Regulated Product Submission (RPS)

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Regulated Product Submission

- **The Next Major Version of the eCTD will use the RPS exchange message**

- Health Level Seven (HL7) exchange standard

- Regulated Product Submission (RPS) Goal
  - Create one standard (exchange message) that can be used for the submission of any regulated product

- Scope
  - Animal and Human products

    Including but not limited to food additives, human therapeutics, veterinary products, and medical devices
  - Worldwide use

    Same model for all product types to all regulatory authorities
  - Out of Scope - Document content

Regulated Product Submission

- Release 1
  - HL7 Normative Standard
  - ANSI Standard
- Release 2
  - HL7 Draft Standard for Trial Use (DSTU)
- Release 3
  - Requirements Phase
  - DSTU – January 2011

- HL7 RPS 2 documentation and activities posted on RPS HL7 wiki
  - http://wiki.hl7.org/index.php?title=Regulated_Product_Submissions

RPS Message Capabilities

- **RPS Release 1 provides the capability to;**
  - Standardize submission format/structure
  - Cross-reference previously submitted material owned by the sponsor*
  - Handle Submission/Document Lifecycle (e.g.; append, replace, delete)
  - Handle bundled/global supplements
  - Correct/modify attributes

- **RPS Release 2 provides the capability to;**
  - Handle two-way communication* - The regulatory authority (e.g. FDA) will use RPS to send correspondence (e.g. request for additional information, meeting minutes, application approval) to the submitter
  - Exchange contact information
  - Classify submission content/purpose
    - From Sponsor/Applicant (e.g. Meeting Request, New Protocol, Response to Hold)
    - From Regulator (e.g. Information Request, Response to Meeting Request, Approval)
  - Handle Multi-regulator submissions
  - Capture basic product information

- **RPS Release 3 requirements include;**
  - Expanding two-way communication capabilities
  - Cross-reference previously submitted material <u>not</u> owned by the sponsor (e.g. Master Files)
  - Additional submission metadata requirements (e.g. product information)
  - Additional regional requirements
  - Input/results of RPS Release 2 testing

* PDUFA Performance Goal

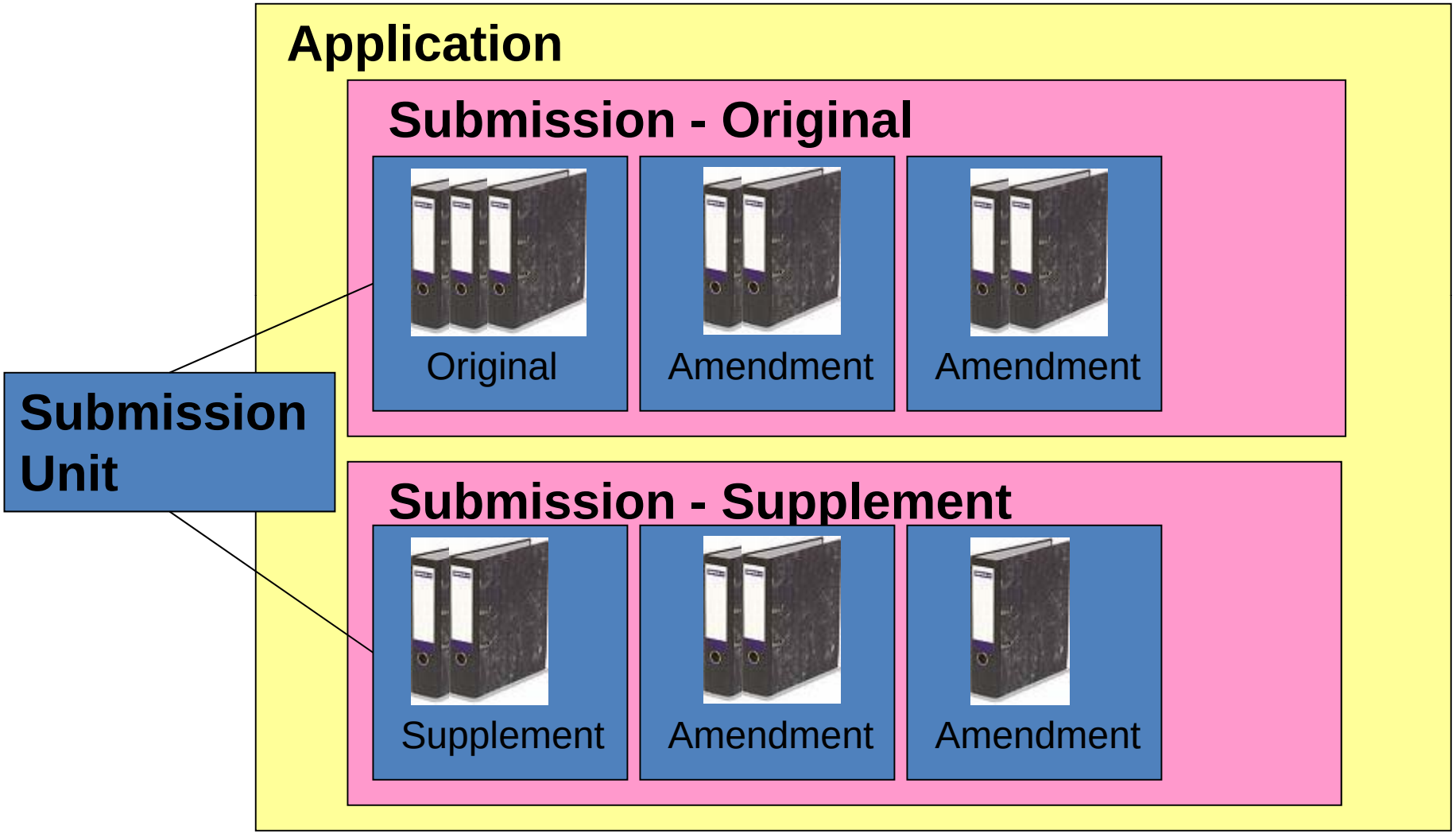
RPS 2 DSTU Testing

- HL7 RPS DSTU Subgroup - Initial scope FDA eCTD human pharmaceuticals
- Testing Approach
  - Target one application type (NDA) to test RPS functionality
  - Develop draft subset of codes to test various scenarios
- Tentative schedule
  - Planning (through 6/2010)
    - Identify test scenarios and testing process
    - Software vendor participation
    - Technical support
  - Testing (7/2010 – 9/2010)
    - Perform testing
    - Determine if modifications are required to the RPS message
    - Identify issues/questions for implementation

RPS Submission Hierarchy

- Application
  - All submissions that are grouped together for regulatory purposes
    - Original NDA and Supplements
    - Original IND and Amendments
- Submission
  - What gets approved (e.g. NDA, NDA Supplement)
- Submission Unit
  - What is being sent to the FDA
  - Can, probably does, contain many documents
  - Equivalent to a set of paper binders/volumes
  - Equivalent to an eCTD sequence

RPS Submission Hierarchy



RPS Submission Hierarchy

- Context of Use
  - Pointer to a file
  - Places a document in the table of contents
  - File can be reused
    - Files in investigational application can be reused in marketing application
  - Version control

- Keyword
  - Keywords are used to further define the context of documentation.

Context of Use

Submission Unit

Original

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

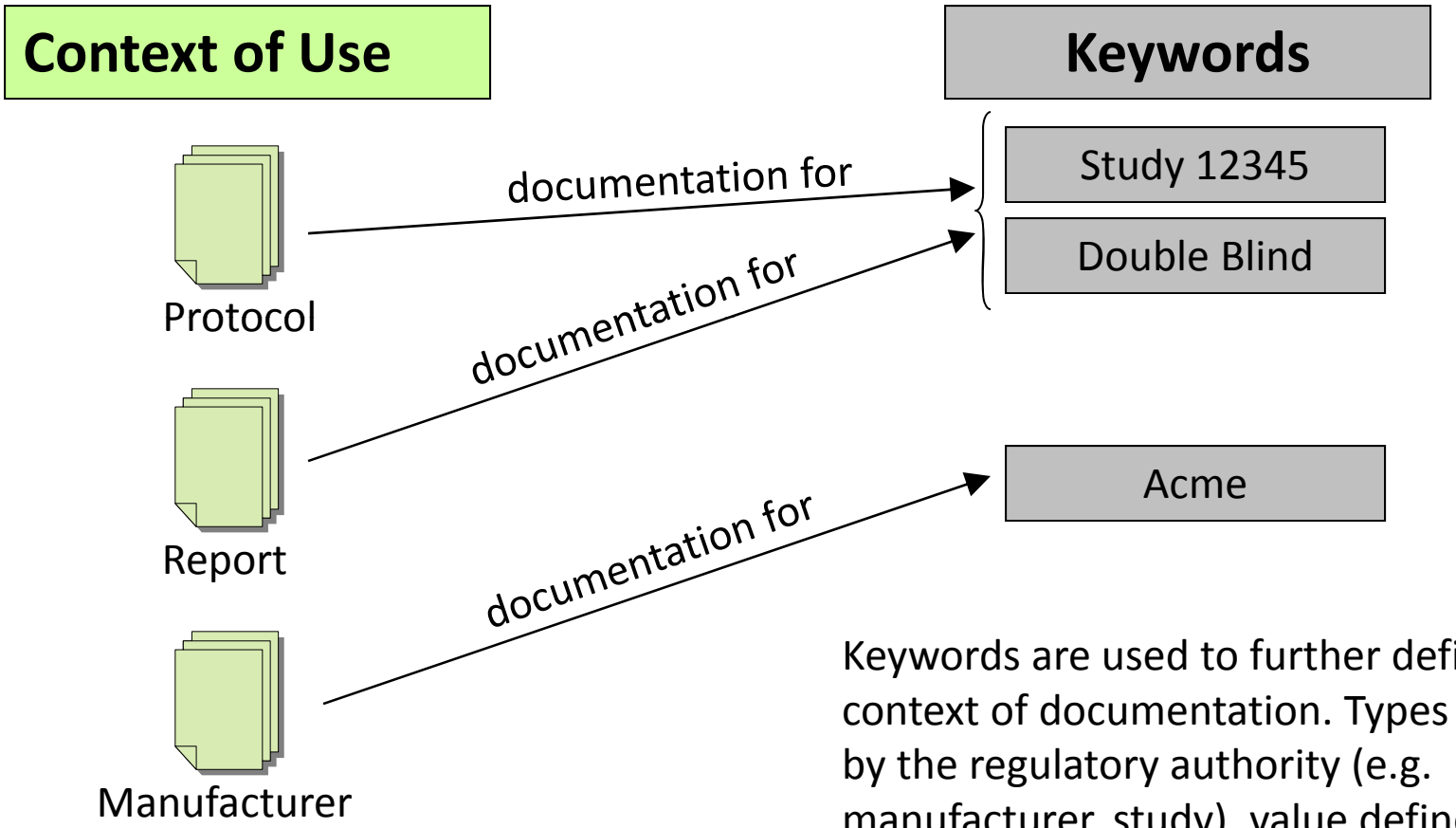
Context of Use

Protocol

Intro

Report

Keywords

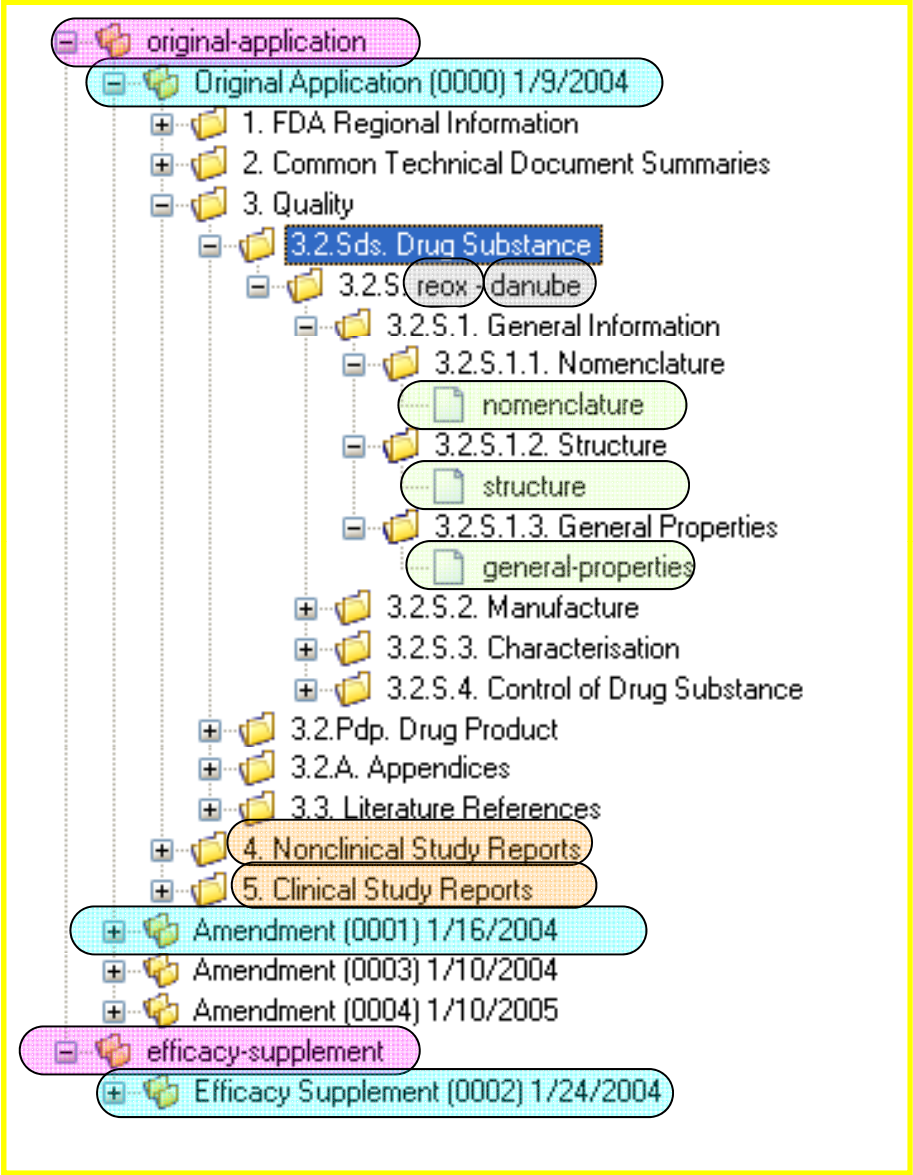


Documentation submitted to support a regulatory review

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

Controlled Vocabulary

- Defines the structure and values
  - Submission Format – Table of Contents
  - Submission Information
    - Contact Type
    - Submission Unit Category/Subcategory
- Can be different based on application type, regulatory authority, and international agreements
  - Application
    - Human pharmaceuticals (IND, NDA, BLA, ANDA)
    - Devices (PMA, 510K)
    - etc.
  - Submission (original, supplement, annual report, etc)
  - Submission units (original, amendment, pre-submission, etc.)
  - Documentation (synopsis, protocol, summary of clinical, etc.)



Application

Submission

Submission Unit

Keyword

Context of Use

Controlled Vocabulary

Keywords are used to further refine the table of contents.

FDA Implementation

- **Production/Implementation**
  - CDER/CBER planning to implement RPS Release 3 for human pharmaceuticals
    - Release 2 implementation based on PDUFA goals and inclusion of the core ICH requirements
    - Reasons for Release 3 implementation
      - CDER/CBER implementation of RPS Release 2 would result in a low number of RPS based submissions
      - In alignment with ICH
  - Target implementation date - TBD