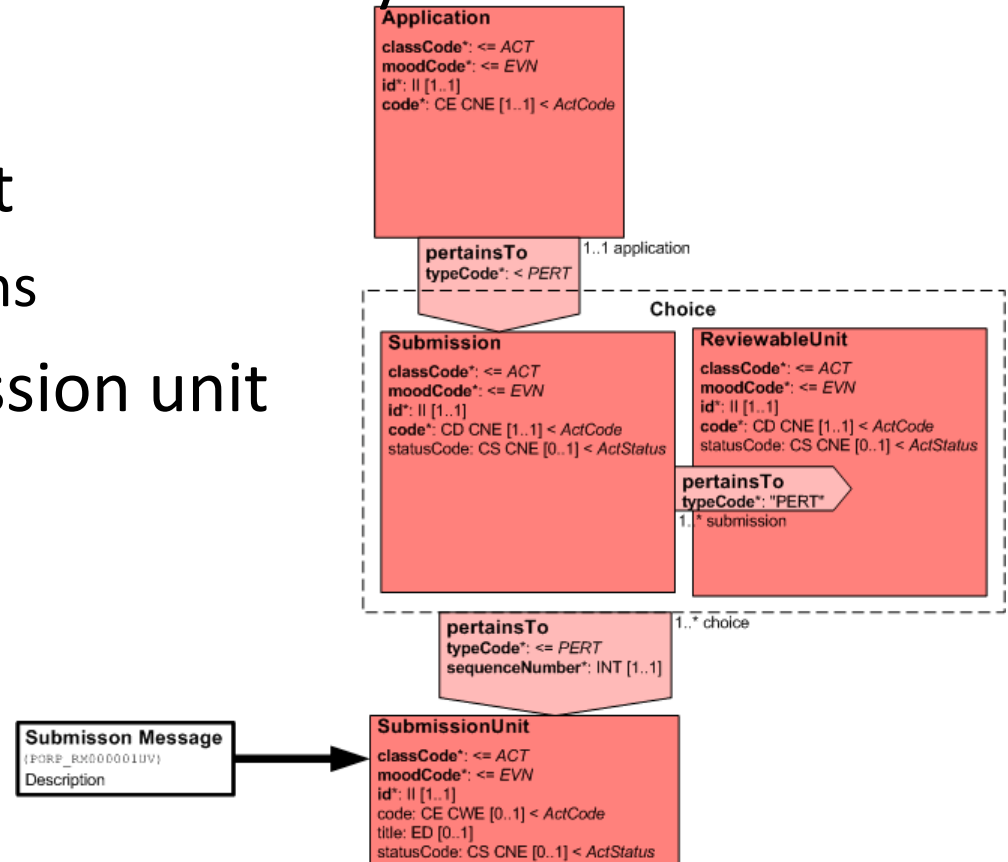
Release 2 Iteration 1

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

- 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

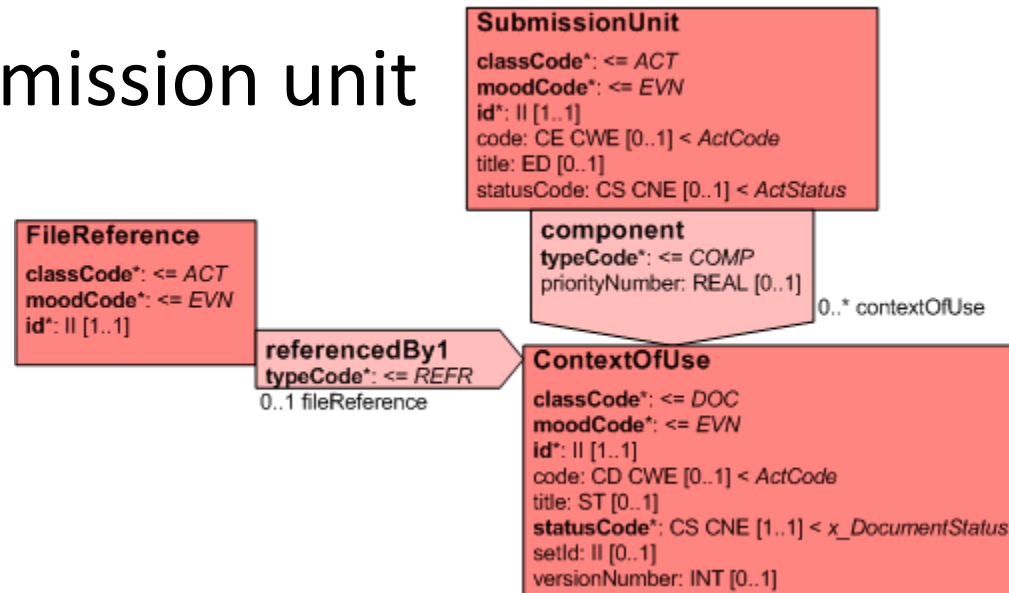
- Status code attribute
 - Withdrawn
 - Complete (approved)
 - Held (clinical hold)
 - etc.

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

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

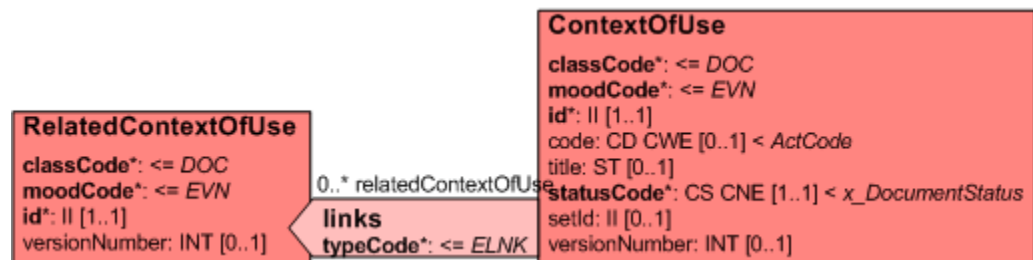
Context of Use

- 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)
- Many in a submission unit



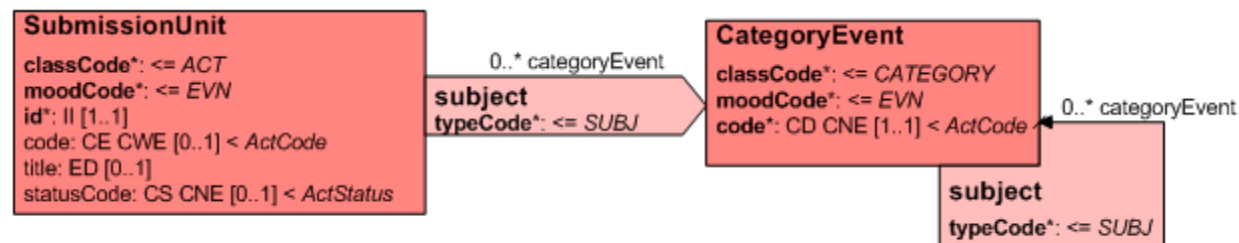
Other content

- 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



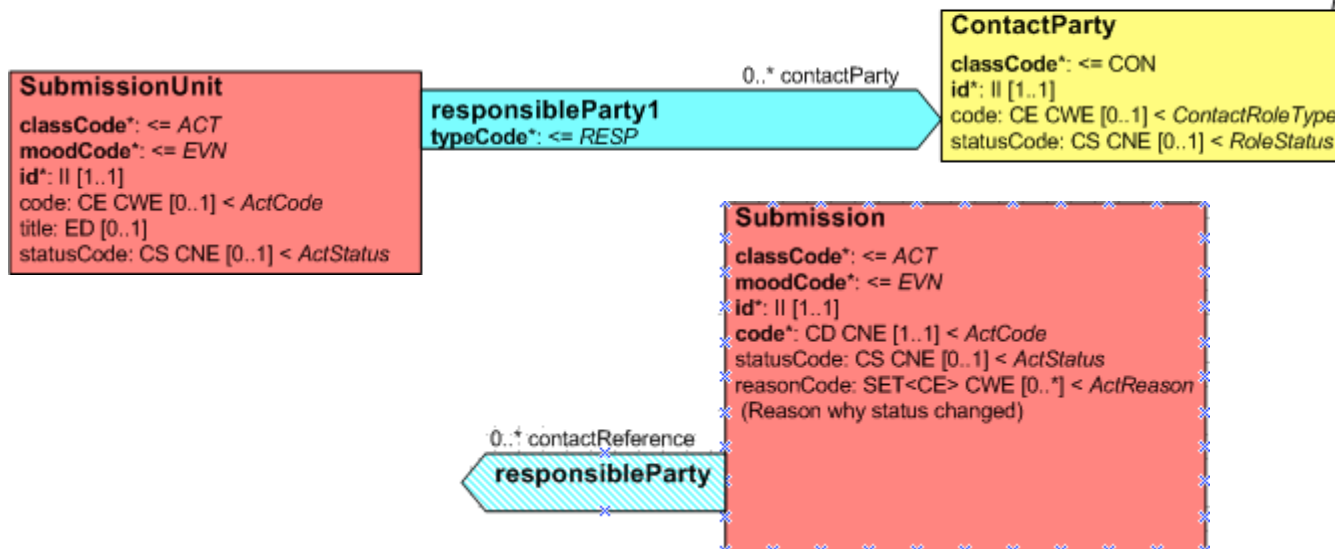
New: Category

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



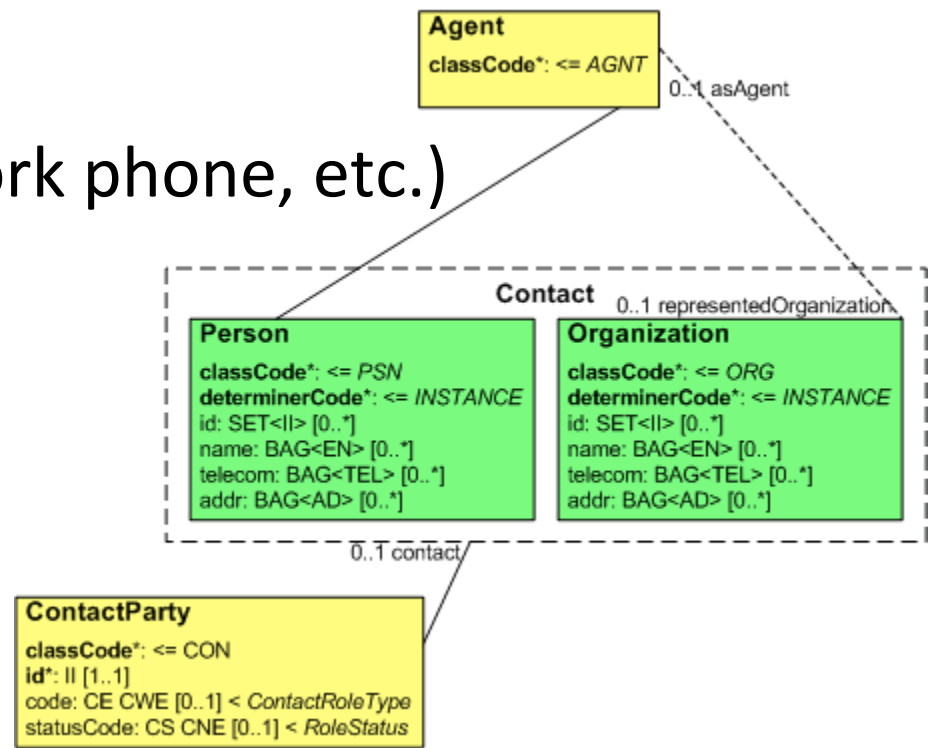
New: Contact Information

- 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



RPS Model

