ICH Req No.	TOPIC	eCTD Next Major Release Business Requirements Collation (12-NOV-08) Requirement		Affects Message?	RPS 1 included	RPS R2 - Iteration 1 Included	RPS R2 - Iteration 2 Included	Scoped for future iterations
ICH01	APPLICATION LIFECYCLE	A regulated product application may have one or more regulatory activities associated with it		Y	Y			
ICH02	APPLICATION LIFECYCLE	It must be possible to define a 'Regulatory Activity' to which a group of sequences will belong		Y	Y			
ICH03	APPLICATION LIFECYCLE	A regulatory activity may have one or more sequences associated with it		Y	Y			
ICH04	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			
ICH05	APPLICATION LIFECYCLE	Each sequence should have a unique identifier	compare to FDA04/HJ05	Y	Y			
ICH06	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		
ICH07	APPLICATION LIFECYCLE	The message should not restrict adoption/implementation of the standard at any point in a product's lifecycle.	principle	N				
ICH08	APPLICATION LIFECYCLE	Compatible both to US/EU product-wise lifecycle and to Japan application-wise lifecycle.	principle	N				
ICH09	ARCHIVE	It must be possible to review and to archive the submission without need for transformation	principle	N				
ICH10	AUTHOR-REVIEW	It should be possible to review the eCTD		N				
ICH11	AUTHOR-REVIEW	The specification should not restrict the types of file formats which can be submitted for use with the standard (allowed file formats are defined by each implementation and are not defined by the exchange specification).	principle	N				
ICH12	AUTHOR-REVIEW	It should be possible for the reviewer to have access to the entire submission from any part of the submission.	principle	N				

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		Requirement						
ICH13	AUTHOR-REVIEW	Clear definition of submission views (cumulative, current)	viewer/implementation requirement	N				
ICH14	BACKWARD COMPATIBLE	Elements and attributes defined by V3.x should be able to be mapped to v4.0 constructs		N				
ICH15	BACKWARD COMPATIBLE	Submitted information does not need to be resubmitted because of a change to the specification; information created using previous versions of the Specification can continue to be utilized using the subsequent versions of the specification without modification (or resubmission) of the previously provided sequences		N				
ICH16	BACKWARD COMPATIBLE	The message should support continued use of the information and documentation provided with previous regional implementations, e.g., Module 1, STF.	principle	N				
ICH17	DATASETS	It should be possible to provide data definitions for data sets.	principle	N				
ICH18	DOCUMENT FORMATTING	It should be possible to support the inclusion of scanned documents, primarily for legacy documents	principle	N				
ICH19	DOCUMENT METADATA	It must be possible to describe, in free text, the titles of the files being submitted		Y	Y			
ICH20	DOCUMENT METADATA	It must be possible to uniquely identify a file being submitted, within a submission		Y	Y			
ICH21	DOCUMENT METADATA	It must be possible for a Submitter to provide user defined information or identifier for a file		Y	DM systems should store message ID not other way around			
ICH22	DOCUMENT REUSE	The message should support the reuse of electronic files from a previously submitted instance within an application.		Y	Y			
ICH23	DOCUMENT REUSE	The message should support the reuse of electronic files from a previously submitted instance across applications.		Y	Y			
ICH24	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			

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		Requirement						
ICH25	DOCUMENT REUSE	It must be possible to include, by reference, a file that has been submitted in a previous sequence and to be able to identify that this is not new but is being used in a different context	implementation-Reviewer Capability	N				
ICH26	ENVELOPE	It must be possible to assign an identifier to a submission		Y	Y			
ICH27	ENVELOPE	It must be possible to identify the regulatory agency for which a specific submission is intended		Y	Process issue, not a message issue	Y		
ICH28	ENVELOPE	It must be possible to identify the applicant making the submission		Y	Which applicant, different per country - sender information is built in to the header	Y		
ICH29	ENVELOPE	It must be possible to assign an application number to the submission		Y	Y			
ICH30	ENVELOPE	It must be possible to assign a submission type being used for the submission		Y	Y			
ICH31	ENVELOPE	It must be possible to describe, in free text, the submission (include a short description of the submission in the administrative section)		Y	DM systems should store message ID not other way around	Y		
ICH32	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?		Yes; would like a better way to handle this requirement, this is not handled by category
ICH33	ENVELOPE	It must be possible to assign an invented name (trade name) for the product covered by the submission	Not just EU Regional	Y	Common Product Model	Y		
ICH34	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	Common Product Model	Y		

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ICH35	EU REGIONAL	It must be possible to identify to which specific country a file is relevant		Y	Is this language or regulatory authority submitted to		Is this part of a multi-regulator scenario?	y
ICH36	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 to	N	Is this part of a multi-regulator scenario?	Y
ICH37	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 to	N	Is this part of a multi-regulator scenario?	Y
ICH38	HARMONISATION	The message should support ICH-harmonized content (documentation and metadata) and ICH-regional content		Y	Y			
ICH39	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			
ICH40	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			
ICH41	HARMONISATION	Ability to reuse of eCTD submitted in other regions. e.g. reuse of leaf files, XML instance by module, eCSR. To achieve this, it is critical to distinguish global part and regional part even in Module2-5, not only in Module1.	Industry building tool need	N				

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ICH42	HARMONISATION	When the same documentation is provided, it should be submitted in the same way across HAs. For example, when a study report is submitted in US it is submitted using the STF which is not acceptable in other HAs. This minimizes reuse capabilities and adds to Industry costs to prepare globally harmonized dossiers.	principle	N				
ICH43	HYPERLINKING	It should be possible for the applicant to include hyperlinks between information		N				
ICH44	HYPERLINKING	It should be possible to utilise relative addressing for all links.		N				
ICH45	HYPERLINKING	When a file is replaced, hyperlinks referencing that file can be redirected to the 'replacement' file or retired.	reviewer requirement	N				
ICH46	HYPERLINKING	Need to support relative links across the product lifecycle		N				

ICH47	ICH PROCEDURE	For validation purposes,
		 - It should be able to uniquely identify:
		    - where in CTD a leaf belongs
		    - the relationship between leafs
		    - the lifecycle relationship (append, delete, or replace) between files
		    - the relationship between submissions
		    - the relationship between applications
		    - the type of relationship (parent-child, reference, etc)
			Principle	N				

ICH48	JP-REGIONAL	Message should support the ability to provide second and subsequent sequences which contain only additional information in XML Instance	Implementation Guide	N				
ICH49	LANGUAGE	It must be possible to assign a language to a document included in the submission		Y	Y			
ICH50	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			
ICH51	LANGUAGE	It must be possible to include files with 1 or 2 byte characters, or a mixture of both		Y	Y			

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ICH52	LANGUAGE	eCTD viewer should recognize section titles defined in CTD, e.g. "2.5 Clinical Overview". It should have an interface capable to show CTD section titles in any languages by switching standard dictionary provided by regional agencies.	viewer requirement / contolled vocabulary					
ICH53	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			
ICH54	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			
ICH55	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			
ICH56	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			
ICH57	LIFECYCLE	Replacement of multiple leafs with single leaf and vice versa should be supported in eCTD.		Y	Y			
ICH58	LIFECYCLE	The process for concatenating individual sequences into a combined sequence view (i.e., the current view and the cumulative view) must be unambiguously defined	viewer requirement / implementation	N				Need to ensure that the requirements are met for why the views are modified (e.g., ordering of the COU)

		eCTD Next Major Release Business Requirements Collation (12-NOV-08)						
ICH Req No.	TOPIC	Requirement		Affects Message?	RPS 1 included	RPS R2 - Iteration 1 Included	RPS R2 - Iteration 2 Included	Scoped for future iterations
ICH59	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			
ICH60	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?			
ICH61	PHYSICAL FILE RULES	Filenames can include underscores		Y	Y			
ICH62	PHYSICAL FILE RULES	It should be possible to constrain the contents to ensure there are no security settings, such as passwords.	Implementation Guide	N				
ICH63	PHYSICAL FILE RULES	The physical file structure. (file/folder structure) should be minimal		N				
ICH64	PHYSICAL FILE RULES	The technical message should not restrict the types of files that may be transferred. However, implementation guides may restrict the types of files and versions of file formats to be transferred or may specify unique file formats for that region.	principle	N				
ICH65	PHYSICAL FILE RULES	It should be possible to support file systems of different operating systems		N				
ICH66	PHYSICAL FILE RULES	It must be possible to constrain the maximum size of any file included in a submission (reword to reflect ICH minimum standard)	Implementation issue	N				
ICH67	SCOPE	Allow the capacity to modify the ICH CTD organizational structure (ToC) without modifying or changing the eCTD message structure		Y	Y			
ICH68	SCOPE	It should be possible to compile an eCTD equivalent to the CTD		N				Need Controlled Vocabulary fully specified.

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ICH69	STANDARDS	The message should interoperate with other healthcare standards, e.g. use controlled vocabularies from established standard-based vocabularies		Y	Need more information	Is this an implemenation detail?		
ICH70	STANDARDS	It should be possible to restrict the technology utilized to use open (ISO, W3C, IETF) standards when ever possible.	Principle	N				Implementation
ICH71	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			
ICH72	STRUCTURE	The message should allow for the control/enforcement of document/structural granularity.		Y	System validation check	Is this an implemenation detail?		
ICH73	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			
ICH74	STRUCTURE	It must be possible to ensure that all files submitted are defined and referenced		Y	System validation check			
ICH75	STRUCTURE	It must be possible to validate the contents of a submission against the CTD (e.g., module 6 is invalid)		Y	Y			
ICH76	STRUCTURE	It should be possible to easily identify all of the files included in a specific section of the submission.		Y	Y			
ICH77	STRUCTURE	It should be possible to review the submission in its entirety or in sections.	Method of transmission should support the consumption	N				
ICH78	TECHNOLOGY	The standard must not be constrained by the need for delivery via a particular medium	principle	N				
ICH79	TECHNOLOGY	It should be possible to include colour and black & white images	principle	N				
ICH80	TECHNOLOGY	It should be possible to support the introduction of new technology to aid in the review process.	principle	N				
ICH81	TERMINOLOGY	The message should support the use of controlled vocabularies for harmonized metadata		Y	Y			

ICH Req No.	TOPIC	Requirement		Affects Message?	RPS 1 included	RPS R2 - Iteration 1 Included	RPS R2 - Iteration 2 Included	Scoped for future iterations
		eCTD Next Major Release Business Requirements Collation (12-NOV-08)						
ICH82	TERMINOLOGY	The message should support the use of controlled vocabularies for regional metadata.		Y	Y			
ICH83	TERMINOLOGY	It should be possible to specify date values in an unambiguous manner.		Y	Y			
ICH84	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?		
ICH85	TRANSFER/SECURITY	The message standard should not restrict the mechanism for transmitting the message (e.g., media type, network)	principle	N				
ICH86	TRANSFER/SECURITY	The message standard should not restrict or prevent regionally implemented secure electronic message delivery standards	Implementation Guide??	N				
ICH87	TWO WAY COMMUNICATION	The message should support submission of an instance from a regulator to a regulated party.		Y		Y		
ICH88	TWO WAY COMMUNICATION	The message should support the identification of the source of an instance, i.e, regulated party or regulator		Y		Y		
ICH89	TWO WAY COMMUNICATION	Deliverables of communication between agency and applicant		N				
ICH90	TWO WAY COMMUNICATION	It should be possible to define the security methods to be used for transmission to the agencies and acknowledgement from the agency.	principle	N				
ICH91	US-REGIONAL	The message should support the identiflication of the role of the instance within the identified regulatory activity, e.g. presubmision, application, amendment, etc.		N				
ICH92	US-REGIONAL	The message should support the identification of the regulatory activity associated with the instance, e.g. original-application, labeling-supplement, etc.		N				
ICH93	VALIDATION	It must be possible to define unambiguously, the validation criteria for a submission	Principle	N				

ICH Req No.	TOPIC	Requirement		Affects Message?	RPS 1 included	RPS R2 - Iteration 1 Included	RPS R2 - Iteration 2 Included	Scoped for future iterations
		eCTD Next Major Release Business Requirements Collation (12-NOV-08)						
ICH94	VALIDATION	Message should contain suffcent information to unambiguously identify which version(s) of the DTD/Schema and controlling vocabularies was used to create the instance	this should be included in the data type and within the implementation guide	N				
ICH95	VALIDATION	The message should not require the submission of the DTD/Schema and controlling vocabularies with each instance		Y	Y - technical			
ICH96	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
ICH97	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
ICH98	COMPATIBILITY	No applicant should be required to resubmit data in the eCTD NMV specification if it has previously been submitted using the eCTD 3.2.x specification. (It is recognised that in the future, further major versions of the eCTD specification may require data migration guidance to ensure the use of data over the life of a drug product)	eCTD to RPS transition - implementation guide	N				
ICH99	COMPATIBILITY	Tools designed to view eCTD NMV submissions must also be able to view a lifecycle started with the eCTD 3.2.x specification. However, the reverse requirement is not needed (i.e. it is not needed that tools for the eCTD 3.2.x specification should be able to view submissions created using the eCTD NMV specification).	eCTD to RPS transition - implementation guide	N				

ICH Req No.	TOPIC	Requirement		Affects Message?	RPS 1 included	RPS R2 - Iteration 1 Included	RPS R2 - Iteration 2 Included	Scoped for future iterations
		eCTD Next Major Release Business Requirements Collation (12-NOV-08)						
ICH100	COMPATIBILITY	It is expected that once an eCTD lifecycle is transitioned to the eCTD NMV specification, then no further submissions/sequences will be made in the eCTD 3.2.x specification.	eCTD to RPS transition - implementation guide	N				
ICH101	COMPATIBILITY	The implementation guide must state how lifecycle relationships can be maintained from eCTD 3.2.x to eCTD NMV.	eCTD to RPS transition - implementation guide	N				
ICH102	COMPATIBILITY	Ability to reuse content; files submitted in eCTD sequences can be referenced in eCTD NMV submission units	eCTD to RPS transition - implementation guide	N				
ICH103	DESIGN CONCEPTS	The eCTD 3.2.x elements/attributes must be mapped to the eCTD NMV elements/attributes	eCTD to RPS transition - implementation guide	N				
ICH104	DESIGN CONCEPTS	The file format of the message should be xml-based.		Y	Y			
ICH105	DESIGN CONCEPTS	The message standard should not prevent or restrict the ability to e-sign the message.	Implementation specific -- technology outside the messsage	N				
ICH106	DESIGN CONCEPTS	The message standard should not prevent or restrict the ability to encrypt the message for secure transfer purposes	Implementation specific -- technology outside the messsage	N				
ICH107	DESIGN CONCEPTS	The message standard must not require encryption	Implementation specific		Y			
ICH108	INTEGRITY	Integrity checks for all files included in the submission are required.		Y	Y			
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			

ICH Req No.	TOPIC	Requirement		Affects Message?	RPS 1 included	RPS R2 - Iteration 1 Included	RPS R2 - Iteration 2 Included	Scoped for future iterations
		eCTD Next Major Release Business Requirements Collation (12-NOV-08)						
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			
ICH114	DESIGN CONCEPTS	In principle, the number of xml files managing content should be kept to a minimum and use a consistent technical design approach even though the content models may differ regionally	Implementation guide	N				
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 requirments 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 value)
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

ICH Req No.	TOPIC	eCTD Next Major Release Business Requirements Collation (12-NOV-08) Requirement		Affects Message?	RPS 1 included	RPS R2 - Iteration 1 Included	RPS R2 - Iteration 2 Included	Scoped for future iterations
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 activitiy
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; rules for replacements (look for previous forum discussions)
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			

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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				
ICH128	DESIGN CONCEPTS	STF construct should be integrated into the message standard	Implementation guide	N				
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