

Category	Scope Topic	Scope Description	Complexity	Priority	Known Dependencies
Additional Info	Procedure Type	Procedure type better defined (note: category and subcategory are not sufficient)	Low	Must have	
Additional Info	Country Information	Country information at the file level – related to all countries specified in the submission, or just a subset			
Additional Info	Country Information	Country information at the submission level – need to identify the intended regulatory authorities for a submission or submission unit (if applicable)	Low	Must have	
Additional Info	Product Information	Revisit Product Information requirements	Medium	Must have	Resolution of CPM
Additional Info	Sender Information	Revisit Sender Information (there may be regional requirements not met)	Low	Must have	
Additional Info	Recipient Information	Revisit Recipient Information (there may be regional requirements not met)	Low	Must have	
Additional Info	Updates to Submission info	Updates of previously submitted information Contact Information Regulatory Activity Product Information Other submission unit attributes (e.g., COU, Keywords)	Medium	Must have	

Two-Way Communication	Master Files	Master Files - International requirements; MF owner and Applicant, separation of communications	High	Could Have	
Two-Way Communication	Multi-regulator	Communication between/among Member States	High	Must have	Procedure
Two-Way Communication	Open/Restricted Section/Master F	Reference from Applicant for the “Open Section” vs “restricted section”			
Referencing	Master Files	References to/from Submission to Master File			
Referencing	Application to Application	Relate an Application to another application	Medium	Must have	
Confidentiality	Confidential vs Public	Submissions that have confidential information at the document level – is there a way to mark documents confidential or public?	Medium	Could Have	
Structure of RPS Content	Hierarchy of RPS Context of Use	Hierarchy of Context of use to provide the structure in the message, which is currently a flat structure	High	Must have	
Structure of RPS Content	Order of Files	Ordering of Files under a Context of Use and lifecycle management of this ordering	High	Must have	
Lifecycle	Merge Context of Use	Merging of Context of Uses over time (how are existing files handled?)			
Lifecycle	Lifecycle issues	This is to handle all lifecycle issues as they are discussed	High		

Document Reuse	Append Operation	Remove operation attribute of append	Low	Wont have	
		Need to define this -- new vs reassign existing file to a new COU; A file to modify more than one file (either new or replaced (single/multiple) context of use) in a previous sequence or sequences ; Allow a single file to be “modified” by more than one files (either new or replaced (single/multiple) context of use) in later sequences			
Document Reuse	Replace operation		Low	Must have	
Document Reuse	Delete operation	Need to define this -- remove one COU for a particular document/file	Low	Must have	
Miscellaneous	Additional Usage	Ability to identify additional usage of files submitted (e.g., SPL, SDTM, etc.) – need to determine if Context of Use and Keyword are sufficient	Low	Should Have	
Miscellaneous	Processing Metadata	Processing metadata – is there any additional metadata that would assist in processing a submission unit (e.g., routing, notifications, etc)			
Miscellaneous	Validation/Integrity Checks	Integrity of the message – is there an additional need for metadata capture to address validation requirements; Validate COU and Keywords			

Miscellaneous	Preserve the cardinality of the CTD	Allow control of the number of files under a Context of Use (is this part of the Controlled Vocabulary?)	Medium	Must have	
Two-Way Communi	Threaded Discussions	Need to discuss how to handle the threads of discussions			

Sources	Notes
EU Procedures	
	Slide 9 - RPS Walk through - I do not see how this is reflected in the RPS R2 RMIM - found in Primary information recipient
ICH Req	
ICH Req	
ICH Req	
ICH and Workgroup	

Bfarm	Follow up with Klaus
EU	
	Confirm requirement with EU
	Confirm requirement
ICH	Define scenarios
Need to identify owner determine if needed	Further discussion to determine if needed
Came from ICH	Further discussion needed - Controlling files within a TOC
ICH	Further discussion needed - Controlling files within a TOC
	Further discussion - Merging or splitting documents over time
	Further discussion needed - Controlling files within a TOC

	Further discussion - look at medical records and health records stds - discuss need/scenarios - clarify in implementation guide?
	Metadata against a file
	Further discussion needed
	Further discussion needed - ensure COU and keywords can be validated - implementation - real requirement is "message must be valid"

ICH	Not a message requirement but a usage requirement - implementation
	Further discussion needed to determine if it is a requirement