

Scope Prioritization for RPS R3 Scope Topics

Category	Scope Topic	Scope Description	Complexity	Priority	Known Dependencies	Sources	Notes
Additional Info	Procedure Type	Procedure type better defined (note: category and subcategory are not sufficient)	Low	Must have		EU Procedures (ICH0032)	
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		ICH and Workgroup	
Additional Info	Sender Information	Revisit Sender Information (there may be regional requirements not met)	Low	Must have		ICH Req (ICH111, ICH118)	
Additional Info	Recipient Information	Revisit Recipient Information (there may be regional requirements not met)	Low	Must have		ICH Req (ICH111, ICH119)	
Additional Info	Product Information	Revisit Product Information requirements	Medium	Must have	Resolution of CPM	ICH Req (ICH117)	
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		ICH Req (ICH035, ICH036, ICH037)	
Additional Info	Country Information	Country information at the file level – related to all countries specified in the submission, or just a subset	Low	Must have		ICH Req (ICH035, ICH036)	Slide 9 - RPS Walk through - I do not see how this is reflected in the RPS R2 RMIM - found in Primary information recipient

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Additional Info	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		ICH Req (ICH109)	Metadata against a file
Additional Info	Processing Metadata	Identification of the submission unit and the process at the regulatory authority by sequence number	Medium	Should Have		ICH Req (ICH006)	separated this from the general "processing data" to make sure that explicitly stated/known requirements are addressed
Additional Info	Processing Metadata	Processing metadata – is there any additional metadata that would assist in processing a submission unit (e.g., routing, notifications, etc)	Medium	Should Have			Further discussion needed
Implementation Requirement	Validation/Integrity Checks	Integrity of the message – is there an additional need for metadata capture to address validation requirements; Validate COU and Keywords	Medium	Could Have		ICH Req (ICH072, ICH074, ICH084, ICH095, ICH115)	Further discussion needed - ensure COU and keywords can be validated - implementation - real requirement is "message must be valid"
Implementation Requirement	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		ICH Req (ICH129)	Not a message requirement but a usage requirement - implementation

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Lifecycle	Replace operation	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	Low	Must have		ICH Req (ICH123)	Further discussion - look at medical records and health records stds - discuss need/scenarios - clarify in implementation guide?
Lifecycle	Delete operation	Need to define this -- remove one COU for a particular document/file	Low	Must have		ICH Req (ICH123)	
Lifecycle	Append Operation	Remove operation attribute of append	Low	Must have		ICH Req (ICH123)	
Lifecycle	Merge Context of Use	Merging of Context of Uses over time (how are existing files handled?)	Medium	Must have		ICH Req (ICH097)	Further discussion - Merging or splitting documents over time
Lifecycle	Lifecycle issues - Application	This is to handle all lifecycle issues as they are discussed	High	Should Have			Further discussion needed - Controlling files within a TOC
Lifecycle	Lifecycle issues - Submission	This is to handle all lifecycle issues as they are discussed	High	Should Have			Further discussion needed - Controlling files within a TOC
Lifecycle	Lifecycle issues - Metadata	This is to handle all lifecycle issues as they are discussed	High	Should Have			Further discussion needed - Controlling files within a TOC

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Lifecycle	Lifecycle issues - Elements	This is to handle all lifecycle issues as they are discussed	High	Should Have			Further discussion needed - Controlling files within a TOC
Miscellaneous	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		ICH Req (ICH116)	Further discussion needed - Controlling files within a TOC
Miscellaneous	Order of Files	Ordering of Files under a Context of Use and lifecycle management of this ordering	High	Must have		ICH Req (ICH121)	Further discussion needed - Controlling files within a TOC
Miscellaneous	Document Groupings	Grouping of Files and lifecycle management of this grouping	High	Must have		ICH (ICH060)	Further discussion needed - Controlling files within a TOC
Miscellaneous	Broken Links	Needs to handle the hyperlinking issues/to mitigate broken links across the submission of content	High	Could Have		ICH Req (ICH043, ICH044, ICH045, ICH046)	Added 24.Nov.2009 based on discussion in WG; this still requires discussion as to whether or not this is out of scope of HL7
Referencing	Application to Application	Relate an Application to another application; including references of Master Files	Medium	Must have		ICH	Define scenarios
Two-Way Communication	Threaded Discussions	Need to discuss how to handle the threads of discussions	High	Could Have			Further discussion needed to determine if it is a requirement

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Two-Way Communication	Master Files	Master Files - International requirements; MF owner and Applicant, separation of communications; Submissions that have confidential information at the document level – is there a way to mark documents confidential or public?; Reference from Applicant for the “Open Section” vs “restricted section”; need to understand the actual requirements around right to reference, etc.	High	Must have		Bfarm; Devices (?)	
Two-Way Communication	Multi-regulator	Communication between/among Member States	High	Must have	Procedure	EU	

ICH Requirements

ICH Req No.	TOPIC	Requirement		Affects Message?	RPS 1 included	RPS R2 - Iteration 1 Included	RPS R2 - Iteration 2 Included	Scoped for future iterations	M2 Feedback on Questions
ICH001	APPLICATION LIFECYCLE	A regulated product application may have one or more regulatory activities associated with it		Y	Y				
ICH002	APPLICATION LIFECYCLE	It must be possible to define a 'Regulatory Activity' to which a group of sequences will belong		Y	Y				
ICH003	APPLICATION LIFECYCLE	A regulatory activity may have one or more sequences associated with it		Y	Y				
ICH004	APPLICATION LIFECYCLE	The message should support the ability to provide one sequence to multiple regulatory activities which may span more than one application.	sequence number values would need to be unique to each application	Y	Y				
ICH005	APPLICATION LIFECYCLE	Each sequence should have a unique identifier	compare to FDA04/HJ05	Y	Y				
ICH006	APPLICATION LIFECYCLE	Capability to identify which eCTD sequences were used at which step of agency review.		Y	Not sure what this means	Needs clarification; need examples that may be illustrative of the requirement			to be able to specify, in the message, the purpose of the submission within the Regulatory processes in Japan (controlled vocabulary - MHLW/PMDA) e.g., PMDA review, expert review, panel meeting)
ICH019	DOCUMENT METADATA	It must be possible to describe, in free text, the titles of the files being submitted		Y	Y				
ICH020	DOCUMENT METADATA	It must be possible to uniquely identify a file being submitted, within a submission		Y	Y				

ICH Requirements

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ICH021	DOCUMENT METADATA	It must be possible for a Submitter to provide user defined information or identifier for a file		Y	Y - DM systems should store message ID not other way around				
ICH022	DOCUMENT REUSE	The message should support the reuse of electronic files from a previously submitted instance within an application.		Y	Y				
ICH023	DOCUMENT REUSE	The message should support the reuse of electronic files from a previously submitted instance across applications.		Y	Y				
ICH024	DOCUMENT REUSE	It must be possible to include by reference, a file that physically resides in another submission (eg. cross-product submission support)	cross-application and cross-sequence	Y	Y				
ICH026	ENVELOPE	It must be possible to assign an identifier to a submission		Y	Y				
ICH027	ENVELOPE	It must be possible to identify the regulatory agency for which a specific submission is intended		Y	N - Process issue, not a message issue	Y			

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ICH028	ENVELOPE	It must be possible to identify the applicant making the submission		Y	N - Which applicant, different per country - sender information is built in to the header	Y			
ICH029	ENVELOPE	It must be possible to assign an application number to the submission		Y	Y				
ICH030	ENVELOPE	It must be possible to assign a submission type being used for the submission		Y	Y				
ICH031	ENVELOPE	It must be possible to describe, in free text, the submission (include a short description of the submission in the administrative section)		Y	N - DM systems should store message ID not other way around	Y			

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ICH032	ENVELOPE	It must be possible to define the Procedure type being used for the submission	refer to HJ05	Y	N	Is this satisfied by category/subcategory? No		Yes; would like a better way to handle this requirement, this is not handled by category	
ICH033	ENVELOPE	It must be possible to assign an invented name (trade name) for the product covered by the submission	Not just EU Regional	Y	N - Common Product Model	Y			
ICH034	ENVELOPE	It must be possible to assign an international non-proprietary name(s) (inn) for the drug substance(s) covered by the submission	Not just EU Regional	Y	N - Common Product Model	Y			
ICH035	EU REGIONAL	It must be possible to identify to which specific country a file is relevant		Y	Is this language or regulatory authority submitted		Is this part of a multi-regulator scenario? -Y		

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ICH036	EU REGIONAL	It must be possible to identify that a file is relevant to all countries covered by a submission		Y	Is this language or regulatory authority submitted	N	Is this part of a multi-regulator scenario? -Y		
ICH037	EU REGIONAL	It must be possible to identify for which country(ies) a specific submission is intended	refer to HJ05	Y	Is this language or regulatory authority submitted	N	Is this part of a multi-regulator scenario? -Y		
ICH038	HARMONISATION	The message should support ICH-harmonized content (documentation and metadata) and ICH-regional content		Y	Y				
ICH039	HARMONISATION	Need to provide a structure that supports all terminologies for dossier (all regulatory activity related to a product) and regulatory activity (collection of sequences that lead to a decision by the regulatory agency (NDS, SNDS)) which can be mapped to individual ICH-regional regulatory processes	controlled vocabularies / Implementation Guide	Y	Y				
ICH040	HARMONISATION	Files should only need to be submitted once to a Health Authority and can be included by reference in multiple regulatory submissions to support multiple regulatory actions even across applications	Clarify meaning of application	Y	Y				
ICH049	LANGUAGE	It must be possible to assign a language to a document included in the submission		Y	Y				
ICH050	LANGUAGE	It must be possible to (incorporate unicode character sets) to deal with languages such as Bulgarian and Greek	Deal with greek and cyrillic	Y	Y				

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ICH051	LANGUAGE	It must be possible to include files with 1 or 2 byte characters, or a mixture of both		Y	Y				
ICH053	LIFECYCLE	The message should support the addition of metadata to a previously submitted instances, e.g., related sequences, submission type, operation attribute, manufacturer name, etc.	Delete examples	Y	Y				
ICH054	LIFECYCLE	The message should support the deletion metadata from previously submitted instances, e.g., related sequences, submission type, operation attribute, manufacturer name, etc.		Y	Y				
ICH055	LIFECYCLE	The message should support the updating of any metadata from previously submitted instances, e.g., related sequences, submission type, operation attribute, manufacturer name, etc.		Y	Y				
ICH056	LIFECYCLE	Information provided in the message (i.e., metadata) used to categorize documentation (e.g., attributes of drug substance, manufacturer, etc) or supplied in the regional envelope (e.g., Company Name, Sponsor) can be modified (i.e., added, edited, removed) during the life cycle of the application.		Y	Y				
ICH057	LIFECYCLE	Replacement of multiple leafs with single leaf and vice versa should be supported in eCTD.		Y	Y				
ICH059	LOGICAL GROUPINGS	Provide ability to group a collection (or set) of files that together represent a document or reviewable grouping (e.g, all files related to a study report, all files related to a labeling document, all files related to a manufacturer or manufacturing component (e.g., container closure))		Y	Y - through the use of like keywords				

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ICH060	LOGICAL GROUPINGS	Provide ability to treat a grouping of files as a single entity and to be treated as if it were a single file (complete with all descriptive attributes e.g., title) for all life cycle operations and relationship management and reuse needs		Y	What is the business need?				refer to groupings defined in ICH59 ex: -delete all files related to a particular manufacturer attribute from 3.2.S (repeating element) -reference a complete study already submitted in an IND from an NDA -sponsor has been required to split a single large file into smaller components (e.g. >100MB file split
ICH061	PHYSICAL FILE RULES	Filenames can include underscores		Y	Y				
ICH067	SCOPE	Allow the capacity to modify the ICH CTD organizational structure (ToC) without modifying or changing the eCTD message structure		Y	Y				
ICH071	STRUCTURE	It must be possible to constrain the inclusion of documents at inappropriate locations in the submission structure (eg. at highest levels of eCTD)		Y	Y				
ICH072	STRUCTURE	The message should allow for the control/enforcement of document/structural granularity.		Y	System validation check	Is this an implementation detail?			enforcement of eCTD granularity document
ICH073	STRUCTURE	It must be possible to assign 'attributes' to the contents of specific sections in the submission to support ICH CTD organizational structure (e.g., repeating section 3.2.S)		Y	Y				
ICH074	STRUCTURE	It must be possible to ensure that all files submitted are defined and referenced		Y	System validation check				can this be better defined to identify what is to be checked in the message? No In current eCTD speak, each file

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ICH075	STRUCTURE	It must be possible to validate the contents of a submission against the CTD (e.g., module 6 is invalid)		Y	Y				
ICH076	STRUCTURE	It should be possible to easily identify all of the files included in a specific section of the submission.		Y	Y				
ICH081	TERMINOLOGY	The message should support the use of controlled vocabularies for harmonized metadata		Y	Y				
ICH082	TERMINOLOGY	The message should support the use of controlled vocabularies for regional metadata.		Y	Y				
ICH083	TERMINOLOGY	It should be possible to specify date values in an unambiguous manner.		Y	Y				
ICH084	TRANSFER/SECURITY	The message should support a means to enable the validation of the integrity of the electronic files within an instance		Y	System validation check	Is this an implementation detail?			is this solely checksum validation of files? Yes
ICH087	TWO WAY COMMUNICATION	The message should support submission of an instance from a regulator to a regulated party.		Y		Y			
ICH088	TWO WAY COMMUNICATION	The message should support the identification of the source of an instance, i.e, regulated party or regulator		Y		Y			
ICH095	VALIDATION	The message should not require the submission of the DTD/Schema and controlling vocabularies with each instance		Y	Y - technical				

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ICH096	Usability-Viewing	The instance should be viewable without access to specialized tools or internet	this requires additional discussion around the hierarchy of the COU in the RPS message	Y				Needs discussions	is this speaking to the need for a stylesheet view? Yes
ICH097	COMPATIBILITY	It should be possible for an applicant to build on an eCTD lifecycle started using the eCTD 3.2.x specification and continued using the eCTD NMV specification	Do we have enough information to merge COU from version to version? Is there enough information to relate a COU to another in future versions throughout the lifecycle? eCTD to RPS transition - implementation	Y				Needs discussions	
ICH104	DESIGN CONCEPTS	The file format of the message should be xml-based.		Y	Y				
ICH108	INTEGRITY	Integrity checks for all files included in the submission are required.		Y	Y				

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ICH109	DESIGN CONCEPTS	The message should provide the ability to identify further specific usage of the file (e.g., SPL, SDTM, application format, packaging insert, CTN) beyond that defined by the CTD		Y				Needs discussion; Does COU and Keyword address this requirement? Need some UC on this requirement to understand whether this requirement is met by COU/Keyword	
ICH110	INTEGRITY	The ability to specify which algorithm is being used for file integrity checks is required.		Y	Y				

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ICH111	TWO-WAY COMMUNICATION	It must be possible to identify the sender and receiver of a message.		Y		Y			
ICH112	TWO-WAY COMMUNICATION	It must be possible to relate any message to a particular message, regulated activity and/or application.		Y	Y				
ICH113	TWO-WAY COMMUNICATION	Every eCTD message must be uniquely identifiable.		Y	Y				

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ICH115	ENVELOPE	The message standard must provide the ability to include information required for the processing (e.g., message standard version) and integrity (e.g., checksum) of the message		Y				Needs discussion; Need to understand the requirements for "processing" the message. ; provide examples of these requirement to ensure that we covered (we have ruled out controlled vocabulary -- as it will have a coded	

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ICH116	ENVELOPE	The message standard must provide a three-level hierarchy of application, regulatory activity and submission unit.		Y	Y				
ICH117	ENVELOPE	The message standard must provide information about the product.		Y			Y	Needs discussion	
ICH118	ENVELOPE	The message standard must provide enough information to identify the sender.		Y		Y		Needs discussion; any regional requirements	
ICH119	ENVELOPE	The message standard must provide enough information to identify the recipient.		Y		Y		Needs discussion; any regional requirements	

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ICH120	DESIGN CONCEPTS	The message standard must provide the ability for the sender or recipient to update previously submitted metadata		Y				Needs discussion; need rules and business requirement for information that needs to be changed; attributes vs sender information vs regulatory activity	

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ICH121	LIFECYCLE	The order/sequence of leaf elements within a CTD section must be able to be controlled		Y				Need discussion; sequence of files under a single COU;	
ICH122	DOCUMENT REUSE	A file can be displayed in multiple sections of the CTD (preserving the leaf - file concept in the current eCTD specification)		Y	Y				
ICH123	DOCUMENT REUSE	Maintain a similar file-leaf model as in the current eCTD in the eCTD NMV, with the following exception/changes: a. The operation attribute value "append" be removed from the list of allowed values (leaving only new, replace and delete) b. Allow a replace or delete leaf to modify more than one leaf in a previous sequence or sequences c. Allow a single leaf to be "modified" by more than one leaf in later sequences (supports changes in granularity)	a. if this is removed; need to understand the lifecycle issues b. this is replacing more than one file with one file and/or the other way around c. Same as above just at a different level.	Y				Needs discussion	
ICH124	DOCUMENT REUSE	A file can be replaced in one existing eCTD section or context without impacting the use of the file in other eCTD sections or contexts		Y	Y				

ICH Requirements

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ICH125	LIFECYCLE	Life cycle operations must occur within the same context as the existing (target) leaf		Y				Needs discussion; this is a validation concern	
ICH126	DESIGN CONCEPTS	There should be no restrictions on the characters used in controlled vocabularies	Implementation; we do not want to constrain the value with respect to special characters	Y				Needs discussion	
ICH127	DESIGN CONCEPTS	There should be a basic ICH stylesheet for presentation purposes	Related to ICH97; this requires additional discussion around the hierarchy of the COU in the RPS message	Y					

ICH Requirements

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ICH129	STRUCTURE	Cardinality rules of the current eCTD Specification should be retained plus those cited in approved Change Requests (e.g., CR#1490/1500 - Module 3.2.A.3 will be made a repeating attribute in Version 3.2 of the specification based on excipient).	Implementation -- constraining number of files for a specific COU vs specifying COU a Keyword; Specifying the controlled vocabulary that specifies the actual COU vs the COU that (e.g., granularity annex)	Y				Needs discussion	
ICH107	DESIGN CONCEPTS	The message standard must not require encryption	Implementation specific	Y	Y				