

eCTD Next Major Version Business Requirements (V2: 28-OCT-09)

ICH Req No.	TOPIC	Requirement
ICH01	APPLICATION LIFECYCLE	A regulated product application may have one or more regulatory activities associated with it
ICH02	APPLICATION LIFECYCLE	It must be possible to define a 'Regulatory Activity' to which a group of sequences will belong
ICH03	APPLICATION LIFECYCLE	A regulatory activity may have one or more sequences associated with it
ICH04	APPLICATION LIFECYCLE	The message should support the ability to provide one sequence to multiple regulatory activities which may span more than one application.
ICH05	APPLICATION LIFECYCLE	Each sequence should have a unique identifier
ICH06	APPLICATION LIFECYCLE	Capability to identify which eCTD sequences were used at which step of agency review.
ICH07	APPLICATION LIFECYCLE	The message should not restrict adoption/implementation of the standard at any point in a product's lifecycle.
ICH08	APPLICATION LIFECYCLE	Compatible both to US/EU product-wise lifecycle and to Japan application-wise lifecycle.
ICH09	ARCHIVE	It must be possible to review and to archive the submission without need for transformation
ICH10	AUTHOR-REVIEW	It should be possible to review the eCTD
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).
ICH12	AUTHOR-REVIEW	It should be possible for the reviewer to have access to the entire submission from any part of the submission.
ICH13	AUTHOR-REVIEW	Clear definition of submission views (cumulative, current)
ICH14	BACKWARD COMPATIBLE	Elements and attributes defined by V3.x should be able to be mapped to v4.0 constructs

eCTD Next Major Version Business Requirements (V2: 28-OCT-09)

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
ICH16	BACKWARD COMPATIBLE	The message should support continued use of the information and documentation provided with previous regional implementations, e.g., Module 1, STF.
ICH17	DATASETS	It should be possible to provide data definitions for data sets.
ICH18	DOCUMENT FORMATTING	It should be possible to support the inclusion of scanned documents, primarily for legacy documents
ICH19	DOCUMENT METADATA	It must be possible to describe, in free text, the titles of the files being submitted
ICH20	DOCUMENT METADATA	It must be possible to uniquely identify a file being submitted, within a submission
ICH21	DOCUMENT METADATA	It must be possible for a Submitter to provide user defined information or identifier for a file
ICH22	DOCUMENT REUSE	The message should support the reuse of electronic files from a previously submitted instance within an application.
ICH23	DOCUMENT REUSE	The message should support the reuse of electronic files from a previously submitted instance across applications.
ICH24	DOCUMENT REUSE	It must be possible to include by reference, a file that physically resides in another submission (eg. cross-product submission support)
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
ICH26	ENVELOPE	It must be possible to assign an identifier to a submission
ICH27	ENVELOPE	It must be possible to identify the regulatory agency for which a specific submission is intended
ICH28	ENVELOPE	It must be possible to identify the applicant making the submission
ICH29	ENVELOPE	It must be possible to assign an application number to the submission
ICH30	ENVELOPE	It must be possible to assign a submission type being used for the submission
ICH31	ENVELOPE	It must be possible to describe, in free text, the submission (include a short description of the submission in the administrative section)
ICH32	ENVELOPE	It must be possible to define the Procedure type being used for the submission

eCTD Next Major Version Business Requirements (V2: 28-OCT-09)

ICH33	ENVELOPE	It must be possible to assign an invented name (trade name) for the product covered by the submission
ICH34	ENVELOPE	It must be possible to assign an international non-proprietary name(s) (inn) for the drug substance(s) covered by the submission
ICH35	EU-REGIONAL	It must be possible to identify to which specific country a file is relevant
ICH36	EU-REGIONAL	It must be possible to identify that a file is relevant to all countries covered by a submission
ICH37	EU-REGIONAL	It must be possible to identify for which country(ies) a specific submission is intended
ICH38	HARMONISATION	The message should support ICH-harmonized content (documentation and metadata) and ICH-regional content
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
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
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.
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.
ICH43	HYPERLINKING	It should be possible for the applicant to include hyperlinks between information
ICH44	HYPERLINKING	It should be possible to utilise relative addressing for all links.
ICH45	HYPERLINKING	When a file is replaced, hyperlinks referencing that file can be redirected to the 'replacement' file or retired.
ICH46	HYPERLINKING	Need to support relative links across the product lifecycle

eCTD Next Major Version Business Requirements (V2: 28-OCT-09)

ICH47	ICH PROCEDURE	For validation purposes, <ul style="list-style-type: none"> - It should be able to uniquely identify: <ul style="list-style-type: none"> - where in CTD a leaf belongs - the relationship between leaves - 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)
ICH48	JP-REGIONAL	Message should support the ability to provide second and subsequent sequences which contain only additional information in XML Instance
ICH49	LANGUAGE	It must be possible to assign a language to a document included in the submission
ICH50	LANGUAGE	It must be possible to (incorporate unicode character sets) to deal with languages such as Bulgarian and Greek
ICH51	LANGUAGE	It must be possible to include files with 1 or 2 byte characters, or a mixture of both
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.
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.
ICH54	LIFECYCLE	The message should support the deletion metadata from previously submitted instances, e.g., related sequences, submission type, operation attribute, manufacturer name, etc.
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.
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.
ICH57	LIFECYCLE	Replacement of multiple leafs with single leaf and vice versa should be supported in eCTD.

eCTD Next Major Version Business Requirements (V2: 28-OCT-09)

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
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))
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
ICH61	PHYSICAL FILE RULES	Filenames can include underscores
ICH62	PHYSICAL FILE RULES	It should be possible to constrain the contents to ensure there are no security settings, such as passwords.
ICH63	PHYSICAL FILE RULES	The physical file structure. (file/folder structure) should be minimal
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.
ICH65	PHYSICAL FILE RULES	It should be possible to support file systems of different operating systems
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)
ICH67	SCOPE	Allow the capacity to modify the ICH CTD organizational structure (ToC) without modifying or changing the eCTD message structure
ICH68	SCOPE	It should be possible to compile an eCTD equivalent to the CTD
ICH69	STANDARDS	The message should interoperate with other healthcare standards, e.g. use controlled vocabularies from established standard-based vocabularies
ICH70	STANDARDS	It should be possible to restrict the technology utilized to use open (ISO, W3C, IETF) standards when ever possible.
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)
ICH72	STRUCTURE	The message should allow for the control/enforcement of document/structural granularity.

eCTD Next Major Version Business Requirements (V2: 28-OCT-09)

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)
ICH74	STRUCTURE	It must be possible to ensure that all files submitted are defined and referenced
ICH75	STRUCTURE	It must be possible to validate the contents of a submission against the CTD (e.g., module 6 is invalid)
ICH76	STRUCTURE	It should be possible to easily identify all of the files included in a specific section of the submission.
ICH77	STRUCTURE	It should be possible to review the submission in its entirety or in sections.
ICH78	TECHNOLOGY	The standard must not be constrained by the need for delivery via a particular medium
ICH79	TECHNOLOGY	It should be possible to include colour and black & white images
ICH80	TECHNOLOGY	It should be possible to support the introduction of new technology to aid in the review process.
ICH81	TERMINOLOGY	The message should support the use of controlled vocabularies for harmonized metadata
ICH82	TERMINOLOGY	The message should support the use of controlled vocabularies for regional metadata.
ICH83	TERMINOLOGY	It should be possible to specify date values in an unambiguous manner.
ICH84	TRANSFER/SECURITY	The message should support a means to enable the validation of the integrity of the electronic files within an instance
ICH85	TRANSFER/SECURITY	The message standard should not restrict the mechanism for transmitting the message (e.g., media type, network)
ICH86	TRANSFER/SECURITY	The message standard should not restrict or prevent regionally implemented secure electronic message delivery standards
ICH87	TWO-WAY COMMUNICATION	The message should support submission of an instance from a regulator to a regulated party.
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.
ICH91	US-REGIONAL	The message should support the identification of the role of the instance within the identified regulatory activity, e.g. presubmission, application, amendment, etc.
ICH92	US-REGIONAL	The message should support the identification of the regulatory activity associated with the instance, e.g. original-application, labeling-supplement, etc.
ICH93	VALIDATION	It must be possible to define unambiguously, the validation criteria for a submission

eCTD Next Major Version Business Requirements (V2: 28-OCT-09)

ICH94	VALIDATION	Message should contain sufficient information to unambiguously identify which version(s) of the DTD/Schema and controlling vocabularies was used to create the instance
ICH95	VALIDATION	The message should not require the submission of the DTD/Schema and controlling vocabularies with each instance
ICH96	USABILITY - VIEWING	The instance should be viewable without access to specialized tools or internet
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
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)
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).
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.
ICH101	COMPATIBILITY	The implementation guide must state how lifecycle relationships can be maintained from eCTD 3.2.x to eCTD NMV.
ICH102	COMPATIBILITY	Ability to reuse content; files submitted in eCTD sequences can be referenced in eCTD NMV submission units
ICH103	COMPATIBILITY	The eCTD 3.2.x elements/attributes must be mapped to the eCTD NMV elements/attributes
ICH104	DESIGN CONCEPTS	The file format of the message should be xml-based.
ICH105	DESIGN CONCEPTS	The message standard should not prevent or restrict the ability to e-sign the message.
ICH106	DESIGN CONCEPTS	The message standard should not prevent or restrict the ability to encrypt the message for secure transfer purposes
ICH107	DESIGN CONCEPTS	The message standard must not require encryption
ICH108	INTEGRITY	Integrity checks for all files included in the submission are required.
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

eCTD Next Major Version Business Requirements (V2: 28-OCT-09)

ICH110	INTEGRITY	The ability to specify which algorithm is being used for file integrity checks is required.
ICH111	TWO-WAY COMMUNICATION	It must be possible to identify the sender and receiver of a message.
ICH112	TWO-WAY COMMUNICATION	It must be possible to relate any message to a particular message, regulated activity and/or application.
ICH113	TWO-WAY COMMUNICATION	Every eCTD message must be uniquely identifiable.
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
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
ICH116	ENVELOPE	The message standard must provide a three-level hierarchy of application, regulatory activity and submission unit.
ICH117	ENVELOPE	The message standard must provide information about the product.
ICH118	ENVELOPE	The message standard must provide enough information to identify the sender.
ICH119	ENVELOPE	The message standard must provide enough information to identify the recipient.
ICH120	DESIGN CONCEPTS	The message standard must provide the ability for the sender or recipient to update previously submitted metadata
ICH121	LIFECYCLE	The order/sequence of leaf elements within a CTD section must be able to be controlled
ICH122	DOCUMENT REUSE	A file can be displayed in multiple sections of the CTD (preserving the leaf - file concept in the current eCTD specification)
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)

eCTD Next Major Version Business Requirements (V2: 28-OCT-09)

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
ICH125	LIFECYCLE	Life cycle operations must occur within the same context as the existing (target) leaf
ICH126	DESIGN CONCEPTS	There should be no restrictions on the characters used in controlled vocabularies
ICH127	DESIGN CONCEPTS	There should be a basic ICH stylesheet for presentation purposes
ICH128	DESIGN CONCEPTS	STF construct should be integrated into the message standard
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).
ICH130	VERSIONING	Version control capability with a defined version ID must be available for all DTDs, Schema, stylesheets and controlling vocabularies necessary to create an instance