Version	Date	Component	Change Description
0.90	1-Jul-14	Multiple	Initial release for eCTD pilot launch
0.91	7-Aug-14	Headers and Elements	Numbering for 1.3.1.3.3.1 Updated
		File-Folder Names	Folder for 1.3.5.1 Added
		Defined Lists	Sequence Type updated to lower-case
0.92	7-Oct-14	eCTD Validation	Update specification version in section 3.3,3.4,3.5,6.3

TH Envelope Attributes

XML Element	Description	Constraint	Occurrence	Defined List*
esub-id	eSubmission Identifier	Mandatory	Single	
seq-type	Sequence Type	Mandatory	Single	X
reg-activity-lead	Regulatory Activity Lead	Mandatory	Single	X
licensee	Licensee	Mandatory	Single	
inn	INN or Generic Name	Mandatory	Multiple	
product-name	Product Name	Mandatory	Multiple	
sequence	Sequence Number	Mandatory	Single	
related-sequence	Related Sequence Number	Optional	Single	
seq-description	Sequence Description	Mandatory	Single	

Sequence Type	
List Value	**Description**
a-ph-newce	A: Pharmaceutics - New Chemical Entity
a-ph-newse	A: Pharmaceutics - New Salt or Ester of Existing Active Ingredient
a-ph-newdosage	A: Pharmaceutics - New Dosage Form
a-ph-newroute	A: Pharmaceutics - New Route of Administration
a-ph-newcomb	A: Pharmaceutics - New Combination
a-ph-newothers	A: Pharmaceutics - New Medicinal Product (Others)
a-ph-newgen	A: Pharmaceutics - New Generic
a-ph-generic	A: Pharmaceutics - Generic
a-ph-house	A: House Hold Remedies
b-bio-vaccine	B: Biologics - Vaccine
b-bio-blood	B: Biologics - Blood and Plasma Derived Product
b-bio-cell	B: Biologics - Cell- and Tissue- Based Therapy Product
b-bio-biotech	B: Biologics - Biotechnology Product
b-bio-biosimilar	B: Biologics - Biosimilar Product
b-bio-others	B: Biologics - Others
c-vet-newprod	C: Veterinary - New Medicinal Product
c-vet-newgeneric	C: Veterinary - New Generic Medicinal Product
c-vet-generic	C: Veterinary - Generic Medicinal Product
c-vet-premixed	C: Veterinary - Medicated Premixed
c-vet-bio	C: Veterinary - Biologics
d-traditional	D: Traditional Medicinal Product
f-var-major	F: Variation - Major Variation (MaV)
f-var-minor-pa	F: Variation - Minor Variation (MiV-PA)
f-var-minor-n	F: Variation - Minor Variation (MiV-N)
f-var-others	F: Variation - Others
g-clin-authapp	G: Clinical Trial Authorization Application
g-clin-authamend	G: Clinical Trial Authorization Amendments
h-review-smph	H: Review of SMP Application
h-riskmgtplan	H: Risk Management Plan
h-pv	H: Pharmacovigilance
h-psur	H: Periodic Safety Update Report

i-dmf	I: Drug Master Files
i-pmf	I: Plasma Master Files
i-vamf	I: Vaccine Antigen Master File
i-tmf	I: Tissue Master File
j-suppl	J: Supplementary Information
k-orphan	K: Orphan Drug Application
k-emergency	K: Emergency Used Application
z-undefined-regact	Z: Undefined Regulatory Activity

Regulatory Activity Lead	
List Value	**Description**
Biologicals	Biological Product Review
Pharmaceuticals	Pharmaceutical Product Review
Pharmacovigilance	Pharmacovigilance Review

Section ID	Business Terminology	XML-Element
1.0	**Cover**	m1-0-cover
1.0.1	Tracking Table	m1-0-1-tracking
1.0.2	Cover Letter	m1-0-2-cover-letter
1.2	**Application Forms**	m1-2-forms
1.2.1	Application Form	m1-2-1-form
1.2.1.1	<Sequence Number> <Description>	leaf-node
1.2.2	Annexes	m1-2-2-annexes
1.2.2.1	<Sequence Number> <Description of Annex>	leaf-node
1.3	**Product Information**	m1-3-pi
1.3.1	SPC, Labelling and Package Leaflet	m1-3-1-spc-label-pl
1.3.1.1	Labelling	m1-3-1-1-label
1.3.1.1.1	<Description of Labelling>	leaf-node
1.3.1.2	SPC	m1-3-1-2-spc
1.3.1.3	Package Leaflet	m1-3-1-3-pl
1.3.1.3.1	Package Leaflet - Thai	m1-3-1-3-pl-th
1.3.1.3.2	Package Leaflet - English	m1-3-1-3-pl-en
1.3.1.3.3	Package Leaflet - Other Language	m1-3-1-3-pl-ot
1.3.1.3.3.1	<Language> <Description>	leaf-node
1.3.2	Mock-up	m1-3-2-mockup
1.3.3	Specimen	m1-3-3-specimen
1.3.4	Consultation with Target Patient Groups	m1-3-4-consultation
1.3.5	Product Information already approved in Other States	m1-3-5-approved
1.3.5.1	Foreign Regulatory Status	m1-3-5-1-status
1.3.5.2	Foreign Product Information	m1-3-5-2-pi
1.3.5.2.1	<Country> <Product Information Type>	leaf-node
1.3.5.3	Data Similarities and Differences	m1-3-5-3-smilarities
1.3.6	Braille	m1-3-6-braille
1.4	**Information about the Experts**	m1-4-expert
1.4.1	Quality	m1-4-1-quality
1.4.2	Non-Clinical	m1-4-2-non-clinical
1.4.3	Clinical	m1-4-3-clinical
1.5	**Specific Requirements for Different Types of**	m1-5-specific
1.5.1	Information for Bibliographical Applications	m1-5-1-bibliographic
1.5.2	Information for Generic, 'Hybrid' or Bio-similar Applications	m1-5-2-generic-hybrid-bio-similar
1.5.2.1	Information for Generic Application	m1-5-2-1-generic
1.5.2.2	Information for 'Hybrid' Applications	m1-5-2-2-hybrid
1.5.2.3	Information for Bio-similar Applications	m1-5-2-3-bio-similar
1.5.3	(Extended) Data/Market Exclusivity	m1-5-3-data-market-exclusivity
1.5.4	Exceptional Circumstances	m1-5-4-exceptional-circumstances
1.5.5	Conditional Marketing Authorisation	m1-5-5-conditional-ma
1.5.6	Additional Trade Name Declarations	m1-5-6-trade-name
1.5.7	Co-marketed Medicines Declarations	m1-5-7-co-marketed
1.6	**Environmental Risk Assessment**	m1-6-environrisk

Section ID	Business Terminology	XML-Element
1.6.1	Non-GMO	m1-6-1-non-gmo
1.6.2	GMO	m1-6-2-gmo
1.7	**Information relating to Orphan Market Exclusivity**	m1-7-orphan
1.7.1	Similarity	m1-7-1-similarity
1.7.2	Market Exclusivity	m1-7-2-market-exclusivity
1.8	**Information relating to Pharmacovigilance**	m1-8-pharmacovigilance
1.8.1	Pharmacovigilance System	m1-8-1-pharmacovigilance-system
1.8.2	Risk-management System	m1-8-2-risk-management-system
1.9	**Information relating to Clinical Trials**	m1-9-clinical-trials
1.10	**Information relating to Paediatrics**	m1-10-paediatrics
1.R	**Responses to Questions**	m1-responses
1.R.1	<Sequence Number> <Sequence Description>	leaf-node
1.A	**Additional Data**	m1-additional-data

Number	Validation Criterion	Type of check	Lifecycle needed? "YES" (Y) *	Comments
Type of	**Description of Type of check**			
P/F	**Pass/Fail** These are validation criteria that can either be passed or failed. eCTDs that fail to meet one or more of these criteria will be returned to the applicant for fixing and resubmission as the same sequence number. The pass/fail category has been introduced for the possibility of future automation of eCTD validation.			
BP	**Best Practices** Any deviation from the criterion should always be reported by the validating tool. These are validation criteria that it is considered good practice to ensure are correct in the submitted eCTD. The applicant should make every effort to address these areas before the eCTD is submitted to the agency. - eCTDs that fail to meet one or more of these criteria will still be accepted by the agency during technical validation and it is possible that agencies may not even check these criteria during technical validation. These criteria assess factors that affect the overall ease of use of the eCTD. All tool vendors should include these criteria in their validation tools so that applicants can produce eCTDs that are easier to use. Users of the validation tool should also be able to check the eCTD without checking for the Best Practice criteria.			
Info	**Information** Data is collected for Information purposes only. Findings will not influence the acceptance of the application.			
*	**"Y"- Criteria** Test marked with "Y" needs the relevant former sequences for the specific criterion to be present for the result to be fully reliable. If these sequences are not present when testing, any FAIL results for these criteria should be interpreted carefully. When reporting a 'Fail' for these 'Y' criteria, validation tools should also report the specific missing sequences that are related to the 'Fail'.			

Number	Validation Criterion	Type of check	Lifecycle needed? "YES" (Y) *	Comments
1 - ICH DTD				
1.1	The specified filename is used	**P/F**		File is named ich-ectd-3-2.dtd
1.2	The file is placed in the correct folder	**P/F**		In the folder /XXXX/util/dtd
1.3	A currently acceptable version of the DTD is used (checksum matches the published value)	**P/F**		Currently acceptable versions are described in the current ICH eCTD Specification. (The checksum for the DTD in eCTD v3.2 (ich-ectd-3-2.dtd) is 1d6f631cc6b6357f0f4fe378e5f79a27)
1.4	The version number of the DTD/specification used in the sequence being tested is higher than or equal to the version of the DTD used in the sequence numerically preceding the incoming sequence in the eCTD lifecycle.	**P/F**	Y	With reference to any transition guidance, going back to an earlier version is not allowed when a newer version has already been used for that eCTD. 'The sequence numerically preceding the incoming sequence in the eCTD lifecycle' refers to the highest numbered sequence that is numerically lower than the incoming sequence. The criterion should only be tested if there are sequences with lower sequence numbers present.
1.5	The version number of the DTD/specification used in the sequence being tested is lower than or equal to the version of the DTD used in the sequence numerically succeeding the incoming sequence in the eCTD lifecycle.	**P/F**	Y	This rule specifically tests in situations where sequences have been submitted out of order. 'The sequence numerically succeeding the incoming sequence in the eCTD lifecycle' refers to the lowest numbered sequence that is numerically higher than the incoming sequence. The criterion should only be tested if there are sequences with higher sequence numbers present.

Number	Validation Criterion	Type of check	Lifecycle needed? "YES" (Y) *	Comments
2 - ICH Style-Sheet				
2.1	The specified filename is used	**P/F**		File is named ectd-2-0.xsl
2.2	The file is placed in the correct folder	**P/F**		In the folder /XXXX/util/style
2.3	The checksum for the stylesheet used must match the published checksum for the stylesheet associated with the DTD used for the sequence	**P/F**		For example, the checksum corresponding to the stylesheet from eCTD specification v3.2 (ectd-2-0.xsl) is 3a07a202455e954a2eb203c5bb443f77
3 - TH M1 Schema				
3.1	The specified filename is used	**P/F**		File is named th-regional.xsd
3.2	The file is placed in the correct folder	**P/F**		In the folder /XXXX/util/dtd
3.3	A currently acceptable version of the Schema is used (checksum matches the published value)	**P/F**		Currently acceptable with reference to any transition guidance The checksum for the Schema for TH m1 v0.92 is c6c0c9dcb64cc267c2985e793ebaa456
3.4	The version number of the Schema/specification used in the sequence being tested is higher than or equal to the version of the Schema used in the sequence numerically preceding the incoming sequence in the eCTD lifecycle.	**P/F**	Y	With reference to any transition guidance, going back to an earlier version is not allowed when a newer version has already been used for that eCTD. 'The sequence numerically preceding the incoming sequence in the eCTD lifecycle' refers to the highest numbered sequence that is numerically lower than the incoming sequence. For example if 0109 used Schema 0.92, 0110 was Schema 1.0, and 0111 is not present, then 0112 must be built in either Schema 1.0 or higher. The criterion should only be tested if there are sequences with lower sequence numbers present.

Number	Validation Criterion	Type of check	Lifecycle needed? "YES" (Y) *	Comments
3.5	The version number of the Schema/specification used in the sequence being tested is lower than or equal to the version of the Schema used in the sequence numerically succeeding the incoming sequence in the eCTD lifecycle.	P/F	Y	This rule specifically tests in situations where sequences have been submitted out of order. 'The sequence numerically succeeding the incoming sequence in the eCTD lifecycle' refers to the lowest numbered sequence that is numerically higher than the incoming sequence. For example if 0010 used Schema 0.92, and 0012 was Schema 1.0, then 0011 must be built in either Schema 1.0 or 0.92. The criterion should only be tested if there are sequences with higher sequence numbers present. Note: This cannot be checked properly in an offline scenario (validation tools may not necessarily know what has alredy been submitted). It is recommended that sponsors check the highest available sequence against criterion number 3.4 instead.
4 - EU M1 Leaf MOD File				
	VALIDATION SECTION NOT APPLICABLE FOR THAILAND			
5 - EU M1 Envelope MOD File				
	VALIDATION SECTION NOT APPLICABLE FOR THAILAND			
6 - TH M1 Style-sheet				
6.1	The specified filename is used	P/F		File is named th-regional.xsl
6.2	The file is placed in the correct folder	P/F		In the folder /XXXX/util/style
6.3	The checksum for the stylesheet used must match the published checksum for the stylesheet associated with the DTD used for the sequence	P/F		For example, the checksum for the stylesheet from TH eCTD Module 1 v0.92 is cb3d43ac42bb6f653360cc3695bea1c9.

Number	Validation Criterion	Type of check	Lifecycle needed? "YES" (Y) *	Comments
7 - Index XML				
7.1	The file is placed in the correct folder	P/F		The root folder /XXXX
7.2	The file is named correctly	P/F		File is named index.xml
7.3	The file is well formed	P/F		Well formed with respect to the rules of the XML specification
7.4	The file is valid	P/F		Valid with respect to the ICH eCTD DTD file included in the util/dtd folder
7.5	The reference to the DTD in index.xml is directed to the DTD provided in the util folder.	P/F		This is the ICH DTD in /XXXX/util/dtd, and tested for validity by rules 1.1 - 1.5. A valid reference means a URI - see http://www.w3.org/TR/xml/ and http://www.ietf.org/rfc/rfc3986.txt (version 2005 page 22, section 3.3)
7.6	The reference to the stylesheet in index.xml is directed to the stylesheet provided in the util folder.	P/F		This is the ICH stylesheet in /XXXX/util/style and tested for validity by rules 2.1 - 2.3. A valid reference means a URI - see http://www.w3.org/TR/xml/ and http://www.ietf.org/rfc/rfc3986.txt (version 2005 page 22, section 3.3)
8 - Index MD5 txt				
8.1	The file is placed in the correct folder	P/F		The root folder /XXXX
8.2	The file is named correctly	P/F		The file is named index-md5.txt
8.3	The regenerated checksum for the index.xml matches the value in the file index-md5.txt.	P/F		

Number	Validation Criterion	Type of check	Lifecycle needed? "YES" (Y) *	Comments
9 - TH Regional XML				
9.1	The file is placed in the correct folder	**P/F**		The folder /XXXX/m1/th
9.2	The file is named correctly	**P/F**		File is named th-regional.xml
9.3	The file is well formed	**P/F**		Well formed with respect to the rules of the XML specification
9.4	The file is valid	**P/F**		Valid with respect to the TH Module 1 Schema file included in the util/dtd folder
9.5	The reference to the Schema in th-regional.xml is directed to the Schema provided in the util folder.	**P/F**		This is the TH Regional Schema in /XXXX/util/dtd, and tested for validity by rules 3.1-3.5. A valid reference means a URI - see http://www.w3.org/TR/xml/ and http://www.ietf.org/rfc/rfc3986.txt (version 2005 page 22, section 3.3)
9.6	The reference to the stylesheet in th-regional.xml is directed to the stylesheet provided in the util folder.	**P/F**		This is the stylesheet in /XXXX/util/style, and tested for validity by rules 6.1-6.3. A valid reference means a URI - see http://www.w3.org/TR/xml/ and http://www.ietf.org/rfc/rfc3986.txt (version 2005 page 22, section 3.3)
10 - Submission Structure				
10.1	All the lowest level heading elements in the XML (including node-extensions) included in the submission contain at least one leaf	**P/F**		

Number	Validation Criterion	Type of check	Lifecycle needed? "YES" (Y) *	Comments
11 - Leaf Attributes				
11.1	The leaf attribute "checksum-type" has a value of md5 or MD5	P/F		Note that this value is not case sensitive
11.2	The regenerated checksum for each file matches the value in the leaf attribute "checksum"	P/F	Y	Note that if the content file is in an earlier sequence within the same eCTD application then the checksum can only be regenerated if access to this file is available. The MD5 checksum is not case sensitive.
11.3	For every leaf the "title" attribute is not empty	P/F		
11.4	All leaves with an operation attribute value of new, replace or append must have a value for the cross reference (xlink:href) ☐	P/F		The value for the cross reference (xlink:href) should be valid, and not contain any illegal characters. (Legal characters are lower case characters a-z, digits 0-9 and hyphens, as documented in the ICH eCTD specification). A valid reference means a URI - see http://www.w3.org/TR/xml/ and http://www.ietf.org/rfc/rfc3986.txt (version 2005 page 22, section 3.3)
11.5	All leaves with an operation attribute value of delete must have no value for the cross reference (xlink:href)	P/F		The attribute does not need to be included, or can be declared but with a null value
11.6	The file referenced by the cross reference (xlink:href) must exist in the same or a previously submitted sequence within the same eCTD application	P/F	Y	The link within the XML leaf element is valid, i.e the target exists
11.7	All leaves with an operation attribute value of replace, delete or append must have a value for modified-file	P/F		
11.8	All leaves with an operation attribute value of new must have no value for modified-file	P/F		The attribute does not need to be included, or can be declared but with a null value
11.9	The leaf referenced by the modified file must exist in a previously submitted sequence within the same eCTD application	P/F	Y	If a <leaf> has the 'modified-file' attribute set, the referenced <leaf> must exist in a previously submitted sequence.

Number	Validation Criterion	Type of check	Lifecycle needed? "YES" (Y) *	Comments
11.10	For all leaves with an operation attribute value of replace, delete or append, the modified file must be present in the same CTD section of the dossier. Using the operation attribute 'delete' to remove content in sections in EU m1 which are no longer used, due to updates of the CTD, should be exempt from this rule.	P/F		'Same CTD section' refers to the position in the table of contents. Sections are defined by the CTD and also by attributes in the eCTD. For example, applicants cannot replace content in the application form section with revised content that is being provided in the cover letter section. eCTD attributes also create applicant defined sections. For example, each 'substance' or 'manufacturer' attribute in m3-2-s-drug-substance, or 'product-name' attribute in m3-2-p–drug-product will create a new CTD section, and lifecycle between these sections is also not allowed.
12 - Node Extensions				
12.1	For every node-extension the "title" attribute is not empty	P/F		If node-extensions are used, the 'title' attribute must be set.
13 - Sequence Number				
13.1	The sequence folder name is a 4 digit number	P/F		i.e. numbers between 0000 and 9999
13.2	The sequence number (folder name) has not already been used	P/F	Y	The sequence number must not have been used in a previous sequence of the same submission. The program will not only check the folder names but also the sequence numbers in the TH regional backbones of previous sequences.
13.3	The sequence folder name matches the sequence number in each envelope in th-regional.xml	P/F		The sequence folder name and the sequence numbers given in the TH envelopes must be identical.

Number	Validation Criterion	Type of check	Lifecycle needed? "YES" (Y) *	Comments
14 - Envelope Attributes				
14.BP1	If the sequence type is supplemental information (j-suppl) then the related-sequence attribute must have a value.	**BP**		If the envelope element 'sequence-type' has the value 'j-suppl' , the 'related-sequence' element value must be specified.
14.BP2	If the sequence type is not supplemental information (j-suppl) then there must not be related sequence attribute	**BP**		Refer to TH M1 speciifcation. If the envelope element 'sequence-type' does not have the value 'j-suppl' the 'related sequence' element must be empty or not present.
15 - Files/Folders				
15.1	The files provided in the folders for Module 1 are in acceptable formats	**P/F**		Refer to table in TH Module 1 specification. : this is XML (where a specification exists), PDF, JPEG/JPG, PNG, SVG and GIF.
15.2	The files provided in the folders for Module 2-5 are in acceptable formats	**P/F**		Refer to ICH eCTD specification. This is XML, PDF, JPEG/JPG, PNG, SVG and GIF.
15.3	Total file folder path length must not exceed 180 characters	**P/F**		Counting starts from the first digit of the sequence number in the sequence number folder name, and includes the filename.
15.4	File names, including the extension, must not exceed 64 characters	**P/F**		
15.5	Folder names must not exceed 64 characters	**P/F**		
15.6	Only valid characters are used in file names	**P/F**		Lower case characters a-z, digits 0-9 and hyphens are allowed (as documented in the ICH eCTD specification). This test should only be applied to the file names in the file system, for checks on the XML see test 11.4.
15.7	Only valid characters are used in folder names	**P/F**		Lower case characters a-z, digits 0-9 and hyphens are allowed (as documented in the ICH eCTD specification). This test should only be applied to the folder names in the file system, for checks on the XML see test 11.4.

Number	Validation Criterion	Type of check	Lifecycle needed? "YES" (Y) *	Comments
15.8	There are no unreferenced files in M1, M2, M3, M4 and M5 folders	**P/F**		Including all subfolders within the m1-m5 folders but excluding 'util' folder and subfolders
15.9	The only files in the sequence folder (/XXXX/…) are the index.xml and index-md5.txt	**P/F**		
15.10	There are no empty folders	**P/F**		
15.11	The tracking table file is present in the correct location	**P/F**		The folder /XXXX/m1/th/10-cover/101-tracking
15.12	The tracking table file is correctly named	**P/F**		File is named tracking-var.pdf ☐
15.BP1	Individual files do not exceed 100 MB in size	**BP**		Any deviation should always be reported by the validating tool. Files larger than 100 MB should be avoided due to potential archiving issues and to make the assessment easier.
15.BP2	The recommended folder structure and folder names in the ICH and TH specifications are used	**Info**		Although navigation of an eCTD is typically carried out via the XML backbone, it is also helpful if the underlying files and folders follow the ICHand TH naming guidance.
15.BP3	The recommended file names from the ICH and TH specifications are used for all files	**Info**		Although navigation of an eCTD is typically carried out via the XML backbone, it is also helpful if the underlying files and folders follow the ICH and TH naming guidance.

Number	Validation Criterion	Type of check	Lifecycle needed? "YES" (Y) *	Comments
16 - PDF Files				
16.1	No PDF has been created and saved as version 1.3 or earlier	**P/F**		PDF 1.3 or earlier is not acceptable for technical reasons. No exceptions will be made. For example, if a literature reference is received in PDF 1.3 or earlier, then the applicant must provide it in PDF 1.4, 1.5, 1.6 or 1.7, even if this means copying the full text into a new document or even getting a paper copy and scanning it. Further guidance is provided about the best ways to check the PDF version in the comment to rule 16.BP1.
16.2	There is no security setting to open any individual file	**P/F**		This includes passwords, certificate security, or adobe policy server settings. This test should not be used to test for corrupted files, instead see 16.5.
16.3	There are no further security settings applied to any individual file (except for files in Modules 1.2, 3.3, 4.3 and 5.4)	**P/F**		All "restrictions" should be "allowed" when viewing the Document Preferences > Security settings. This includes any of the following document restrictions: printing, changing the document, document assembly, content copying, content copying for accessibility, page extraction, filling of form fields, signing, creation of template pages. Specific security settings of files in m1.2 are tested in criterion 16.4.
16.4	Individual files in section 1.2 have no security settings except for the following, which are allowed: Changing the document Document assembly Page extraction Creation of template pages.	**P/F**		These limiited security settings are allowable for the application form, because they are necessary for the functioning of the eAF.

Number	Validation Criterion	Type of check	Lifecycle needed? "YES" (Y) *	Comments
16.5	The submission does not contain corrupted files	P/F		This can be achieved by opening a PDF file in software which is compliant to ISO 32000-1; if the file opens without error, the PDF file is considered to be conformant. Absence of detection of conformance means corrupted PDF.
16.BP1	Files have been created and saved as PDF 1.4, 1.5, 1.6, or PDF 1.7	BP		For PDF files with apparent versions of 1.3 or earlier, the version information should be taken from the first eight characters from the first line of the header in the file. For versions 1.4 and higher, the version should be taken from the document catalogue dictionary, if present. If both the header information and the catalogue information are present, then the document catalogue dictionary information takes precedent, see PDF 32000-1:2008 specification, chapter 7.5.2 for further details. Only the PDF versions specified are recommended by ICH. This test is important due to archiving and also that PDF files can be correctly open and read by assessors.
16.BP2	Hyperlinks and bookmarks within documents, or between documents within the same sequence, have a valid target.	BP		Only links that open in the same software application are tested. Other links (e.g. web links and e-mail addresses) are not considered to link to essential content and should not be tested. If this BP criterion is not met, the assessor might not be able to conveniently find the relevant documents and read the submission as intended by the applicant.

Number	Validation Criterion	Type of check	Lifecycle needed? "YES" (Y) *	Comments
16.BP3	Hyperlinks and bookmarks to destinations in a different sequence in the same eCTD have a valid target.	**BP**	Y	Only links that open in the same software application are tested. Other links (e.g. web links and e-mail addresses) are not considered to link to essential content and should not be tested. If this BP criterion is not met, the assessor might not be able to conveniently find the relevant documents and read the submission as intended by the applicant.
16.BP4	All hyperlinks and bookmarks are set to "inherit zoom"	**BP**		Using 'inherit zoom' ensures that assessors do not need to spend time repeatedly setting the view when using the links for navigation to new documents.
16.BP5	PDFs must have "Fast Web View" active	**BP**		The use of 'Fast Web View' helps ensure optimum performance of the review system.
16.BP6	PDF Document Properties for the Initial View are set for "Page Layout = Default" and "Magnification = Default"	**BP**		Setting page layout and magnification to default allows the assessor to set his/her own preferences to define how the PDF is displayed, rather than the settings being taken from each individual PDF file.
16.BP7	All PDF hyperlinks and bookmarks are relative	**BP**		Relative links and bookmarks will continue to work when the submission is copied and loaded into new a environment at the agency side. Absolute (rooted) links and bookmarks will not.
16.BP8	The bookmarks pane should be visible if bookmarks are included within a PDF document	**BP**		Fulfilling this BP criterion make it more convenient for the assessor in knowing there are bookmarks without opening the pane.
16.BP9	The bookmarks pane should not be visible if there are no bookmarks included within a PDF document	**BP**		Fulfilling this BP criterion makes it more convenient for the assessor in knowing there are no bookmarks without opening the pane to check.

Number	Validation Criterion	Type of check	Lifecycle needed? "YES" (Y) *	Comments
16.BP10	All hyperlinks and bookmarks between two PDFs must be configured as specified in ISO 32000-1:2008	BP		Consult the PDF specifications as in ISO 32000-1:2008 for section 7.11.2.3 on how the paths need to be written in PDF. The paths cannot contain back slashes, only forward slashes. See also 12.6.4.3 for the remote goto action. The link to another PDF cannot be made with javascript code in the PDF. Please note, not all PDF tools display the path for the link with forward slashes. However, the presence of a backslash in a link as displayed in a PDF viewer or editor does not necessarily mean that the link is NOT according to the ISO specifications. Therefore, tests for backslashes must be performed in eCTD validation software. This BP criterion is important because links who are not according to section 7.11.2.3 may not work on certain devices, such as non-Windows operating systems or tablets.
17 - Study Tagging Files (STFs)				
17.1	Check Index Reference	P/F		The files from the xlink:href references must exist. Corresponds to US FDA criterion 1833.
17.2	Check Index Reference (title match)	BP		The titles from the doc-content elements must match the corresponding leaf title values from the ICH backbone.See FDA criterion 3001.
17.3	Content Block are not accepted	BP		Using content-block elements must be avoided. Corresponds to US FDA criterion 3029.
17.4	No backslash in xlink:href reference	P/F		The xlink:href values must not contain backslashes
17.5	Study Identifier category must not be empty	BP		The value of the study-identifier/category element must not be empty.

Number	Validation Criterion	Type of check	Lifecycle needed? "YES" (Y) *	Comments
17.6	Study Identifier study-id must not be empty	BP		The value of the study-identifier/study-id element must not be empty.
17.7	Study Identifier title must not be empty	BP		The value of the study-identifier/title element must not be empty. Corresponds to US FDA criterion 1985.
17.8	Categories and file tags	BP		Checks file tag values and category values against definitions in valid-values.xml file
17.9	STF leaf elements must reference other STF leaf upon append	P/F		Such leaf elements must not reference PDF files as modified files.
17.10	Category information must be provided for certain STFs	BP		ICH eCTD STF Specification V 2.6.1 3-June-2008: The category element provides an additional level of study organization not currently provided by the eCTD DTD. This element is only relevant for studies provided in the specific CTD sections cited below. - 4.2.3.1 Single dose toxicity (grouped by species and route of administration) - 4.2.3.2 Repeat dose toxicity (grouped by species, route of administration, and duration if applicable) - 4.2.3.4.1 Long term [carcinogenicity] studies (grouped by species) - 5.3.5.1 Study reports of controlled clinical studies pertinent to the claimed indication (grouped by type of control)
17.11	STF cannot reference another STF	BP		Leaf references in STFs must always target content files, not STFs. Corresponds to US FDA criterion 1789.
17.12	STF files must reference at least one leaf	BP		Any STF that does not relate to any leaf elements will be reported here. Corresponds to US FDA criterion 1816.
17.13	Study ID for STF must remain constant	BP		The STF study IDs must not change in the application life cycle. Corresponds to US FDA criterion 1850.

Number	Validation Criterion	Type of check	Lifecycle needed? "YES" (Y) *	Comments
17.14	Invalid STF TOC location	**BP**		STFs should only be associated with certain headings under Modules 4 or 5. Corresponds to US FDA criterion 1901.
17.15	STF doc-content file tag count	**BP**		There should be one and only one file tag for each doc-content. Corresponds to US FDA criteria 1918 and 1935.
17.16	STF XML title and leaf element title do not match	**BP**		For all leaf elements in the STF, the leaf title must be identical to the title of the corresponding leaf in the ICH backbone. Corresponds to US FDA criterion 1953.
17.17	Detect invalid life cycle pattern: Append operations not appending to most recent STF leaf	**BP**		For STF leaf elements the append operation should not reference the leaf where the STF has been added initially but the most recent update to this file.
STF_INFO	Informational output about the number and total size of non E3 documents.	**Info**		Sample: Non E3 study files Total size (KB): 133.76 Number of 16.3 files: 3 Number of US files: 4 Number of JP files: 1

LEGEND

Bold	Fixed Folder Name
Regular	Fixed File Name
Black	Fixed Component
Red	Variable Component
	Consistent with EU
	Thailand Specific

Suggested TH eCTD Naming Conventions

Content	Correlating eCTD Section	
eSubmission Identifier		
0000		
index.xml		
index-md5.txt		
m1		
th		
th-regional.xml		
10-cover	1.0	Cover
101-tracking	1.0.1	Tracking Table
tracking-var.pdf		
102-cover-letter	1.0.2	Cover Letter
cover-var.pdf		
12-forms	1.2	Application Forms
121-form	1.2.1	Application Form
form-var.pdf		
122-annex	1.2.2	Annexes
annex-var.pdf		
13-pi	1.3	Product Information
131-spclabelpl	1.3.1	SPC, Labelling and Package Leaflet
1311-labelling	1.3.1.1	Labelling
labelling-var.pdf		
1312-spc	1.3.1.2	SPC
spc-var.pdf		
1313-pl	1.3.1.3	Package Leaflet
pl-en-var.pdf	1.3.1.3.1	Package Leaflet - Thai
pl-th-var.pdf	1.3.1.3.2	Package Leaflet - English
pl-other-var.pdf	1.3.1.3.3	Package Leaflet - Other Language
132-mockup	1.3.2	Mock-up
mockup-var.pdf		
mockup-var.jpg		
mockup-var.jpeg		
mockup-var.gif		
mockup-var.png		
mockup-var.svg		
133-specimen	1.3.3	Specimen
specimen-var.pdf		
134-consultation	1.3.4	Consultation with Target Patient Groups
consultation-var.pdf		
135-approved	1.3.5	Product Information already approved in Other States
1351-status	1.3.5.1	Foreign Regulatory Status
status-var.pdf	1.3.5.1	
1352-pi	1.3.5.2	Foreign Product Information
pi-var.pdf		
1353-similarities	1.3.5.3	Data Similarities and Differences
similarities-var.pdf		
136-braille	1.3.6	Braille
braille-var.pdf		
14-expert	1.4	Information about the Experts
141-quality	1.4.1	Quality
quality-var.pdf		
142-nonclinical	1.4.2	Non-Clinical
nonclinical-var.pdf		
143-clinical	1.4.3	Clinical
clinical-var.pdf		
15-specific	1.5	Specific Requirements for Different Types of Applications
151-bibliographic	1.5.1	Information for Bibliographical Applications
bibliographic-var.pdf		
152-generic-hybrid-bio-similar	1.5.2	Information for Generic, 'Hybrid' or Bio-similar Applications
generic-var.pdf	1.5.2.1	Information for Generic Application
hybrid-var.pdf	1.5.2.2	Information for 'Hybrid' Applications
biosimilar-var.pdf	1.5.2.3	Information for Bio-similar Applications
153-data-market-exclusivity	1.5.3	(Extended) Data/Market Exclusivity
datamarketexclusivity-var.pdf		

LEGEND

Bold	Fixed Folder Name
Regular	Fixed File Name
Black	Fixed Component
Red	Variable Component
	Consistent with EU
	Thailand Specific

Suggested TH eCTD Naming Conventions

Content	Correlating eCTD Section		
154-exceptional	1.5.4	Exceptional Circumstances	
exceptional-var.pdf			
155-conditional-ma	1.5.5	Conditional Marketing Authorisation	
conditionalma-var.pdf			
156-add-tradename	1.5.6	Additional Trade Name Declarations	
add-tradename-var.pdf			
157-co-marketed	1.5.7	Co-marketed Medicines Declarations	
co-marketed-var.pdf			
16-environrisk	1.6	Environmental Risk Assessment	
161-nongmo	1.6.1	Non-GMO	
nongmo-var.pdf			
162-gmo	1.6.2	GMO	
gmo-var.pdf			
17-orphan	1.7	Information relating to Orphan Market Exclusivity	
171-similarity	1.7.1	Similarity	
similarity-var.pdf		**NOT APPLICABLE FOR THAILAND**	
172-market-exclusivity	1.7.2	Market Exclusivity	
marketexclusivity-var.pdf		**NOT APPLICABLE FOR THAILAND**	
18-pharmacovigilance	1.8	Information relating to Pharmacovigilance	
181-phvig-system	1.8.1	Pharmacovigilance System	
phvigsystem-var.pdf			
182-riskmgt-system	1.8.2	Risk-management System	
riskmgtsystem-var.pdf			
19-clinical-trials	1.9	Information relating to Clinical Trials	
clinicaltrials-var.pdf			
110-paediatrics	1.10	Information relating to Paediatrics	
paediatrics-var.pdf			
responses	1.R	Responses to Questions	
responses-var.pdf			
additional-data	1.A	Additional Data	
additionaldata-var.pdf			
m2			
m3	**Recommended to be consistent with EU Naming Conventions for all content**		
m4			
m5			
util			
dtd			
th-regional.xsd			
xlink.xsd			
xml.xsd			
ich-ectd-3-2.dtd			
style			
ectd-2-0.xsl			
th-regional.xsl			