

eCTD v4.0 JP Check Items List

v1.6.0.0

Pharmaceuticals and Medical Devices Agency

CHANGE HISTORY

Version	Date	Comments
1.4.0.0	2 February 2022	First version
1.4.0.1	17 May 2022	Removed the description of the form field from ID: JP-eCTD4-029.
1.5.0.0	15 March 2023	<ul style="list-style-type: none"> Abolished the ID: JP-eCTD4-299. Updated the description about the XML escape character in the 'Remarks' column of the ID below. <ul style="list-style-type: none"> JP-eCTD4-102, JP-eCTD4-206, JP-eCTD4-217, JP -eCTD4-232, JP-eCTD4-283, JP-eCTD4-310, JP-eCTD4-326, JP-eCTD4-329, JP- eCTD4-334
1.5.0.1	26 April 2023	<p>Updated the 'Remarks' column of the ID: JP-eCTD4-004.</p> <ul style="list-style-type: none"> Added a supplement about the number of folder levels to the 'Remarks' column of JP-eCTD4-004.
1.5.0.2	9 May 2024	<ul style="list-style-type: none"> Added the ID: JP-eCTD4-362 Removed unnecessary descriptions of eCTD type in Section 2.3
1.6.0.0	26 March 2025	<p>Updated the descriptions in the 'Check item' column for the following IDs related to checks of CV code values (the condition that the code must be valid (active) has been added due to the assignment of statuses to CV code values in the ICH IG v1.6 and JP IG v1.6.0).</p> <ul style="list-style-type: none"> JP-eCTD4-075, JP-eCTD4-097, JP-eCTD4-135, JP-eCTD4-178, JP-eCTD4-221, JP-eCTD4-239, JP-eCTD4-255, JP-eCTD4-272, JP-eCTD4-295, JP-eCTD4-316, JP-eCTD4-345, JP-eCTD4-356

Table of Contents

1.	Purpose.....	5
2.	Definition of terms and notation.....	5
2.1	Terms.....	5
2.2	Character notation	6
2.3	How to read the table	6
3.	Validation rules for packages	7
4.	Validation rules for messages	12
4.1	General message	12
4.2	Message Header	13
4.3	controlActProcess.....	15
4.4	Submission Unit.....	16
4.5	Priority number	18
4.6	Context of Use	20
4.7	Context of Use - Related Context of Use	25
4.8	Context of Use - Document Reference	27
4.9	Keyword	29
4.10	Sequence number	34
4.11	Submissions	35
4.12	Reviews	37
4.13	Review - Manufactured Product	40
4.14	Review - Ingredient Substance	42
4.15	Review - Applicant.....	44
4.16	Review - Product Category.....	47
4.17	Application	48
4.18	Application Reference	50
4.19	Documents.....	53
4.20	Keyword definitions.....	60

4.21 Category Event.....67

1. Purpose

This document has been prepared as a reference when applying for manufacturing and marketing approval of prescription drugs using eCTD v4.0 in Japan (hereinafter referred to as "eCTD v4.0 application"). Validation for eCTD v4.0 application in Japan is based on "Approval Application with Electronic Common Technical Document (eCTD)" (PSEHB/PED Notification No. 0705-1 as of July 5, 2017, by the Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labor and Welfare; hereinafter referred to as "eCTD notification") and its revision notifications. By using this document for confirmation before submitting eCTD, it is expected to prevent troubles that may occur at the time of acceptance and during the review.

2. Definition of terms and notation

2.1 Terms

Definitions of terms used in this document, in principle, conform to the eCTD notification. Definitions of terms used in this document that are not defined in the eCTD notification are shown in the table below.

Term	Definition
JP IG	eCTD notification Appendix 1. (i.e., eCTD v4.0 Implementation Guide in Japan)
JP CV	eCTD v4.0 controlled vocabulary in Japan.
ICH CV	Controlled vocabulary for eCTD v4.0 agreed at the ICH.
CTD dossier	Dossier of CTD Module 1 to 5 specified by "Approval Application with Electronic Common Technical Document (eCTD)" (PSEHB/PED Notification No. 0705-1 as of July 5, 2017, by the Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labor and Welfare; hereinafter referred to as "eCTD notification")
CTD dossier folder, CTD dossier file	Folders or files that: <ul style="list-style-type: none"> · “m1”, “m2”, “m3”, “m4”, “m5” folders corresponding to each Module of CTD · Folders or files excluding the components under the “m5/datasets” folder and the cover letter electronic file (cover.pdf) among the components stored in the “m1” to “m5” folders above

Electronic study data folder, Electronic study data file	“m5/datasets” folder and folders or files under “m5/datasets” folder.
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2.2 Character notation

In this document, XML constructs (elements and attributes) are shown in bold italic. However, this is not the case with XML snippet. In addition, concepts indicated by XML constructs are expressed in standard form.

2.3 How to read the table

The following explains how to read the tables shown in section 3 and 4 of this document.

ID	Check item	Remarks	eCTD type		
			a)	b)	c)

ID : Validation check items ID for eCTD v4.0 application in Japan

Check item : Details of validation check items for eCTD v4.0 application in Japan

Remarks : Remarks for check items

The following items indicate the types of submissions to be checked for the relevant check item. If it is subject to check, write “X”, otherwise write “-”.

eCTD type

a) : Submission corresponding to eCTD type a)

b) : Submission corresponding to eCTD type b)

c) : Submission corresponding to eCTD type c)

3. Validation rules for packages

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-001	The 1st level folder name shall be the eCTD receipt number.		X	X	X
JP-eCTD4-002	The 2nd level folder name shall be the submission sequence number.		X	X	X
JP-eCTD4-003	<p>Directly under 2nd level folder, the following components shall be located, and the other folders or files shall not be located.</p> <ul style="list-style-type: none"> · eCTD v4.0 XML message [file name: submissionunit.xml] · File containing checksum for eCTD v4.0 XML message (checksum file) [file name: sha256.txt] · Folders for each Module of CTD ("m1", "m2", "m3", "m4" and "m5" folders) 	However, folders for each Module of CTD shall not be created if they do not have subfolders or files to be stored.	X	X	X
JP-eCTD4-004	Except under the "m5/datasets" folder, the maximum number of folder hierarchy that can be configured under the 2nd level folder shall be up to 6th level including the 2nd level folder.	It is not allowed to create 7th or more levels of folder counting from the eCTD receipt number folder, which is the 1st level.	X	X	X
JP-eCTD4-005	Folders that do not contain subfolders or files (i.e., empty folders) shall not be located in or below the 3rd level.		X	X	X
JP-eCTD4-006	In the eCTD type b), the 3rd level folder shall be only the "m5" folder.	When submitting the eCTD to the reception of PMDA for approval applications that do not use the gateway system, it is allowed to create the "m1/jp" folder on the 3rd level only for the purpose of placing the cover letter.	-	X	-

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-007	The "jp" folder shall exist under the "m1" folder.		X	X	X
JP-eCTD4-008	Files related to the CTD Module 1 shall be placed in the "m1/jp" folder.		X	-	X
JP-eCTD4-009	When submitting the eCTD to the reception of PMDA for approval applications that do not use the gateway system, the electronic file of the cover letter (cover.pdf) shall be placed in the "m1/jp" folder.		X	X	X
JP-eCTD4-010	The files related to the CTD Module 2 shall be placed directly under the "m2" folder.		X	-	X
JP-eCTD4-011	The files related to the CTD Module 3 shall be placed in the following folders under the "m3" folder: 3.2.S : "32-sub" folder 3.2.P : "32-prod" folder 3.2.A : "32-app" folder 3.2.R : "32-reg" folder 3.3 : "33-lit" folder	The folder name shown on the left can be shortened or omitted, if the file path may exceed the maximum length. Also, it is possible to create an additional folder under these folders.	X	-	X
JP-eCTD4-012	The files related to CTD Module 4 shall be placed in the following folders under the "m4" folder. 4.2.1 : "421-phm" folder 4.2.2 : "422-pk" folder 4.2.3 : "423-tox" folder 4.3 : "43-lit" folder	The folder name shown on the left can be shortened or omitted, if the file path may exceed the maximum length. Also, it is possible to create an additional folder under these folders.	X	-	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-013	<p>The files related to CTD Module 5 shall be placed in the following folders under the "m5" folder.</p> <p>5.3.1 : "531-biopharm" folder</p> <p>5.3.2 : "532-pkbiomat" folder</p> <p>5.3.3 : "533-humanpk" folder</p> <p>5.3.4 : "534-pd" folder</p> <p>5.3.5 : "535-eff-safe" folder</p> <p>5.3.6 : "536-pms" folder</p> <p>5.3.7 : "537-listing" folder</p> <p>5.4 : "54-lit" folder</p>	<p>The folder name shown on the left can be shortened or omitted, if the file path exceeds the maximum length.</p> <p>Also, it is possible to create an additional folder under these folders.</p>	X	-	X
JP-eCTD4-014	A folder shall be created for each individual report that composes the CTD Modules 4 and 5.		X	-	X
JP-eCTD4-015	The files related to the electronic study data shall be placed in the "m5/datasets" folder.		X	X	-
JP-eCTD4-016	<p>The folder name and file name (except the file extension and the preceding period) of the CTD dossier shall consist of the following characters.</p> <ul style="list-style-type: none"> Single-byte lower case: a to z Single-byte numbers: 0 to 9 Single-byte symbols: \$ [dollar sign], - [hyphen], _ [underscore], + [plus sign], ! [exclamation mark], ' [apostrophe], ([left parenthesis],) [right parenthesis] 		X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-017	The folder name and file name (except the file extension and the preceding period) of the electronic study data shall consist of the following characters. <ul style="list-style-type: none"> Single-byte lower case: a to z Single-byte numbers: 0 to 9 Single-byte symbols: - [hyphen], _ [underscore] 		X	X	-
JP-eCTD4-018	The maximum length of the path from the 1st level folder in the CTD dossier shall be 180 characters or less.		X	X	X
JP-eCTD4-019	The maximum length of the path from the "m5" folder in the electronic study data shall be 160 characters or less.		X	X	-
JP-eCTD4-020	The maximum length of the folder name of the CTD dossier folder shall be 64 characters or less.		X	X	X
JP-eCTD4-021	The maximum length of the folder name of the electronic study data folder shall be 32 characters or less.		X	X	-
JP-eCTD4-022	The maximum length of the file name (including extension) of the CTD dossier file shall be 64 characters or less.		X	X	X
JP-eCTD4-023	The maximum length of the file name (including extension) of the electronic study data file shall be as follows. <ul style="list-style-type: none"> Dataset (file extension ".xpt" or ".sas7bdat"): 32 characters or less Files other than datasets: 64 characters or less 		X	X	-
JP-eCTD4-024	Each file name shall contain only one file extension.	Filenames must not contain strings that indicate multiple file extensions, such as double file extensions.	X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-025	The length of the file extension in the CTD dossier file shall be 3 or 4 characters.		X	X	X
JP-eCTD4-026	Compressed archives (such as ".zip") are not used for files contained in CTD Modules 2 through 5.		X	X	X
JP-eCTD4-027	The CTD dossier file shall be PDF format (.pdf) or Microsoft Excel format (.xlsx).	If it becomes necessary to submit a file in the format other than PDF or Microsoft Excel, then consult with the regulatory authority in advance.	X	X	X
JP-eCTD4-028	File size of the CTD dossier file shall be 500MB or less.		X	X	X
JP-eCTD4-029	A PDF file of CTD dossier shall not be annotated.		X	X	X
JP-eCTD4-030	The value described in the checksum file (sha256.txt) shall match the checksum calculated from the eCTD v4.0 XML message file (submissionunit.xml) in the submission.	The checksum shall be calculated according to the SHA256 algorithm.	X	X	X
JP-eCTD4-031	Except for the checksum file (sha256.txt) and the cover letter electronic file (cover.pdf), there shall not be files in the submission that are not referenced from the eCTD v4.0 XML message.		X	X	X

4. Validation rules for messages

4.1 General message

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-032	The eCTD v4.0 XML message shall be valid on the ICH eCTD v4.0 XML Schema.		X	X	X
JP-eCTD4-033	UTF-8 shall be used for character encoding of eCTD v4.0 XML messages.		X	X	X
JP-eCTD4-034	All elements except the <i>integrityCheck</i> element shall not have content other than child elements.		X	X	X
JP-eCTD4-035	The XML message shall not have attributes with dummy or null values.		X	X	X
JP-eCTD4-036	The XML message shall not have elements/attributes not described in JP IG.		X	X	X
JP-eCTD4-037	The forward slash (/) shall be used to separate folders in the file path described in the eCTD v4.0 XML message.		X	X	X

4.2 Message Header

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-038	The PORP_IN000001UV element and as attributes of the PORP_IN000001UV element shall have the following. ITSVersion="XML_1.0" xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:hl7-org:v3 PORP_IN000001UV.xsd"		X	X	X
JP-eCTD4-039	The PORP_IN000001UV element shall have the following elements. Note that these elements must be self-closing tags and have no child elements, attributes, or values. PORP_IN000001UV.id PORP_IN000001UV.creationTime PORP_IN000001UV.interactionId PORP_IN000001UV.processingCode PORP_IN000001UV.processingModeCode PORP_IN000001UV.acceptAckCode		X	X	X
JP-eCTD4-040	The PORP_IN000001UV element shall have the PORP_IN000001UV.receiver element.		X	X	X
JP-eCTD4-041	The PORP_IN000001UV.receiver element shall have the PORP_IN000001UV.receiver.device element.		X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-042	The PORP_IN000001UV.receiver.device element shall have the PORP_IN000001UV.receiver.device@classCode attribute.		X	X	X
JP-eCTD4-043	The PORP_IN000001UV.receiver.device@classCode attribute value shall be "DEV".		X	X	X
JP-eCTD4-044	The PORP_IN000001UV.receiver.device element shall have the PORP_IN000001UV.receiver.device@determinerCode attribute.		X	X	X
JP-eCTD4-045	The PORP_IN000001UV.receiver.device@determinerCode attribute value shall be "INSTANCE".		X	X	X
JP-eCTD4-046	The PORP_IN000001UV.receiver.device element shall have the PORP_IN000001UV.receiver.device.id element.		X	X	X
JP-eCTD4-047	The PORP_IN000001UV.receiver.device.id element shall have two PORP_IN000001UV.receiver.device.id.item elements.		X	X	X
JP-eCTD4-048	Each PORP_IN000001UV.receiver.device.id.item element shall have root attribute.		X	X	X
JP-eCTD4-049	The two values of PORP_IN000001UV.receiver.device.id.item@root attribute shall be the ICH Implementation Guide OID and the JP Implementation Guide OID.	The code list version identified by the OID must be valid as of the earliest application date of the approval applications included in the eCTD.	X	X	X
JP-eCTD4-050	Each PORP_IN000001UV.receiver.device.id.item element shall have the identifierName attribute.		X	X	X
JP-eCTD4-051	The PORP_IN000001UV.receiver.device.id.item@identifierName attribute value shall be 128 characters or less.		X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-052	The PORP_IN000001UV element shall have the PORP_IN000001UV.sender element.		X	X	X
JP-eCTD4-053	The PORP_IN000001UV.sender element shall have the PORP_IN000001UV.sender.device element.		X	X	X
JP-eCTD4-054	The PORP_IN000001UV.sender.device shall have the PORP_IN000001UV.sender.device@classCode attribute.		X	X	X
JP-eCTD4-055	The PORP_IN000001UV.sender.device@classCode attribute value shall be "DEV".		X	X	X
JP-eCTD4-056	The PORP_IN000001UV.sender.device element shall have the PORP_IN000001UV.sender.device@determinerCode attribute.		X	X	X
JP-eCTD4-057	The PORP_IN000001UV.sender.device@determinerCode attribute value shall be "INSTANCE".		X	X	X
JP-eCTD4-058	The PORP_IN000001UV.sender.device element shall have the PORP_IN000001UV.sender.device.id element. The element shall be represented with self-closing tags and shall have no child elements, attributes, or values.		X	X	X

4.3 controlActProcess

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-059	The XML message shall have the controlActProcess element.		X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-060	The <i>controlActProcess</i> element shall have the <i>controlActProcess@classCode</i> attribute.		X	X	X
JP-eCTD4-061	The <i>controlActProcess@classCode</i> attribute value shall be "ACTN".		X	X	X
JP-eCTD4-062	The <i>controlActProcess</i> element shall have the <i>controlActProcess@moodCode</i> attribute.		X	X	X
JP-eCTD4-063	The <i>controlActProcess@moodCode</i> attribute value shall be "EVN".		X	X	X
JP-eCTD4-064	The <i>controlActProcess</i> element shall have the <i>controlActProcess.subject</i> element.		X	X	X
JP-eCTD4-065	The <i>controlActProcess.subject</i> element shall have the <i>controlActProcess.subject@typeCode</i> attribute.		X	X	X
JP-eCTD4-066	The <i>controlActProcess.subject@typeCode</i> attribute value shall be "SUBJ".		X	X	X

4.4 Submission Unit

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-067	The XML message shall have the <i>submissionUnit</i> element.		X	X	X
JP-eCTD4-068	The one payload message shall have the only one <i>submissionUnit</i> element.	The one payload message shall not have multiple <i>submissionUnit</i> elements.	X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-069	The <i>submissionUnit</i> element shall have the <i>submissionUnit.id</i> element.		X	X	X
JP-eCTD4-070	The <i>submissionUnit.id</i> element shall have <i>submissionUnit.id@root</i> attribute.		X	X	X
JP-eCTD4-071	The <i>submissionUnit.id@root</i> attribute value shall be a UUID as defined in ISO/IEC 11578:1996 and ITU-T Rec X.667 ISO/IEC 9834-8:2005.		X	X	X
JP-eCTD4-072	The UUID specified in the <i>submissionUnit.id@root</i> attribute value shall be able to uniquely identify the Submission Unit.		X	X	X
JP-eCTD4-073	The <i>submissionUnit</i> element shall have the <i>submissionUnit.code</i> element.		X	X	X
JP-eCTD4-074	The <i>submissionUnit.code</i> element shall have the <i>submissionUnit.code@code</i> attribute.		X	X	X
JP-eCTD4-075	The <i>submissionUnit.code@code</i> attribute value shall be a valid code value listed in the JP CV "JP Submission Unit Code" code list indicated by the OID provided by the <i>submissionUnit.code@codeSystem</i> attribute.	In principle, do not use the "jp_other" code. If you want to use the "jp_other" code, then consult with the regulatory authority in advance.	X	X	X
JP-eCTD4-076	The <i>submissionUnit.code</i> element shall have the <i>submissionUnit.code@codeSystem</i> attribute.		X	X	X
JP-eCTD4-077	The <i>submissionUnit.code@codeSystem</i> attribute value shall be the OID that identifies the JP CV "JP Submission Unit Code" code list.	The code list version identified by the OID must be valid as of the earliest application date of the approval applications included in the eCTD.	X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-078	The <i>submissionUnit.title@value</i> attribute value shall be 1000 characters or less.		X	X	X
JP-eCTD4-079	The <i>submissionUnit</i> element shall not have the <i>submissionUnit.statusCode</i> element.		X	X	X
JP-eCTD4-080	When submitting the first version, the <i>submissionUnit</i> element shall have the <i>submissionUnit.component</i> element, and the <i>submissionUnit.component</i> element shall have the <i>priorityNumber</i> and <i>contextOfUse</i> element.		X	X	X

4.5 Priority number

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-081	The <i>submissionUnit.component</i> element shall have a <i>priorityNumber</i> element.		X	X	X
JP-eCTD4-082	The <i>priorityNumber</i> element shall have a <i>value</i> attribute.		X	X	X
JP-eCTD4-083	The <i>priorityNumber@value</i> attribute value shall be a single-byte numeric type.		X	X	X
JP-eCTD4-084	The <i>priorityNumber@value</i> attribute value shall be a positive integer with a maximum of 6 digits (1-999999).	In consideration of reordering and/or inserting the Context of Use, it is recommended that Priority Number start with "1000" and intervals of 1000 (e.g., "2000", "3000", etc.).	X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-085	The Priority Number shall not be duplicated within the valid Contexts of Use belonging to one context group within the same Application.		X	X	X
JP-eCTD4-086	When updating the <i>priorityNumber@value</i> attribute value of the already submitted Context of Use, the <i>priorityNumber</i> element of the updated Context of Use shall have the <i>updateMode</i> attribute.	<p>If the following Context of Use is provided, the Submission Unit will be rejected.</p> <ul style="list-style-type: none"> The <i>priorityNumber@value</i> attribute value has changed since the last submission, but the <i>priorityNumber@updateMode</i> attribute value has not been provided. 	X	-	-
JP-eCTD4-087	The <i>priorityNumber@updateMode</i> attribute shall be "R".		X	-	-

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-088	For a Context of Use with no update of the <i>priorityNumber@value</i> attribute value, the <i>priorityNumber</i> element shall not have the <i>priorityNumber@updateMode</i> attribute.	<p>The <i>priorityNumber@updateMode</i> attribute appears for the Context of Use that corresponds to any of the following, the Submission Unit will be rejected.</p> <ul style="list-style-type: none"> It is a Context of Use that appears for the first time throughout the Application life cycle including the first version submission. The <i>statusCode@code</i> attribute value is "suspended" The <i>priorityNumber@value</i> attribute value not updated 	X	X	X

4.6 Context of Use

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-089	Each <i>submissionUnit.component</i> element shall have a <i>contextOfUse</i> element.		X	X	X
JP-eCTD4-090	Each <i>contextOfUse</i> element shall have an <i>id</i> element.		X	X	X
JP-eCTD4-091	<p>The <i>root</i> attribute shall appear for each <i>contextOfUse.id</i> element.</p> <p>Each <i>contextOfUse.id</i> element shall have a <i>root</i> attribute.</p>		X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-092	The <i>contextOfUse.id@root</i> attribute value shall be a UUID as defined in ISO/IEC 11578:1996 and ITU-T Rec X.667 ISO/IEC 9834-8:2005.		X	X	X
JP-eCTD4-093	The UUID specified in the <i>contextOfUse.id@root</i> attribute value must be able to uniquely identify this Context of Use.		X	X	X
JP-eCTD4-094	The <i>contextOfUse</i> element with the <i>statusCode@code</i> attribute value "active" and the <i>priorityNumber@updateMode</i> attribute value not provided shall have the <i>code</i> element.		X	X	X
JP-eCTD4-095	The <i>contextOfUse</i> elements with the <i>statusCode@code</i> attribute value "suspended" or the <i>priorityNumber@updateMode</i> attribute value provided shall not have the <i>code</i> element.		X	X	X
JP-eCTD4-096	Each <i>contextOfUse.code</i> element shall have a <i>code</i> attribute.		X	X	X
JP-eCTD4-097	The <i>contextOfUse.code@code</i> attribute value shall be a valid code value listed in either the ICH CV "ICH Context of Use" or the JP CV "JP Context of Use" code list indicated by the OID provided by the <i>contextOfUse.code@codeSystem</i> attribute.	In principle, do not use the "jp_other" code. If you want to use the "jp_other" code, then consult with the regulatory authority in advance.	X	X	X
JP-eCTD4-098	In the eCTD type b), the CTD heading indicated by the <i>contextOfUse.code@code</i> attribute value shall belong to Section 3 of Module 5 of the CTD.		-	X	-
JP-eCTD4-099	Each <i>contextOfUse.code</i> element shall have a <i>codeSystem</i> attribute.		X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-100	The <i>contextOfUse.code@codeSystem</i> attribute shall be an OID that identifies either the ICH CV "ICH Context of Use" or the JP CV "JP Context of Use" code list.	The code list version identified by the OID must be valid as of the earliest application date of the approval applications included in the eCTD.	X	X	X
JP-eCTD4-101	Each <i>contextOfUse.code.originalText</i> element shall have a <i>value</i> attribute.		X	X	X
JP-eCTD4-102	<p>The <i>contextOfUse.code.originalText@value</i> attribute value shall be the Text type (*).</p> <p>*The character types that can be used as Text types are as follows.</p> <ul style="list-style-type: none"> · Single-byte alphabets upper and lower case · Single-byte numbers · Single-byte symbols (\$'(),+-. / ; : ! ? [] _ # @) and white space · Double-byte characters in the JISX0208 range (Kanji (JIS 1st level, JIS 2nd level), alphabets upper and lower case, numbers, hiragana, katakana, symbols, white space, etc.) · Model-dependent characters (limited to 30 characters from ① to ㊾ and I to X) 	<p>The following symbols are prohibited characters in XML, so do not use them in principle. If applicants have to use it, they can use the escape character instead as an exception.</p> <ul style="list-style-type: none"> · & (ampersand) [Escape character: &amp;] · " (double-quote) [Escape character: &quot;] · < (less-than) [Escape character: &lt;] · > (greater-than) [Escape character: &gt;] 	X	X	X
JP-eCTD4-103	The <i>contextOfUse.code.originalText@value</i> attribute value shall be 128 characters or less.		X	X	X
JP-eCTD4-104	Each <i>contextOfUse</i> element shall have a <i>statusCode</i> element.		X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-105	Each <i>contextOfUse.statusCode</i> element shall have a <i>code</i> attribute.		X	X	X
JP-eCTD4-106	The <i>contextOfUse.statusCode@code</i> attribute shall be either "active" or "suspended".		X	X	X
JP-eCTD4-107	The <i>statusCode@code</i> attribute value of the Context of Use that appears for the first time in the Application life cycle including the first version submission shall be "active".		X	X	X
JP-eCTD4-108	There shall not be the <i>contextOfUse</i> element with the same <i>id@root</i> attribute value as the Context of Use that was replaced or suspended in the previous life cycle of the Application.	If applicants want to make the replaced or suspended Context of Use enable again, resubmit it as the new Context of Use.	X	-	-

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-109	One Context of Use identified by UUID must not be performed multiple operations (e.g., new submissions and replacements, suspendings and updates) within the same Submission Unit.	<p>The following Submission Unit will be rejected:</p> <ul style="list-style-type: none"> The newly submitted Context of Use is replaced by another Context of Use in the same Submission Unit (i.e., the UUID of the newly submitted Context of Use is specified in the <i>relatedoContextOfUse.id@root</i> attribute value of another Context of Use in the same Submission Unit) The Priority Number is updated for the suspended Context of Use in the same Submission Unit (i.e., The same values of <i>id@root</i> attribute and <i>priprorityNumber@updateMode</i> attribute as of suspended Context of Use are used in the same Submission Unit.) 	X	-	-

4.7 Context of Use - Related Context of Use

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-110	In the first version submission, the <i>contextOfUse</i> element shall not have the following elements. <ul style="list-style-type: none"> · <i>contextOfUse.replacementOf</i> · <i>contextOfUse.replacementOf.relatedContextOfUse</i> 		X	X	X
JP-eCTD4-111	The <i>contextOfUse</i> element whose <i>statusCode@code</i> attribute value is "suspended" or whose <i>priorityNumber@updateMode</i> attribute value is provided shall not have the following elements. <ul style="list-style-type: none"> · <i>contextOfUse.replacementOf</i> · <i>contextOfUse.replacementOf.relatedContextOfUse</i> 		X	-	-
JP-eCTD4-112	Each <i>contextOfUse.replacementOf</i> element shall have a <i>typeCode</i> attribute.		X	-	-
JP-eCTD4-113	The <i>contextOfUse.replacementOf@typeCode</i> attribute value shall be "RPLC".		X	-	-
JP-eCTD4-114	Each <i>relatedContextOfUse</i> element shall have an <i>id</i> element.		X	-	-
JP-eCTD4-115	Each <i>relatedContextOfUse.id</i> element shall have a <i>root</i> attribute.		X	-	-
JP-eCTD4-116	The UUID provided by <i>relatedContextOfUse.id@root</i> attribute value shall indicate the Context of Use provided in a previous Submission Unit of the same Application.		X	-	-

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-117	The UUID provided by <i>relatedContextOfUse.id@root</i> attribute value shall indicate the valid Context of Use (the Context of Use where the <i>statusCode@code</i> attribute value is "active") at the time of the relevant Submission Unit.		X	-	-
JP-eCTD4-118	The Context of Use indicated by the <i>id@root</i> attribute value of the <i>relatedContextOfUse</i> element shall belong to the same context group as this Context of Use.		X	-	-
JP-eCTD4-119	When replacing the Context of Use that refers to the electronic study data file, the file path under "m5/datasets" of both the file referenced by Context of Use before replacement and the file referenced by Context of Use after replacement shall match.		X	-	-
JP-eCTD4-120	When replacing the Context of Use that refers to the electronic study data file, the replacement shall be one file for one file.	<p>The following replacements cannot be performed for the Context of Use that refers to the electronic study data file.</p> <ul style="list-style-type: none"> · Replace one file with multiple files · Replace multiple files with one file · Replace multiple files with multiple files 	X	-	-

4.8 Context of Use - Document Reference

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-121	In the first version submission, each <i>contextOfUse</i> element shall have the following elements. <ul style="list-style-type: none"> · <i>contextOfUse.derivedFrom</i> · <i>contextOfUse.derivedFrom.documentReference</i> 		X	X	X
JP-eCTD4-122	The <i>contextOfUse</i> element with the <i>statusCode@code</i> attribute value of "active" and no <i>priorityNumber@updateMode</i> attribute value provided shall have the following elements. <ul style="list-style-type: none"> · <i>contextOfUse.derivedFrom</i> · <i>contextOfUse.derivedFrom.documentReference</i> 		X	X	X
JP-eCTD4-123	The <i>contextOfUse</i> element whose <i>statusCode@code</i> attribute value is "suspended" or whose <i>priorityNumber@updateMode</i> attribute value is provided shall not have the following elements. <ul style="list-style-type: none"> · <i>contextOfUse.derivedFrom</i> · <i>contextOfUse.derivedFrom.documentReference</i> 		X	-	-
JP-eCTD4-124	Each <i>documentReference</i> element shall have a <i>documentReference.id</i> element.		X	X	X
JP-eCTD4-125	Each <i>documentReference.id</i> element shall have a <i>root</i> attribute.		X	X	X
JP-eCTD4-126	The Document indicated by the <i>documentReference.id@root</i> attribute value shall exist in the relevant Submission Unit or regulatory authority database.		X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-127	<p>When submitting the new Context of Use that refers to the electronic study data file, the file that meets all the following conditions shall not exist at the time of this submission sequence of Application life cycle.</p> <ul style="list-style-type: none"> · The path after "m5/datasets" matches the file referenced by the newly submitted Context of Use. · Referenced from the Context of Use where the <i>statusCode@code</i> attribute value is "active". 		X	X	-
JP-eCTD4-128	<p>When reusing the Document, either of the following conditions 1) or 2) shall be satisfied.</p> <p>1) The two Submission Units both belong to the same Application, one is defining the Document reused, and the other contains the documentReference element that references the Document reused.</p> <p>2) All of the following conditions shall be satisfied:</p> <ul style="list-style-type: none"> · The application defining the Document reused has already been approved. · Both applications are submitted as originals in accordance with the eCTD v4.0 specifications, one is defining the Document reused, and the other contains the documentReference element that references the Document reused. · The application dossier defining the Document reused is subject to document retention by the regulatory authority and is within the prescribed retention period. 		X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-129	<p>When reusing a Document that references an electronic study data, all of the following conditions must be met.</p> <ul style="list-style-type: none"> · A valid Context of Use referring to a reused Document must not exist two or more times in same Application. · A valid Context of Use referring to the same file in the same path under m5/datasets folder as a reused Document referring to, must not exist at the time of this submission sequence of Application life cycle. 		X	X	-

4.9 Keyword

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-130	<p>Under the Context of Use with the <i>statusCode@code</i> attribute value "suspended" or the <i>priorityNumber@updateMode</i> attribute provided shall have not the following elements.</p> <ul style="list-style-type: none"> · <i>contextOfUse.referencedBy</i> · <i>contextOfUse.referenceBy.keyword</i> 		X	-	-
JP-eCTD4-131	Each <i>contextOfUse.referencedBy</i> element shall have a <i>typeCode</i> attribute.		X	X	X
JP-eCTD4-132	The <i>contextOfUse.referencedBy@typeCode</i> attribute shall be "REFR".		X	X	X
JP-eCTD4-133	Each <i>keyword</i> element shall have a <i>code</i> element.		X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-134	Each keyword.code element shall have a code attribute.		X	X	X
JP-eCTD4-135	The keyword.code@code attribute value shall be a valid code value listed in the code list indicated by the contextOfUse.code@codeSystem attribute value (including the code list defined by Keyword Definition).	In principle, do not use the "jp_other" code in the code list below. If you want to use the "jp_other" code, then consult with the regulatory authority in advance. <ul style="list-style-type: none"> · JP CV "JP Study Data Category" · JP CV "JP Terminology (Tabulation)" · JP CV "JP Terminology (Analysis)" · JP CV "JP Analysis Type" 	X	X	X
JP-eCTD4-136	Each keyword.code element shall have a codeSystem attribute.		X	X	X
JP-eCTD4-137	The keyword.code@codeSystem attribute shall be the OID that identifies the CV code list or the value that identifies the Keyword Definition defined in the Application.	The code list version identified by the OID must be valid as of the earliest application date of the approval applications included in the eCTD.	X	X	X
JP-eCTD4-138	The Keyword required by either the ICH CV "ICH Context of Use" or the JP CV "JP Context of Use" shall be assigned to the CTD heading indicated by the Context of Use code. However, in the case of Context of Use that refers to the electronic study data, the ICH Document Type Keyword does not necessarily have to be assigned.		X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-139	Keywords that are not permitted to be assigned by either the ICH CV "ICH Context of Use" or the JP CV "JP Context of Use" shall not be assigned to the CTD heading indicated by the Context of Use code of Context of Use that refers to the CTD dossier file.		X	-	X
JP-eCTD4-140	<p>The Keywords that do not correspond to any of the following shall not be assigned to the CTD heading indicated by the Context of Use code of the Context of Use that refers to the electronic study data.</p> <ul style="list-style-type: none"> · The keyword that is permitted to be assigned by the ICH CV "ICH Context of Use" or the JP CV "JP Context of Use" · JP Study Data Category Keyword · JP Terminology (Tabulation) Keyword · JP Terminology (Analysis) Keyword · JP Analysis Type Keyword 		X	X	-
JP-eCTD4-141	Multiple Keywords of the same type shall not be assigned to one Context of Use.		X	X	X
JP-eCTD4-142	The study id_study title Keyword shall be assigned to the Context of Use to which the ICH Study Group Order Keyword is assigned.		X	X	X
JP-eCTD4-143	The JP Study Data Category Keyword and the JP Analysis Type Keyword shall be assigned to the Context of Use that refers to the electronic study data.		X	X	-

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-144	<p>The following Keywords shall not be assigned to the Context of Use that does not refer to the electronic study data.</p> <ul style="list-style-type: none"> · JP Study Data Category Keyword · JP Terminology(Tabulation) Keyword · JP Terminology(Analysis) Keyword · JP Analysis Type Keyword 		X	-	X
JP-eCTD4-145	The JP Study Data Category Keyword shall be assigned to the Context of Use provided by the eCTD type b).		-	X	-
JP-eCTD4-146	The JP Study Data Category Keyword shall not be assigned to the Context of Use provided by eCTD type c).		-	-	X
JP-eCTD4-147	If the JP analysis Type Keyword except for the one indicating "not clinical pharmacology study results" (jp_non_cp) is assigned, the Document referenced by this Context of Use shall have the <i>text.description@value</i> attribute value.	When submitting electronic study data of clinical pharmacology area, it is necessary to provide the description of the file content as the <i>text.description@value</i> attribute value of Document.	X	X	-
JP-eCTD4-148	<p>The JP Terminology(Tabulation) Keyword shall be assigned to the Context of Use that refers to the SDTM dataset file (*).</p> <p>*All files under "tabulation/sdtm" or "tabulation/sdtm_j"</p>		X	X	-

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-149	<p>The JP Terminology(Analysis) Keyword shall be assigned to the Context of Use that refers to the ADaM dataset file (*).</p> <p>*All files under "analysis/adam" or "analysis/adam_j"</p>		X	X	-
JP-eCTD4-150	The study id part of the study id_study title Keyword assigned to the Context of Use that refers to the electronic study data shall be same as the name of the study ID folder in which this electronic study data is stored.	However, it is not necessary to match alphabets upper and lower case.	X	X	-
JP-eCTD4-151	<p>The following conditions 1) and 2) must be met for the Context of Use that refers to the electronic study data and the Context of Use that refers to the clinical study report corresponding to the electronic study data.</p> <p>1) The code@code and code@codeSystem attribute values of the study id_study title Keyword shall be the same between them.</p> <p>2) The following information shall match between the Context of Use that references the electronic study data and at least one of the Context of Use that references the clinical study report corresponding to it, including the presence or absence of the information:</p> <ul style="list-style-type: none"> · The code@code and code@codeSystem attribute values of Context of Use · The code@code and code@codeSystem attribute values of the CoU Keyword below: <ul style="list-style-type: none"> ➤ ICH Study Group Order ➤ indication 	<p>The version numbers included at the end of the OID indicated by the code@codeSystem attribute of the Context of Use and ICH Study Group Order Keywords do not need to match.</p> <p>The Context of Use that references the corresponding clinical study report is not submitted at the time of submitting eCTD type b), but need to be met the 1) and 2) at the time of submitting the eCTD type c) instead.</p>	X	X	X

4.10 Sequence number

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-152	The <i>submissionUnit</i> element shall have the following elements: · <i>submissionUnit.componentOf1</i> · <i>submissionUnit.componentOf1.sequenceNumber</i>		X	X	X
JP-eCTD4-153	In the one payload message shall have only one <i>sequenceNumber</i> element.	A payload message shall not have multiple <i>sequenceNumber</i> elements.	X	X	X
JP-eCTD4-154	The <i>sequenceNumber</i> element shall have a <i>sequenceNumber@value</i> attribute.		X	X	X
JP-eCTD4-155	The <i>sequenceNumber@value</i> attribute value shall be a single-byte numeric type.		X	X	X
JP-eCTD4-156	The <i>sequenceNumber@value</i> attribute shall be a positive integer starting from 1 and less than or equal to 999999.		X	X	X
JP-eCTD4-157	The <i>sequenceNumber@value</i> attribute value shall be a unique Sequence Number that identifies the relevant Submission Unit in one Application.		X	X	X
JP-eCTD4-158	The <i>sequenceNumber@value</i> attribute value shall match the sequence number of the 2nd level folder name.		X	X	X
JP-eCTD4-159	In the first version submission, the <i>sequenceNumber@value</i> attribute value of eCTD type a) shall be "1".		X	-	-
JP-eCTD4-160	In the first version submission, the <i>sequenceNumber@value</i> attribute value of eCTD type b) shall be "1".		-	X	-
JP-eCTD4-161	In the first version submission, the <i>sequenceNumber@value</i> attribute value of eCTD type c) shall be "2".		-	-	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-162	At the time of eCTD revision submission, the <i>sequenceNumber@value</i> attribute value shall be the value obtained by adding 1 to the maximum value among the Sequence Numbers already provided in the same Application at the time of submission of the revised version.		X	-	-

4.11 Submissions

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-163	The <i>submissionUnit</i> element shall have the following elements. · <i>submissionUnit.componentOf1</i> · <i>submissionUnit.componentOf1.submission</i>		X	X	X
JP-eCTD4-164	A payload message shall have only one <i>submission</i> element.	A payload message shall not have multiple <i>submission</i> elements.	X	X	X
JP-eCTD4-165	The <i>submission</i> element shall have a <i>submission.id</i> element.		X	X	X
JP-eCTD4-166	The <i>submission.id</i> element shall have <i>submission.id.item</i> element.		X	X	X
JP-eCTD4-167	The <i>submission.id</i> element shall not have the multiple <i>item</i> elements.		X	X	X
JP-eCTD4-168	The <i>submission.id.item</i> element shall have a <i>submission.id.item@root</i> attribute.		X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-169	The <i>submission.id.item@root</i> attribute value shall be a UUID as defined in ISO/IEC 11578:1996 and ITU-T Rec X.667 ISO/IEC 9834-8:2005.		X	X	X
JP-eCTD4-170	The UUID specified in the <i>submission.id.item@root</i> attribute value must be able to uniquely identify this Submission.		X	X	X
JP-eCTD4-171	The <i>submission.id.item@root</i> attribute value shall remain the same value throughout the Application life cycle.		X	-	X
JP-eCTD4-172	The <i>submission.id.item</i> element shall have a <i>submission.id.item@extension</i> attribute.		X	X	X
JP-eCTD4-173	The <i>submission.id.item@extension</i> attribute value shall be a single-byte alphanumeric type.		X	X	X
JP-eCTD4-174	The <i>submission.id.item@extension</i> attribute shall be the eCTD reception number of this application.		X	X	X
JP-eCTD4-175	The <i>submission.id.item@extension</i> attribute value shall remain the same throughout the Application life cycle.		X	-	X
JP-eCTD4-176	The submission element shall have a <i>submission.code</i> element.		X	X	X
JP-eCTD4-177	The <i>submission.code</i> element shall have a <i>submission.code@code</i> attribute.		X	X	X
JP-eCTD4-178	The <i>submission.code@code</i> attribute value shall be a valid code value listed in the JP CV "JP Submission" code list indicated by the OID provided by the <i>submission.code@codeSystem</i> attribute value.	In principle, do not use the "jp_other" code. If you want to use the "jp_other" code, then consult with the regulatory authority in advance.	X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-179	The <i>submission.code@code</i> attribute value shall remain the same value throughout the Application life cycle.		X	-	X
JP-eCTD4-180	The code specified in the <i>submission.code@code</i> attribute value shall match the original/reference submission of the eCTD.		X	X	X
JP-eCTD4-181	The <i>submission.code</i> element shall have a <i>submission.code@codeSystem</i> attribute.		X	X	X
JP-eCTD4-182	The <i>submission.code@codeSystem</i> attribute shall be the OID that identifies the JP CV "JP Submission" code list.	The code list version identified by the OID must be valid as of the earliest application date of the approval applications included in the eCTD.	X	X	X
JP-eCTD4-183	The <i>submission.code@codeSystem</i> attribute value shall remain the same value throughout the Application life cycle.	However, the version numbers included at the end of the OID indicated by the <i>code@codeSystem</i> attribute do not need to be matched.	X	-	X

4.12 Reviews

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-184	In the first version submission, in the case of eCTD types a) and c), the XML message shall have the following elements. <ul style="list-style-type: none"> · <i>submission.subject2</i> · <i>submission.subject2.review</i> 		X	-	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-185	In the eCTD type b), the XML message shall not have the following elements. · <i>submission.subject2</i> · <i>submission.subject2.review</i>		-	X	-
JP-eCTD4-186	Each <i>review</i> element shall have an <i>id</i> element.		X	-	X
JP-eCTD4-187	Each <i>review.id</i> element shall have a <i>root</i> attribute.		X	-	X
JP-eCTD4-188	The <i>review.id@root</i> attribute value shall be a UUID as defined in ISO/IEC 11578:1996 and ITU-T Rec X.667 ISO/IEC 9834-8:2005.		X	-	X
JP-eCTD4-189	The UUID specified in the <i>review.id@root</i> attribute value must be able to uniquely identify this review.		X	-	X
JP-eCTD4-190	Each <i>review</i> element shall have a <i>statusCode</i> element.		X	-	X
JP-eCTD4-191	Each <i>review.statusCode</i> element shall have a <i>code</i> attribute.		X	-	X
JP-eCTD4-192	The <i>review.statusCode@code</i> attribute shall be either "active" or "suspended".		X	-	X
JP-eCTD4-193	The <i>statusCode@code</i> attribute value of the Review that appears for the first time through the Application life cycle including the first version submission shall be "active".		X	-	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-194	There shall not be the review element with the same id@root attribute value as the review removed in the previous life cycle of the Application.	Applicants must resubmit the removed review as the new review if they want to reactivate it.	X	-	-
JP-eCTD4-195	One Review identified by UUID must not be performed multiple operations (e.g., new submissions and withdrawal) within the same Submission Unit.	<p>The following Submission Unit will be rejected:</p> <ul style="list-style-type: none"> · The newly submitted Review is withdrawn (removed) in the same Submission Unit (i.e., the UUID of the newly submitted Review is specified in the id@root attribute value of another Review whose statusCode@code attribute value is "suspended" within the same Submission Unit) · The specific Review has been withdrawn (removed) multiple times within the same Submission Unit (i.e., multiple Reviews whose id@root attribute values match between them and statusCode@code attribute values are "suspended", exist within the same Submission Unit) 	X	-	-

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-196	One or more the Review with the <i>statusCode@code</i> attribute value "active" exists in one Application.		X	-	X
JP-eCTD4-197	At the time of eCTD revision, the application is not withdrawn and the review element with no update of contents is not provided.		X	-	-

4.13 Review - Manufactured Product

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-198	Each <i>review</i> element, in the case that <i>statusCode@code</i> attribute value is "active", shall have the following elements. <ul style="list-style-type: none"> · <i>subject1</i> · <i>subject1.manufacturedProduct</i> 		X	-	X
JP-eCTD4-199	For each <i>review</i> element, in the case that <i>statusCode@code</i> attribute value is "active", shall not have the following element shall not appear multiple times. <ul style="list-style-type: none"> · <i>subject1</i> · <i>subject1.manufacturedProduct</i> 		X	-	X
JP-eCTD4-200	Each <i>review</i> element, in the case that <i>statusCode@code</i> attribute value is "suspended", shall not have the following elements. <ul style="list-style-type: none"> · <i>subject1</i> · <i>subject1.manufacturedProduct</i> 		X	-	-
JP-eCTD4-201	Each <i>manufacturedProduct</i> element shall have a <i>manufacturedProduct</i> element.		X	-	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-202	Each <i>manufacturedProduct.manufacturedProduct</i> element shall have a <i>name</i> element.		X	-	X
JP-eCTD4-203	Each <i>manufacturedProduct.name</i> element shall have a <i>part</i> element.		X	-	X
JP-eCTD4-204	Each <i>manufacturedProduct.name</i> element shall not have the multiple <i>part</i> elements.		X	-	X
JP-eCTD4-205	Each <i>manufacturedProduct.name.part</i> element shall have a <i>value</i> attribute.		X	-	X
JP-eCTD4-206	<p>The <i>manufacturedProduct.name.part@value</i> attribute value shall be Text type (*).</p> <p>*The character types that can be used as Text types are as follows.</p> <ul style="list-style-type: none"> Single-byte alphabets upper and lower case Single-byte numbers Single-byte symbols (\$'(),+-. /;: !?[_#@) and white space Double-byte characters in the JISX0208 range (Kanji (JIS 1st level, JIS 2nd level), alphabets upper and lower case, numbers, hiragana, katakana, symbols, white space, etc.) Model-dependent characters (limited to 30 characters from ① to ㊾ and I to X) 	<p>The following symbols are prohibited characters in XML, so do not use them in principle. If applicants have to use it, they can use the escape character instead as an exception.</p> <ul style="list-style-type: none"> & (ampersand) [Escape character: &#38;] " (double-quote) [Escape character: &#34;] < (less-than) [Escape character: &#60;] > (greater-than) [Escape character: &#62;] 	X	-	X
JP-eCTD4-207	The <i>manufacturedProduct.name.part@value</i> attribute value shall be 240 characters or less.		X	-	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-208	The <i>manufacturedProduct.name.part@value</i> attribute shall match the brand name described in the application form.		X	-	X
JP-eCTD4-362	There shall not be multiple valid Reviews with the same <i>manufacturedProduct.name.part@value</i> attribute value in the same Application.	One Review will be provided per one application form. Therefore, applicants must not provide the same Product information across multiple Reviews.	X	-	X
JP-eCTD4-209	Each <i>manufacturedProduct.manufacturedProduct</i> element shall have the <i>ingredient</i> elements.		X	-	X
JP-eCTD4-210	Each <i>ingredient</i> element shall have a <i>classCode</i> attribute.		X	-	X
JP-eCTD4-211	The <i>ingredient@classCode</i> attribute shall be "INGR".		X	-	X

4.14 Review - Ingredient Substance

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-212	Each <i>ingredient</i> element shall have a <i>ingredientSubstance</i> element.		X	-	X
JP-eCTD4-213	Each <i>ingredientSubstance</i> element shall have a <i>name</i> element.		X	-	X
JP-eCTD4-214	Each <i>ingredientSubstance.name</i> element shall have a <i>part</i> element.		X	-	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-215	Each <i>ingredientSubstance.name</i> element shall not have the multiple <i>part</i> elements.		X	-	X
JP-eCTD4-216	Each <i>ingredientSubstance.name.part</i> element shall have a <i>value</i> attribute.		X	-	X
JP-eCTD4-217	<p>The <i>ingredientSubstance.name.part@value</i> attribute value shall be the Text type (*).</p> <p>*The character types that can be used as Text types are as follows.</p> <ul style="list-style-type: none"> Single-byte alphabets upper and lower case Single-byte numbers Single-byte symbols (\$'(),+-./:;!?'[_#@]) and white space Double-byte characters in the JISX0208 range (Kanji (JIS 1st level, JIS 2nd level), alphabets upper and lower case, numbers, hiragana, katakana, symbols, white space, etc.) Model-dependent characters (limited to 30 characters from ① to ⑳ and I to X) 	<p>The following symbols are prohibited characters in XML, so do not use them in principle. If applicants have to use it, they can use the escape character instead as an exception.</p> <ul style="list-style-type: none"> & (ampersand) [Escape character: &amp;] " (double-quote) [Escape character: &quot;] < (less-than) [Escape character: &lt;] > (greater-than) [Escape character: &gt;] 	X	-	X
JP-eCTD4-218	The <i>ingredientSubstance.name.part@value</i> attribute value shall be 240 characters or less.		X	-	X
JP-eCTD4-219	The <i>ingredientSubstance.name.part@value</i> attribute value shall match the generic name described in the application form in principle.		X	-	X
JP-eCTD4-220	Each <i>ingredientSubstance.name.part</i> element shall have a <i>code</i> attribute.		X	-	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-221	The <i>ingredientSubstance.name.part@code</i> attribute value shall be a valid code value listed in the JP CV "JP Substance Name Type" code list indicated by the OID provided by the <i>part@codeSystem</i> attribute value.	In principle, do not use the "jp_other" code. If you want to use the "jp_other" code, then consult with the regulatory authority in advance.	X	-	X
JP-eCTD4-222	Each <i>ingredientSubstance.name.part</i> element shall have a <i>codeSystem</i> attribute.		X	-	X
JP-eCTD4-223	The <i>ingredientSubstance.name.part@codeSystem</i> attribute shall be an OID that identifies the JP CV "JP Substance Name Type" code list.	The code list version identified by the OID must be valid as of the earliest application date of the approval applications included in the eCTD.	X	-	X

4.15 Review - Applicant

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-224	Each <i>review</i> element, in the case that <i>statusCode@code</i> attribute value is "active", shall have the following elements. <ul style="list-style-type: none"> · <i>holder</i> · <i>holder.applicant</i> 		X	-	X
JP-eCTD4-225	For each <i>review</i> element, in the case that <i>statusCode@code</i> attribute value is "active", the following element shall not appear multiple times. <ul style="list-style-type: none"> · <i>holder</i> · <i>holder.applicant</i> 		X	-	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-226	Each review element, in the case that statusCode@code attribute value is "suspended", the following elements shall not appear. · holder · holder.applicant		X	-	-
JP-eCTD4-227	Each applicant element shall have a sponsorOrganization element.		X	-	X
JP-eCTD4-228	Each applicant.sponsorOrganization element shall have a name element.		X	-	X
JP-eCTD4-229	Each applicant.sponsorOrganization.name element shall have a part element.		X	-	X
JP-eCTD4-230	Each applicant.sponsorOrganization.name element shall not have multiple part elements.		X	-	X
JP-eCTD4-231	Each applicant.sponsorOrganization.name.part element shall have a value attribute.		X	-	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-232	<p>The <i>applicant.sponsorOrganization.name.part@value</i> attribute value shall be the Text type (*).</p> <p>*The character types that can be used as Text types are as follows.</p> <ul style="list-style-type: none"> · Single-byte alphabets upper and lower case · Single-byte numbers · Single-byte symbols (\$'(),+-. / ; : ! ? [] _ # @) and white space · Double-byte characters in the JISX0208 range (Kanji (JIS 1st level, JIS 2nd level), alphabets upper and lower case, numbers, hiragana, katakana, symbols, white space, etc.) · Model-dependent characters (limited to 30 characters from ㊦ to ㊴ and I to X) 	<p>The following symbols are prohibited characters in XML, so do not use them in principle. If applicants have to use it, they can use the escape character instead as an exception.</p> <ul style="list-style-type: none"> · & (ampersand) [Escape character: &#amp;#38;] · " (double-quote) [Escape character: &#34;] · < (less-than) [Escape character: &#60;] · > (greater-than) [Escape character: &#62;] 	X	-	X
JP-eCTD4-233	The <i>applicant.sponsorOrganization.name.part@value</i> attribute value shall be 240 characters or less.		X	-	X
JP-eCTD4-234	The <i>applicant.sponsorOrganization.name.part@value</i> attribute shall match the applicant's name described in the application form.		X	-	X

4.16 Review - Product Category

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-235	Each review element, in the case that statusCode@code attribute value is "active", shall have the following elements. · subject2 · subject2.productCategory		X	-	X
JP-eCTD4-236	Each review element, in the case that statusCode@code attribute value is "suspended", shall not have the following elements. · subject2 · subject2.productCategory		X	-	-
JP-eCTD4-237	Each productCategory element shall have a code element.		X	-	X
JP-eCTD4-238	Each productCategory.code element shall have a code attribute.		X	-	X
JP-eCTD4-239	The productCategory.code@code attribute value shall be a valid code value listed in the JP CV "JP Product Category" code list indicated by the OID provide by the productCategory.code@codeSystem attribute value.	In principle, do not use the "jp_other" code. If you want to use the "jp_other" code, then consult with the regulatory authority in advance.	X	-	X
JP-eCTD4-240	The productCategory.code@code attribute value shall match the application category described in the application form.		X	-	X
JP-eCTD4-241	Each productCategory.code element shall have a codeSystem attribute.		X	-	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-242	The <i>productCategory.code@codeSystem</i> attribute shall be the OID that identifies the JP CV "JP Product Category" code list.	The code list version identified by the OID must be valid as of the earliest application date of the approval applications included in the eCTD.	X	-	X

4.17 Application

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-243	The <i>submission</i> element shall have the following elements. · <i>submission.componentOf</i> · <i>submission.componentOf.application</i>		X	X	X
JP-eCTD4-244	The <i>application</i> element shall have only one appear in one payload message.	The one payload message shall not have multiple <i>application</i> elements	X	X	X
JP-eCTD4-245	The <i>application</i> element shall have a <i>application.id</i> element.		X	X	X
JP-eCTD4-246	The <i>application.id</i> element shall have a <i>application.id.item</i> element.		X	X	X
JP-eCTD4-247	The <i>application.id</i> element shall not have multiple <i>Item</i> elements.		X	X	X
JP-eCTD4-248	The <i>application.id.item</i> element shall have a <i>application.id.item@root</i> attribute.		X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-249	The <i>application.id.item@root</i> attribute value shall be a UUID as defined in ISO/IEC 11578:1996 and ITU-T Rec X.667 ISO/IEC 9834-8:2005.		X	X	X
JP-eCTD4-250	The UUID specified in the <i>application.id.item@root</i> attribute value shall be able to uniquely identify the Application.		X	X	X
JP-eCTD4-251	The <i>application.id.item@root</i> attribute value shall remain the same value throughout the Application life cycle.		X	-	X
JP-eCTD4-252	The <i>application.id.item@extension</i> attribute value shall be 1000 characters or less.		X	X	X
JP-eCTD4-253	The <i>application</i> element shall have a <i>application.code</i> element.		X	X	X
JP-eCTD4-254	The <i>application.code</i> element shall have a <i>application.code@code</i> attribute.		X	X	X
JP-eCTD4-255	The <i>application.code@code</i> attribute value shall be a valid code value listed in the JP CV "JP Application" code list indicated by the OID provided by the <i>application.code@codeSystem</i> attribute value.	In principle, do not use the "jp_other" code. If you want to use the "jp_other" code, then consult with the regulatory authority in advance.	X	X	X
JP-eCTD4-256	The <i>application.code@code</i> attribute value shall remain the same throughout the Application life cycle.		X	-	X
JP-eCTD4-257	The <i>application.code</i> element shall have a <i>application.code@codeSystem</i> attribute.		X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-258	The <i>application.code@codeSystem</i> attribute value shall be the OID that identifies the JP CV "JP Application" code list.	The code list version identified by the OID must be valid as of the earliest application date of the approval applications included in the eCTD.	X	X	X
JP-eCTD4-259	The <i>application.code@codeSystem</i> attribute value shall remain the same value throughout the Application life cycle.	However, the version numbers included at the end of the OID indicated by the <i>code@codeSystem</i> attribute do not need to be matched.	X	-	X

4.18 Application Reference

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-260	Each <i>application.reference</i> element shall have the <i>applicationReference</i> element.	If it does not provide an <i>applicationReference</i> element, it shall not provide an <i>application.reference</i> element.	X	X	X
JP-eCTD4-261	Each <i>applicationReference</i> element shall have an <i>id</i> element.		X	X	X
JP-eCTD4-262	Each <i>applicationReference.id</i> element shall have a <i>root</i> attribute.		X	X	X
JP-eCTD4-263	The <i>applicationReference.id@root</i> attribute value shall be a single-byte alphanumeric type.		X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-264	The application with the eCTD reception number indicated by the <i>applicationReference.id@root</i> attribute value shall exist in the regulatory authority database.		X	X	X
JP-eCTD4-265	The application with the eCTD reception number indicated by the <i>applicationReference.id@root</i> attribute value shall not be withdrawn.		X	X	X
JP-eCTD4-266	The eCTD reception number indicated by the <i>applicationReference.id@root</i> attribute value and the eCTD reception number provided by the relevant Submission Unit shall be different.		X	X	X
JP-eCTD4-267	The <i>id@root</i> attribute value of each <i>applicationReference</i> element within the same Submission Unit shall be different.		X	X	X
JP-eCTD4-268	<p>The <i>id@root</i> attribute value of the <i>applicationReference</i> element whose Application Reference Reason code indicates the already approved application to be submitted at the time of the application for partial changes (*), shall be the eCTD reception number of an already approved application.</p> <p>* The <i>applicationReference</i> element whose the <i>reasonCode.item@code</i> attribute provide the code that indicates "the eCTD Receipt Number of the application for the documents that should be placed in JP CTD module 1.13.1" (jp_pca).</p>		X	X	X
JP-eCTD4-269	Each <i>applicationReference</i> element shall have a <i>reasonCode</i> element.		X	X	X
JP-eCTD4-270	Each <i>applicationReference.reasonCode</i> element shall have the <i>item</i> elements.		X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-271	Each <i>applicationReference.reasonCode.item</i> element shall have a <i>code</i> attribute.		X	X	X
JP-eCTD4-272	The <i>reasonCode.item@code</i> attribute value shall be a valid code value listed in the JP CV "JP Application Reference Reason" code list indicated by the OID provided by the <i>reasonCode.item@codeSystem</i> attribute value.	In principle, do not use the "jp_other" code. If you want to use the "jp_other" code, then consult with the regulatory authority in advance.	X	X	X
JP-eCTD4-273	Each <i>applicationReference.reasonCode.item</i> element shall have a <i>codeSystem</i> attribute.		X	X	X
JP-eCTD4-274	The <i>reasonCode.item@codeSystem</i> attribute shall be the OID that identifies the JP CV "JP Application Reference Reason" code list.	The code list version identified by the OID must be valid as of the earliest application date of the approval applications included in the eCTD.	X	X	X
JP-eCTD4-275	The combination of <i>code</i> attribute and <i>codeSystem</i> attribute of each <i>reasonCode.item</i> element under one <i>applicationReference</i> element shall be different.	However, even if the version number included at the end of the OID indicated by the <i>codeSystem</i> attribute does not match, if other information matches, the combination of <i>code</i> attribute and <i>codeSystem</i> attribute will be regarded as identical.	X	X	X

4.19 Documents

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-276	Each application.component element shall have a document element.	If a document element is not provided, application.component element shall not be provided.	X	X	X
JP-eCTD4-277	Each document element shall have an id element.		X	X	X
JP-eCTD4-278	Each document.id element shall have a root attribute.		X	X	X
JP-eCTD4-279	The document.id@root attribute value shall be a UUID as defined in ISO/IEC 11578:1996 and ITU-T Rec X.667 ISO/IEC 9834-8:2005.		X	X	X
JP-eCTD4-280	The UUID specified in the document.id@root attribute value shall be able to uniquely identify this Document.		X	X	X
JP-eCTD4-281	Each document element shall have a title element.		X	X	X
JP-eCTD4-282	Each document.title element shall have a value attribute.		X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-283	<p>The <i>document.title@value</i> attribute value shall be the Text type (*).</p> <p>*The character types that can be used as Text types are as follows.</p> <ul style="list-style-type: none"> · Single-byte alphabets upper and lower case · Single-byte numbers · Single-byte symbols (\$'(),+-. / ; ! ? [] _ # @) and white space · Double-byte characters in the JISX0208 range (Kanji (JIS 1st level, JIS 2nd level), alphabets upper and lower case, numbers, hiragana, katakana, symbols, white space, etc.) · Model-dependent characters (limited to 30 characters from ㊦ to ㊴ and I to X) 	<p>The following symbols are prohibited characters in XML, so do not use them in principle. If applicants have to use it, they can use the escape character instead as an exception.</p> <ul style="list-style-type: none"> · & (ampersand) [Escape character: &amp;] · " (double-quote) [Escape character: &quot;] · < (less-than) [Escape character: &lt;] · > (greater-than) [Escape character: &gt;] 	X	X	X
JP-eCTD4-284	The <i>document.title@value</i> attribute value shall be 1000 characters or less.		X	X	X
JP-eCTD4-285	When updating the <i>title@value</i> attribute value of the already submitted Document, the <i>title</i> element of the updated Document shall have the <i>updateMode</i> attribute.		X	-	-
JP-eCTD4-286	The <i>document.title@updateMode</i> attribute shall be "R".		X	-	-

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-287	For a Document with no update of the <i>title@value</i> attribute value, the Document element shall not have the <i>title@updatemode</i> attribute.	<p>The <i>title@updateMode</i> attribute appears for the Document that corresponds to any of the following, the Submission Unit will be rejected.</p> <ul style="list-style-type: none"> · It is a Document that appears for the first time throughout the Application life cycle including the first version submission. · The <i>title@value</i> attribute value is not updated 	X	X	X
JP-eCTD4-288	The Document to be provided by different Application shall not have the <i>title@updateMode</i> attribute.		X	-	-

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-289	One Document identified by UUID must not be performed with multiple operations (e.g., new submissions and updates) within the same Submission Unit.	<p>The following Submission Unit will be rejected:</p> <ul style="list-style-type: none"> The Document is newly submitted and its title is updated in the same Submission Unit (i.e., the UUID of the newly submitted Document is specified in the <i>id@root</i> attribute value of another Document that has <i>title@updateMode</i> attribute value within the same Submission Unit.) For a specific Document, the Document title is updated multiple times within the same Submission Unit (Documents with the same <i>id@root</i> attribute value and the specified <i>title@updateMode</i> attribute value are multiple exist) 	X	-	-
JP-eCTD4-290	Each <i>document</i> element shall have a <i>text</i> element unless <i>title@updateMode</i> attribute exists.		X	X	X
JP-eCTD4-291	The <i>document</i> element with the <i>title@updateMode</i> attribute shall not have the text element.		X	-	-

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-292	Each document.text element shall have a integrityCheckAlgorithm attribute.		X	X	X
JP-eCTD4-293	The document.text@integrityCheckAlgorithm attribute shall be "SHA256".		X	X	X
JP-eCTD4-294	The document element that refers to files in SAS XPORT format(.xpt) shall have the text@charset attribute.		X	X	-
JP-eCTD4-295	The document.text@charset attribute value shall be a valid code value listed in the JP CV "JP Japanese Character Code" code list.	In principle, do not use the "jp_other" code. If you want to use the "jp_other" code, then consult with the regulatory authority in advance.	X	X	-
JP-eCTD4-296	Each document.text element shall have a reference element.		X	X	X
JP-eCTD4-297	Each document.text.reference element shall have a value attribute.		X	X	X
JP-eCTD4-298	The document.text.reference@value attribute value shall be the relative path of the file that physically exists in this Application.		X	X	X
JP-eCTD4-299	(abolition)	-	-	-	-
JP-eCTD4-300	In the eCTD type b), the location indicated by the document.text.reference@value attribute value shall be the location where the electronic study data should be stored (the file path under "m5/datasets" folder).		-	X	-

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-301	In the eCTD type c), the location indicated by the <i>document.text.reference@value</i> attribute value shall not be the location where the electronic study data should be stored (the file path under "m5/datasets" folder).		-	-	X
JP-eCTD4-302	When reusing a file, the following shall belong to the same Application. <ul style="list-style-type: none"> · The Submission Unit submitting the reused file · The Submission Unit containing the <i>document</i> element that references the reused file 	Only file submitted within the same Application can be reused. Reuse of files submitted in different Application is not permitted.	X	-	X
JP-eCTD4-303	The electronic study data files shall not be reused.		X	X	X
JP-eCTD4-304	Each <i>document.text</i> element shall have a <i>integrityCheck</i> element.		X	X	X
JP-eCTD4-305	The checksum of the file referenced by the document is provided as the content of the <i>document.text.integrityCheck</i> element.	The checksum shall be calculated according to the SHA256 algorithm.	X	X	X
JP-eCTD4-306	Each <i>document.text.thumbnail</i> element shall have a <i>value</i> attribute.		X	X	X
JP-eCTD4-307	The <i>document.text.thumbnail@value</i> attribute value shall be 1000 characters or less.		X	X	X
JP-eCTD4-308	If the Document is referenced by the Context of Use that includes a JP Analysis Type Keyword except for the one indicating "not clinical pharmacology study results" (jp_non_cp), its <i>document.text</i> element shall have a <i>description</i> element.	When submitting electronic study data of clinical pharmacology area, it is necessary to provide a description of the file content as the <i>text.description@value</i> attribute value of Document.	X	X	-

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-309	Each <i>document.text.description</i> element shall have a <i>value</i> attribute.		X	X	X
JP-eCTD4-310	<p>The <i>document.text.description@value</i> attribute value shall be the Text type (*).</p> <p>*The character types that can be used as Text types are as follows.</p> <ul style="list-style-type: none"> · Single-byte alphabets upper and lower case · Single-byte numbers · Single-byte symbols (\$'(),+-.;/:!?[_#@) and white space · Double-byte characters in the JISX0208 range (Kanji (JIS 1st level, JIS 2nd level), alphabets upper and lower case, numbers, hiragana, katakana, symbols, white space, etc.) · Model-dependent characters (limited to 30 characters from ① to ㊟ and I to X) 	<p>The following symbols are prohibited characters in XML, so do not use them in principle. If applicants have to use it, they can use the escape character instead as an exception.</p> <ul style="list-style-type: none"> · & (ampersand) [Escape character: &amp;] · " (double-quote) [Escape character: &quot;] · < (less-than) [Escape character: &lt;] · > (greater-than) [Escape character: &gt;] 	X	X	X
JP-eCTD4-311	The <i>document.text.description@value</i> attribute value shall be 100 characters or less.		X	X	X
JP-eCTD4-312	A new Document that is not referenced by the Context of Use of the same Submission Unit must not be provided.		X	X	X

4.20 Keyword definitions

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-313	Each <i>application.referencedBy</i> element shall have a <i>keywordDefinition</i> element.	If the <i>keywordDefinition</i> element is not provided, the <i>application.referencedBy</i> element must not be provided.	X	X	X
JP-eCTD4-314	Each <i>keywordDefinition</i> element shall have a <i>code</i> element.		X	X	X
JP-eCTD4-315	Each <i>keywordDefinition.code</i> element shall have a <i>code</i> attribute.		X	X	X
JP-eCTD4-316	The <i>keywordDefinition.code@code</i> attribute value shall be a valid code value listed in the ICH CV "ICH Keyword Definition Type" code list indicated by the OID provided by the <i>keywordDefinition.code@codeSystem</i> attribute value.		X	X	X
JP-eCTD4-317	Each <i>keywordDefinition.code</i> element shall have a <i>codeSystem</i> attribute.		X	X	X
JP-eCTD4-318	The <i>keywordDefinition.code@codeSystem</i> attribute value shall be the OID that identifies the ICH CV "ICH Keyword Definition Type" code list.	The code list version identified by the OID must be valid as of the earliest application date of the approval applications included in the eCTD.	X	X	X
JP-eCTD4-319	Each <i>keywordDefinition</i> element shall have a <i>statusCode</i> element.		X	X	X
JP-eCTD4-320	Each <i>keywordDefinition.statusCode</i> element shall have a <i>code</i> attribute.		X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-321	The <i>keywordDefinition.statusCode@code</i> attribute shall be "active".		X	X	X
JP-eCTD4-322	Each <i>keywordDefinition</i> element shall have a <i>value</i> element.		X	X	X
JP-eCTD4-323	Each <i>keywordDefinition.value</i> element shall have an <i>item</i> element.		X	X	X
JP-eCTD4-324	Each <i>keywordDefinition.value</i> element shall not have the multiple <i>item</i> elements.		X	X	X
JP-eCTD4-325	Each <i>keywordDefinition.value.item</i> element shall have a <i>code</i> attribute.		X	X	X
JP-eCTD4-326	<p>The <i>keywordDefinition.value.item@code</i> attribute value shall be the Text type (*).</p> <p>*The character types that can be used as Text types are as follows.</p> <ul style="list-style-type: none"> · Single-byte alphabets upper and lower case · Single-byte numbers · Single-byte symbols (\$'(),+-. /;:!?[]_#@) and white space · Double-byte characters in the JISX0208 range (Kanji (JIS 1st level, JIS 2nd level), alphabets upper and lower case, numbers, hiragana, katakana, symbols, white space, etc.) · Model-dependent characters (limited to 30 characters from ① to ㊾ and I to X) 	<p>The following symbols are prohibited characters in XML, so do not use them in principle. If applicants have to use it, they can use the escape character instead as an exception.</p> <ul style="list-style-type: none"> · & (ampersand) [Escape character: &#amp;#38;] · " (double-quote) [Escape character: &#34;] · < (less-than) [Escape character: &#60;] · > (greater-than) [Escape character: &#62;] 	X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-327	The <i>keywordDefinition.value.item@code</i> attribute value shall be 128 characters or less.		X	X	X
JP-eCTD4-328	Each <i>keywordDefinition.value.item</i> element shall have a <i>codeSystem</i> attribute.		X	X	X
JP-eCTD4-329	<p>The <i>keywordDefinition.value.item@codeSystem</i> attribute value shall be the Text type (*).</p> <p>*The character types that can be used as Text types are as follows.</p> <ul style="list-style-type: none"> · Single-byte alphabets upper and lower case · Single-byte numbers · Single-byte symbols (\$'(),+-./:;!?[_#@) and white space · Double-byte characters in the JISX0208 range (Kanji (JIS 1st level, JIS 2nd level), alphabets upper and lower case, numbers, hiragana, katakana, symbols, white space, etc.) · Model-dependent characters (limited to 30 characters from ① to ㊾ and I to X) 	<p>The following symbols are prohibited characters in XML, so do not use them in principle. If applicants have to use it, they can use the escape character instead as an exception.</p> <ul style="list-style-type: none"> · & (ampersand) [Escape character: &amp;] · " (double-quote) [Escape character: &quot;] · < (less-than) [Escape character: &lt;] · > (greater-than) [Escape character: &gt;] 	X	X	X
JP-eCTD4-330	The <i>keywordDefinition.value.item@codeSystem</i> attribute value shall be 256 characters or less.		X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-331	The combination of <i>value.item@code</i> and <i>value.item@codeSystem</i> attribute values in Keyword Definition shall be unique within the Keyword Definition of the Application.	<p>If the <i>keywordDefinition</i> element that satisfies all of the following conditions is provided, the Submission Unit will be rejected.</p> <ul style="list-style-type: none"> · The <i>displayName@updateMode</i> attribute is not provided · The combination of <i>value.item@code</i> and <i>value.item@codeSystem</i> attribute values is same as other Keyword Definition provided in this Application 	X	X	X
JP-eCTD4-332	Each <i>keywordDefinition.value.item</i> element shall have a <i>displayName</i> element.		X	X	X
JP-eCTD4-333	Each <i>keywordDefinition.value.item.displayName</i> element shall have a <i>value</i> attribute.		X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-334	<p>The <i>keywordDefinition.value.item.displayName@value</i> attribute value shall be the Text type (*).</p> <p>*The character types that can be used as Text types are as follows.</p> <ul style="list-style-type: none"> · Single-byte alphabets upper and lower case · Single-byte numbers · Single-byte symbols (\$'(),+-. / ; ! ? [] _ # @) and white space · Double-byte characters in the JISX0208 range (Kanji (JIS 1st level, JIS 2nd level), alphabets upper and lower case, numbers, hiragana, katakana, symbols, white space, etc.) · Model-dependent characters (limited to 30 characters from ㉠ to ㉪ and I to X) 	<p>The following symbols are prohibited characters in XML, so do not use them in principle. If applicants have to use it, they can use the escape character instead as an exception.</p> <ul style="list-style-type: none"> · & (ampersand) [Escape character: &amp;] · " (double-quote) [Escape character: &quot;] 	X	X	X
JP-eCTD4-335	The <i>keywordDefinition.value.item.displayName@value</i> attribute value shall be 1000 characters or less.		X	X	X
JP-eCTD4-336	If the <i>keywordDefinition.code@code</i> attribute value is a code (ich_keyword_type_8) indicating "study id_study title", the study ID and study title in the <i>displayName@value</i> attribute value shall be able to be separated by a single-byte underscore and a dollar sign (_\$).		X	X	X
JP-eCTD4-337	When updating the <i>displayName@value</i> attribute value of the already submitted Keyword Definition, the <i>displayName</i> element of the updated Keyword Definition shall have the <i>updateMode</i> attribute.		X	-	-

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-338	The <i>keywordDefinition.value.item.displayName@updateMode</i> attribute shall be "R".		X	-	-
JP-eCTD4-339	For a Keyword Definition with no update of the <i>displayName@value</i> attribute value, the <i>keywordDefinition</i> element shall not have the <i>displayName@updateMode</i> attribute.	<p>The <i>displayName@updateMode</i> attribute appears for the Keyword Definition that corresponds to any of the following, the Submission Unit will be rejected.</p> <ul style="list-style-type: none"> · It is a Keyword Definition that appears for the first time throughout the Application life cycle including the first version submission. · The <i>displayName@value</i> attribute value is not updated 	X	X	X

JP-eCTD4-340	One Keyword Definition identified by UUID must not be performed with multiple operations (e.g., new submissions and updates) within the same Submission Unit.	<p>The following Submission Unit will be rejected:</p> <ul style="list-style-type: none"> · The Keyword Definition is newly submitted and its display name is updated in the same Submission Unit (The Keyword Definition that has same combination of <i>value.item@code</i> and <i>codeSystem</i> attribute values as the another Keyword Definition newly submitted, and the <i>displayName@updateMode</i> attribute value exists in the same Submission Unit) · To a specific Keyword Definition, the Keyword display string updates are performed multiple times within the same Submission Unit (Keyword Definition with the same combination of <i>value.item@code</i> and <i>codeSystem</i> attribute values and the <i>displayName@updateMode</i> attribute values assigned exists multiple times in the same Submission Unit) 	X	-	-
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4.21 Category Event

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-341	The <i>submissionUnit</i> element shall have the following elements. · <i>submissionUnit.componentOf2</i> · <i>submissionUnit.componentOf2.categoryEvent</i>		X	X	X
JP-eCTD4-342	One payload message shall have the only one <i>submissionUnit.componentOf2.categoryEvent</i> element.	Multiple <i>submissionUnit.componentOf2.categoryEvent</i> elements shall not appear in one payload message.	X	X	X
JP-eCTD4-343	The <i>componentOf2.categoryEvent</i> element shall have a <i>componentOf2.categoryEvent.code</i> element.		X	X	X
JP-eCTD4-344	The <i>componentOf2.categoryEvent.code</i> element shall have a <i>componentOf2.categoryEvent.code@code</i> attribute.		X	X	X
JP-eCTD4-345	The <i>componentOf2.categoryEvent.code@code</i> attribute value shall be a valid code value listed in the JP CV "JP Category Even" code list indicated by the OID provided by the <i>componentOf2.categoryEvent.code@codeSystem</i> attribute value.	In principle, do not use the "jp_other" code. If you want to use the "jp_other" code, then consult with the regulatory authority in advance.	X	X	X
JP-eCTD4-346	In the first version submission, the <i>componentOf2.categoryEvent.code@code</i> attribute value shall be a code (jp_initial) indicating "initial submission of ectd".		X	X	X
JP-eCTD4-347	For submissions other than the first version, the <i>componentOf2.categoryEvent.code@code</i> attribute value shall not be a code (jp_initial) indicating "initial submission of ectd".		X	-	-

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-348	If the <i>componentOf2.categoryEvent.code@code</i> attribute value is either one of codes below, then ensure that the same code was not provided in the previous life cycle of the Application. <ul style="list-style-type: none"> The code indicating "for expert discussion" (jp_expert_discussion) The code indicating "for committee meeting" (jp_committee_meeting) 		X	-	-
JP-eCTD4-349	The <i>componentOf2.categoryEvent.code</i> element shall have a <i>componentOf2.categoryEvent.code@codeSystem</i> attribute.		X	X	X
JP-eCTD4-350	The <i>componentOf2.categoryEvent.code@codeSystem</i> attribute value shall be the OID that identifies the JP CV "JP Category Even" code list.	The code list version identified by the OID must be valid as of the earliest application date of the approval applications included in the eCTD.	X	X	X
JP-eCTD4-351	The following elements shall appear in the first version submission. <ul style="list-style-type: none"> <i>categoryEvent.component</i> <i>categoryEvent.component.categoryEvent</i> 		X	X	X
JP-eCTD4-352	The <i>categoryEvent.component.categoryEvent</i> element shall appear in one payload message.	Multiple <i>categoryEvent.component.categoryEvent</i> elements shall not be one in one payload message.	X	X	X
JP-eCTD4-353	The XML message shall not have the <i>categoryEvent.component.categoryEvent</i> element in submission other than the first version.		X	-	-
JP-eCTD4-354	The XML message shall have the <i>component.categoryEvent.code</i> element in the first version submission.		X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-355	The XML message shall have the <i>component.categoryEvent.code@code</i> attribute in the first version submission.		X	X	X
JP-eCTD4-356	The <i>component.categoryEvent.code@code</i> attribute value shall be a valid code value listed in the JP CV "JP Initial Submission Type" code list indicated by the OID provided by the <i>component.categoryEvent.code@codeSystem</i> attribute value.	In principle, do not use the "jp_other" code. If you want to use the "jp_other" code, then consult with the regulatory authority in advance.	X	X	X
JP-eCTD4-357	When submitting as method 1 in the first version submission, the <i>component.categoryEvent.code@code</i> attribute value in the submission with the submission sequence number of "1" shall be the code (jp_initial_a) that indicates the eCTD type a).		X	-	-
JP-eCTD4-358	When submitting as method 2 in the first version submission, the <i>component.categoryEvent.code@code</i> attribute value in the submission with the submission sequence number of "1" shall be the code (jp_initial_b) that indicates the eCTD type b).		-	X	-
JP-eCTD4-359	When submitting as method 2 in the first version submission, the <i>component.categoryEvent.code@code</i> attribute value in the submission with the submission sequence number of "2" shall be the code (jp_initial_c) that indicates the eCTD type c).		-	-	X
JP-eCTD4-360	The XML message shall have the <i>component.categoryEvent.code@codeSystem</i> attribute in the first version submission.		X	X	X

ID	Check item	Remarks	eCTD type		
			a)	b)	c)
JP-eCTD4-361	The <i>component.categoryEvent.code@codeSystem</i> attribute value shall be the OID that identifies the JP CV "JP Initial Submission Type" code list.	The code list version identified by the OID must be valid as of the earliest application date of the approval applications included in the eCTD.	X	X	X