Appendix 1

ICH Electronic Common Technical Document (eCTD) v4.0 Implementation Guide in Japan v1.5.0

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Version No.	Date	Overview		
1.2.0	July 5, 2017	First version		
1.3.0	Feb 19, 2020	Editorial corrections		
		Revisions due to consistency with ICH IG v1.3		
1.4.0	Feb 18, 2022	 Revisions to remove and change of description related to the response life cycle abolition Adds to the single-byte ampersand (&) to character types (Section 2.5) that can be used as text type Corrects to the description when submitting the eCTD to the PMDA reception desk to be more accurate Changes to the number of characters limit for the following attribute values: submissionUnit.title@value document.title@value document.title@value keywordDefinition.value.item.displayName@value Adds to the business rule regarding the file path description for the document.text.reference@value attribute value due to the addition of the file path description when reusing files in ICH IG v1.4 Add the description that the study id of attribute "study id_study title Keyword" in the Context of Use refering to the electronic study data and the folder name of study ID does not always need to mach the alphabet letter Revisions to make clearer expressions and correction of clerical errors 		
1.5.0	Feb 6, 2023	 Revisions due to consistency with ICH IG v1.5 Expanded the available scope of escape characters in the character types that can be used as text type (Section 2.5) Changes in the notation of the notification name, etc., due to the revision of the electronic study data-related notification Added "Submission type of eCTD application" as information to be described in electronic media when submitting to the PMDA reception (Section 3.3.2) Moved the description about Security settings for each file to JP SSF and remove it. Revisions of business rules (Section 7.4.17.3 and 8.2) regarding file path description method in <i>document.text.reference@value</i> attribute value Added a supplement to how to express the attachment numbers (Section 12.3) Clerical corrections 		

DOCUMENT CHANGE HISTORY

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1. Purpose

This document describes the handling of Appendix 3 "ICH electronic common technical document (eCTD) v4.0 Implementation guide v1.5" (hereinafter referred to as "ICH IG") in Japan upon implementing eCTD. As the requirement for creating eCTD v4.0 XML messages and other components, it describes how the applicant should electronically submit the information related to the approval application for pharmaceutical products to the regulatory authority. This document shall be used together with ICH IG. If there is any different on the descriptions between this document and the description of ICH IG, the description of this document shall take precedence.

2. Definitions of terminology, notations, symbols, etc.

2.1 Terminology

Terminology	Definition		
UUID	Abbreviation of Universally Unique Identifier. For the definition, refer to ICH IG		
OID	Abbreviation of Object Identifier. For the definition, refer to ICH IG		
JP CV	Japan-specific controlled vocabulary used for operation of eCTD v4.0		
CTD	Acronym of Common Technical Document Format of the data that should be attached to the marketing application when making a marketing application for manufacturing or import of new drugs, which was agreed upon in The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).		
eCTD	Acronym of Electronic Common Technical Document Technical specifications that enable CTD to be electronically submitted by the applicant to the regulatory authority.		
eCTD application	Pharmaceutical product marketing approval application with eCTD submitted as the original of an attachment to the approval application		
eCTD data	Data to be submitted for eCTD application		
eCTD v4.0 XML message	Submissionunit.xml to be submitted to the regulatory authority according to ICH IG and this document		
PMDA	Pharmaceuticals and Medical Devices Agency		
Payload	The body of the data excluding the header section		
Application dossier	Documents that should be attached to the approval application form for the approval application of a prescription drug		
Electronic study data (Study dataset files)	Electronic clinical study results and associated documents In this document, it refers to the electronic study data indicated by "Notification on Handling of Submission of Electronic Study Data for New Drug Applications" (PSEHB/PED Notification No. 0401-10 as of April 1, 2022, Notification by the Director, Pharmaceutical Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare) (hereinafter referred to as "electronic study data notification")		

The terminology used in this document is defined in the table below.

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Electronic study data system	The system to provide the function for the applicant to submit
	electronic study data via the Internet, the advance notice
	function for application, the function to response inquiries, the
	function to confirm the review status, etc. It is sometimes
	referred to as the "gateway system".

2.2 Character notation

In this document, components of XML (elements and attributes) are notated in bold italic characters. However, this does not apply to XML snippets. Also, the concepts indicated by components of XML are expressed in the standard characters.

2.3 Symbol used in this document

Legends of Symbol used in 7 of this document is provided below.

Symbol	Description	
>> The element described on the right to this symbol is a chi		
	element of the element described on the left.	

2.4 Color of the characters in XML snippets

Legends of the color of characters in XML snippets in 7 of this document are provided below.

Character color	Description		
Blue	Components in terms of XML notation		
	Example: <, =, ", ", >		
Brown	XML element		
	Example: <i>id</i> , <i>code</i>		
Red	XML attribute		
	Example: root, extension		
Black	Contents of the XML element or attribute value		
	Example: 2.16.840.1.113883		

2.5 XML element and attribute table

The section below describes how to view the table provided in 7 of this document.

Element		Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description	
Submission rules for						
elements and						
attı	ibutes	_				
Business		General				
Ru	les	a)				
		b)				
		c)				

Element: It indicates the name of the element. Indentation indicates the parent-child relationship between elements. The element expressed in the colored right column is an element holding information or an element to store attributes;

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therefore, the information on the attribute, Cardinality, etc. in the same line in the table is omitted.

Attribute: It indicates the name of the attribute.

Cardinality: If the object is an element, then it indicates the lower limit and the upper limit of the number of occurrences of the relevant element for the parent element. If the object is an attribute, then it indicates the lower limit and the upper limit of the number of occurrences of the relevant attribute for the element. Expressed the "[n..m]" format. n denotes the lower limit. m denotes the upper limit. An asterisk ("*") denotes 0 times or more. The Cardinality described in this document does not necessarily agree with the definition on the schema. Give priority to this document in eCTD submitted to the regulatory authority.

Value Type It indicates the contents of the relevant element or the type which the value of the attribute can take. The kinds of values allowed are as follows.

- Text: UTF-8 characters (including Japanese characters)* can be used.
- Fixed: Only the values provided as examples can be used.
- Single-byte Only single-byte alphabetic characters (from a to z and from A to Z) can be used.
- Single-byte Single-byte Arabic numerals (from 0 to 9) can only be used. numbers:
- Single-byte Only single-byte alphabets and single-byte numbers can be used. characters:

*In principle, the character types that can be used as text types are as follows.

[The character types that can be used as a text type]

- Single-byte alphabets upper and lower case
- Single-byte numbers
 - Single-byte symbols (\$'(),+-./;:!?[]_#@) and white space Note: 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.
 - & (ampersand) [Escape character: & amp;]
 - " (double-quote) [Escape character: "]
 - < (less-than) [Escape character: <]
 - > (greater-than) [Escape character: >]
- 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 ②) and I to X)

Theabove rules are applied only about the required or used text type elements/attributes by the Regulatory Authority – i.e., the character types that can be used for text type elements/attributes such as *application.id.item@extension* are not limited to the above character types.

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Example of value:	It shows an example of the contents of the relevant element or the value of the attribute.
Description:	The relevant element or attribute is described.
Submission rules for elements and attributes:	The rules for providing the relevant element or attribute are shown in addition to the contents of "Cardinality", "Value type" and "Description" above.
Business Rules - General:	Of the business rules that should be followed upon providing the relevant element or attribute, the rules to be applied to all of a), b) and c) indicated in 3.3.1 of this document are shown.
Business Rules -a):	Of the business rules that should be followed upon providing the relevant element or attribute, the rules to be applied to a) indicated in 3.3.1 of this document in addition to "Business Rules - General" above are shown.
Business Rules -b):	Of the business rules that should be followed upon providing the relevant element or attribute, the rules to be applied to b) indicated in 3.3.1 of this document in addition to "Business Rules - General" above are shown.
Business Rules -c):	Of the business rules that should be followed upon providing the relevant element or attribute, the rules to be applied to c) indicated in 3.3.1 of this document in addition to "business rules - General" above are shown.

3. General matters

3.1 Components that should be included for eCTD application

Components that should be included for eCTD application are shown below.

- Folder
- eCTD v4.0 XML message
- File*

* The following types of files are available.

- 1) ICH CTD document file referred to from the eCTD v4.0 XML message
- 2) Japan-specific document file referred to from the eCTD v4.0 XML message (Example: Module 1 document)
- 3) Electronic study data referred to from the eCTD v4.0 XML message
- 4) The file to be submitted to the regulatory authority but not referred to from the eCTD v4.0 XML message (Example: A file containing the checksum for the eCTD v4.0 XML message (sha256.txt))

3.2 Components not to be included in eCTD to be submitted to the regulatory authority

The following component shall not be included in the eCTD to be submitted to the regulatory authority.

- 1) Folders or files not described in this document
- 2) XML elements and attributes not described in this document

3.3 Matters related to submission

There are 2 methods for the applicant to submit eCTD to the regulatory authority in association with the approval application procedures: The method to submit it via the electronic study data system, and the method to deliver it to the reception (including mail) of the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as "PMDA").

For the approval application supposed to be submitted in the method to use the gateway system according to the "Notification on New Drug Applications Using the Gateway System" (PSEHB/PED Notification 0401 No.7 as of April 1, 2022 Notification by the Director of the Pharmaceutical Evaluation

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Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare) (hereinafter referred to as "Notification on gateway application"), follow this.

3.3.1 Submission method via the electronic study data system

For the specific submission method and procedures via the electronic study data system, refer to the Notification on gateway application and "Technical Conformance Guide on Electronic Study Data Submissions" (PMDA/CPE Notification No. 0401003 and PMDA/CRS Notification No.0401001 as of April 1, 2022 Notification by the Director Center for Product Evaluation, Director of Center for Regulatory Science, Pharmaceuticals and Medical Devices Agency) (hereinafter referred to as "Technical Conformance Guide"), etc.

Of the following 3 eCTD types, either submit a) or submit b) and c).

- a) eCTD to be submitted referring to the material specified by "About guidelines for creating the data that should be attached for new drug marketing approval application" as of June 21, 2001
 Pharmaceutical Affairs Bureau Notification No 899 Notification by the Director of the Evaluation and Licensing Division, Pharmaceutical (and Food Safety) Bureau, Ministry of Health, Labour and Welfare) (hereinafter referred to as "CTD notification") as well as the electronic study data from one eCTD v4.0 XML message.
- b) eCTD to be submitted by referring to only the electronic study data from 1 eCTD v4.0 XML message among a) above.
- c) eCTD to be submitted by referring to the data specified by the CTD notification from 1 eCTD v4.0 XML message among a) above.

In this document, the method to submit a) is called "Method 1", and the method to submit b) and c) is called "Method 2". When submitting the first version of the data attached to the marketing application, submit it through either Method 1 or Method 2. In any other situation than the first version submission, it is only allowed through submission by Method 1.

In Method 1, only the electronic study data or the data specified by the CTD notification may be included depending on the situation of submission and the type of the data. Also, in Method 2, be sure to submit b) prior to c). For details of the eCTD type and the submission method, refer to 10 of this document.

3.3.2 Method to deliver to the reception of PMDA

To deliver the eCTD to the reception of PMDA, create a cover letter for eCTD (format 1) to submit it in writing, and include it in eCTD, too. In this case, an electronic file of the cover letter (cover.pdf) shall be included in "m1/jp" and does not need to be referred to from the eCTD v4.0 XML message. If there are multiple applicants, the cover letter may be created for each applicant.

If applicants also submit a copy of the cover letter, PMDA will return the copy with a seal of receipt when the submitted electronic files are deemed acceptable. Applicants can use it as proof that the eCTD has been received by PMDA. In the case of mail, PMDA send back a copy of the cover letter, so the applicant shall enclose with a return envelope. The return envelope can also be used in combination with the envelope used to copy the approval application.

In principle, the medium to be submitted shall be DVD-R/RW or BD-R/RE (each of which includes a multi-layer disk). If you wish to submit it in any other medium, consult PMDA in advance.

Attach a label describing the following contents for identification to the electronic medium to be submitted or directly describe them on it. When multiple applications are made in the one eCTD, then representative application information will do.

- 1. eCTD reception number
- 2. Application category
- 3. Application date
- 4. Data submission date
- 5. Brand name

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- 6. Applicant name
- 7. The number to identify the sequence of the media if multiple media are submitted (The number of the relevant medium / total number of media)
- 8. Submission sequence number
- 9. Submission type of eCTD application (submission for original or reference, etc.)
- 10. Remarks

3.4 Operation requirements

When making an eCTD application, you must guarantee that the functions (display, link, etc.) required by the Appendix 2 will work considering the standard environment for review to be announced by the Regulatory Authority. Applicants should notify the Regulatory Authority of the environment in which they have confirmed the operation of the eCTD. When submitting to the reception counter, include it in the cover letter, or when submitting via the electronic study data system, transmit it via the electronic study data system. If the file referenced by hypertext links in other files is replaced among the eCTD revision, the link destination may not be displayed correctly. In this case, submit the revised version of all files affected by the change. If the Regulatory Authority cannot confirm the above-mentioned operation in the announced standard environment for review or judges that there will be a problem in review such as misrepresentations recognized, then the applicant will be requested to replace it. If there is a display problem in the eCTD data in the applicant's environment making it impossible to electronically submit it, then consult the regulatory authority about handling and procedures for taking action, etc. in advance to take action appropriately. For how to confirm the operation before submission, confirm the information posted on the PMDA web site (https://www.pmda.go.jp/) to carry it out appropriately.

Also, the use of any plug-in software required for perusal is not permitted in principle. However, this does not apply to plug-in software used for creation.

3.5 Requirements for using eCTD

When making an eCTD application, you must submit all the documents to be submitted, which should be included in eCTD, in electronic files. Scan the relevant page signed or signed and sealed, etc. on a paper medium, replace it with the corresponding page on the electronic medium and save it and include it in eCTD. In that case, submit a statement indicating that the corresponding page has been correctly scanned. Although it is not necessary to submit any written statement at the time of application, prepare it so that you can submit it upon request from the regulatory authority. Include an electronic file of the statement in Section 3 of Module 1.

Only if you confirm with the regulatory authority in advance and it is permitted, then you may submit eCTD which deviates from the handling according to this document and Appendix 2. In this case, submit a document containing the reason for the deviation and points of attention. Include an electronic file of this document in the submission to the Ministry of Health, Labour and Welfare in Section 13 of Module 1. Note that you must not submit an eCTD intended for bidirectional communication described in ICH IG, and an application associated with more than one submission and forward compatibility from v3.2.2 to v4.0 to the regulatory authority.

3.6 Handling of electronic signatures

When electronically signing the data to be submitted to the regulatory authority, if the target of indication of your intention by the relevant act of the signature is not the regulatory authority (for example, internal document approval, a contract with an outsourcing company, etc.), then you may submit eCTD containing the electronically signed file. However, any electronic signature, for which signer verification is required by the regulatory authority upon perusing the relevant data, is not permitted. If the electronic signature hinders the regulatory authority perusing the data, then you may be requested to remove the relevant electronic signature.

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3.7 Controlled vocabulary

In addition to the controlled vocabulary specified by ICH (hereinafter referred to as "ICH CV"), the controlled vocabulary specific to Japan (hereinafter referred to as "JP CV") specified separately shall be used. When submitting vocabulary, the valid versions as of the earliest date of applications included in the eCTD must be provided. The expiration date of each code list is specified in "OID Listing". "JP OID Listing" is published in the eCTD v4.0 domestic implementation package.

4. Security

4.1 Checksums

In eCTD application, submit a file containing the checksum for the eCTD v4.0 XML message (sha256.txt) (hereinafter referred to as the "checksum file"), and include the checksums of the individual submitted files except for the checksum file in the eCTD v4.0 XML message. For how to submit the checksum file and how to include the checksum in the eCTD v4.0 XML message, refer to "5.1 Contents of Submission Unit" and "5.6 Checksums", etc., in the ICH IG.

5. Requirements for the folder structure and file path contained in eCTD

5.1 Basic folder structure

The basic folder structure shall be as follows.

- To be created based on the folder structure described in ICH IG.
- If there is no file to be stored due to reuse of the document or file, then do not create any folder for the corresponding CTD number.
- The first level folder name shall be the eCTD reception number, and the second level folder name shall be the submission sequence number.
- The folder of each section of CTD ("m1", "m2", "m3", "m4" and "m5") shall be placed at the third level. However, do not create any lower folder or folder not having any file to be stored in the folder at the third level or lower.
- For the structure of Module 1, refer to 15 of this document.
- Create a folder for each individual report that makes up Module 4 and Module 5.
- Place the electronic study data indicated under the "m5" folder in the folder structure described in ICH IG. In this case, place it as follows by regarding the relevant "m5" folder and the "m5" folder of the folder structure indicated in the technical conformance guide as the same folder.

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(For the following, refer to the technical conformance guide.)

5.2 Naming Conventions

For the folders and files to be included in Module 1 through Module 5, follow the folder and file naming conventions provided in ICH IG. For the naming conventions for the electronic study data referred to from the eCTD v4.0 XML message, follow the technical conformance guide.

5.3 The maximum path length

For the maximum path length, follow the description of ICH IG.

6. Requirements for the format of the file included in eCTD

Of the files referred to from the eCTD v4.0 XML message, for the format of the file for electronic study data, refer to the technical conformance guide. If it is necessary to submit any other document than the electronic study data in any other file format than the PDF format or the Microsoft Excel format (.xlsx), then consult the regulatory authority in advance.

7. Requirements for the eCTD v4.0 XML message

7.1 Character encode

Use UTF-8.

7.2 Message header

In addition to ICH IG, the following business rules apply to the message header description rules.

- *receiver.device.id.item@root* should indicate the OID of the Implementation Guide, its version must be valid as of the earliest date of applications included in the eCTD. The expiration date of each version is specified separately in "JP OID Listing".
- The *receiver.device.id.item@identifierName* attribute value shall be 128 characters or less. The Regulatory Authority does not use this attribute value.

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7.3 Handling of the elements and attributes not having any value

In the payload of the eCTD v4.0 XML message, do not let any elements except for the *integrityCheck* element have any other contents than the child element. Also, do not submit any *integrityCheck* element having no contents or *integrityCheck* element having dummy value as the content. As for the attribute, do not submit any attribute having a dummy value or empty value.

7.4 How to use the XML elements and attributes included in the payload

The schema of the eCTD v4.0 XML message contains the elements and attributes not used by the regulatory authority, the elements and attributes whose usage is different from other poles as well as the elements and attributes used only in Japan. For how to use the elements and attributes contained in the eCTD v4.0 XML message to be submitted to the regulatory authority, follow the description of this document, and do not submit any elements or attributes not described in this document. The complete RPS R2 schema includes the Common Product Model schemas, but for the time being, the Regulatory Authorities does not use the Common Product Model schemas. For details on the Common Product Model, refer to the HL7 website.

7.4.1 Required elements (controlActProcess)

For the *controlActProcess* element and attribute required to start the payload of the eCTD v4.0 XML message as well as its child element and attribute, refer to the description of ICH IG. To be provided according to ICH IG

7.4.2 submissionUnit

The Submission Unit refers to a collection of documents and pieces of information to be provided for the regulatory authority through a single act of submission. The Submission Unit will be provided through the *submissionUnit* element.

7.4.2.1 Place of description on XML

For the place to describe the *submissionUnit* element, follow ICH IG.

7.4.2.2 XML snippet

An XML snippet of the *submissionUnit* element is shown below.

```
<subject typeCode="SUBJ">
<submissionUnit>
<id root="c64abdbd-c052-439a-bbcc-e00198139790"/>
<code code="jp_ctd" codeSystem=" 2.16.840.1.113883.3.989.5.1.3.3.1.1.1"/>
<component>
...[Partially omitted]...
</componentOf1>
...[Partially omitted]...
</componentOf1>
<componentOf1>
<componentOf2>
...[Partially omitted]...
</componentOf2>
</submissionUnit>
```

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^{*} This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

7.4.2.3 XML elements and attributes

The *submissionUnit* element and the elements under it as well as their attributes are as follows.

Element	Attribute	Cardinality	Value(s) Allowed Example of value	Description
submissionUnit		[11]		This element stores the documents and pieces of information to be provided for the regulatory authority.
id		[11]		Follow the description of ICH IG.
	root	[11]	Valid UUID	Follow the description of ICH IG.
			root="c64abdbd- c052-439a-bbcc- e00198139790"	
code		[11]		Follow the description of ICH IG.
	code	[11]	Text Example: code="jp_ctd"	The code indicating the type of this Submission Unit Select the code value from the "JP Submission Unit" code list of JP CV.
	codeSystem	[11]	Valid OID <i>Example:</i> <i>codeSystem="2.16.</i> 840.1.113883.3.989. 5.1.3.3.1.1.1"	OID of the "JP Submission Unit" code list of JP CV
title		[01]		Follow the description of ICH IG.
	value	[11]	Text Example: value="First version"	Follow the description of ICH IG.
component		[0*]		This element stores the <i>contextOfUse</i> element. For details of the <i>contextOfUse</i> element, refer to 7.4.4 of this document.
componentOf1		[11]		This element stores the <i>sequenceNumber</i> element and the <i>submission</i> element. For details of the <i>sequenceNumber</i> element, refer to 7.4.8 of this document. For details of the <i>submission</i> element, refer to 7.4.9.

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Element		Attribute	Cardinality	Value(s) Allowed Example of value	Description	
componentOf2			[11]		This element stores the <i>categoryEvent</i> element. For details of the <i>categoryEvent</i> element, refer to 7.4.19 of this document.	
Submission rules for elements and attributes		 When providing a new Context of Use, or when replacing, deleting or updating an existing Context of Use, provide the <i>component</i> element for each Context of Use. For details on the Context of Use, refer to 7.4.4 of this document. The applicant shall determine whether to provide the <i>submissionUnit.title</i> element arbitrarily. 				
Business Rules General		 In addition applied. The Sul rejected Mi The Th W The W The sul Submis The reg attribute attribute types th 	 lition to the business rules provided in ICH IG, the following will be ed. he Submission Unit, which falls under any of the following, will be geted. Multiple <i>submissionUnit</i> elements are provided. The <i>submissionUnit</i> element is not provided. The <i>title@value</i> attribute value has 1001 characters or more. When submitting the first version, the <i>component</i> element is not provided. he <i>submissionUnit.statusCode</i> element is not used. To withdraw the ubmission Unit, consult the regulatory authority. he regulatory authority does not use the <i>submissionUnit.title@value</i> tribute in principle. In addition, the character types that can be used for this tribute is not limited to the character types specified in 2.5 [The character 			
		There are no bi particular.	usiness rules th	at should be followed	in addition to General above in	
	b)	There are no buparticular.	usiness rules th	at should be followed	in addition to General above in	
c)		There are no business rules that should be followed in addition to General above in particular.				

7.4.3 priorityNumber for contextOfUse

Priority Number defines the display order of the Context of Use within the context group and is provided by the *priorityNumber* element. The Context of Use will be displayed in ascending order of the Priority Number for each context group. In plinciple, the electronic study data will be displayed in ascending order of the folder name or the file name at the Regulatory Authority's viewing tool.

7.4.3.1 Place of description on XML

For the place to describe the *priorityNumber* element, refer to "9.2.5 Priority Number for Context of Use", etc., in the ICH IG.

7.4.3.2 XML snippet

An XML snippet of the *priorityNumber* element is shown below.

```
<component>
<priorityNumber value="1000" updateMode="R"/>
<contextOfUse>
```

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...[Partially omitted]... </contextOfUse> </component>

7.4.3.3 XML elements and attributes

The *priorityNumber* element and the elements under it as well as their attributes are as follows.

Element	Attribute	Cardinality	Value(s) Allowed	Description			
• • • • •		F1 11	Example of value				
priorityNumber		[11]		This element stores the			
				information indicating the			
				display order of the Contexts of			
	1	[1 1]	G' 1 1 4	Use in the context group.			
	value	[11]	Single-byte	Specify the integer to be used			
			numbers	for display ordering of the			
			Examples	Context of Use element.			
			Example.				
	undataMada	[0, 1]	Value= 1000	When undeting the Driverity			
	upaaiemoae	[01]	rixeu	Number specify "P"			
			undateMode-"P"	Number, specify K.			
Submission rules for	\searrow If the contr	rtOfUse eleme	μ updatemode = π	lowing is required			
elements and	nriorit	Number@valı		iowing is required.			
attributes	\succ When und	ting the priorit	v V Numher@value attri	bute value of the already			
	submitted (Context of Use.	the following is requi	ired.			
	priorit	Number@upd	ateMode				
Business Genera	$1 \geq$ In addition	to the business	rules provided in ICH	I IG, the following will be			
Rules	applied.		1	, U			
	• The Su	bmission Unit,	which falls under any	of the following, will be			
	rejecte	d.		2			
	♦ M	ultiple valid Co	ontexts of Use within	the same context group have the			
	sa	me (value of th	e) Priority Number in	the application.			
	♦ T	The <i>priorityNumber@updateMode</i> is included in the Context of Use					
	su	bmitted for the	first time throughout	the life cycle.			
	♦ A	t the time of rev	vision, the <i>priorityNu</i>	mber@updateMode attribute			
	Va	lue is provided	l, but the <i>priorityNum</i>	ber@value attribute value is not			
	• The Pr	iority Number :	assigned to the Contex	xt of Use, which refers to the			
	electro	electronic study data does not affect the display order of the electronic study					
	data at	the regulatory	authority.	F-n)			
	• It is de	sirable that the	priorityNumber@val	<i>ue</i> attribute value provided when			
	deletin	g the submitted	Context of Use is the	same as the Priority Number of			
	the Context of Use to be deleted. If other values are provided, it is not						
	recogn	ized that the va	lues have been provid	ed to the regulatory authority.			
	The Pr	iority Number of	of the Context of Use	to be deleted will be available in			
	the san	ne Submission	Unit and later.				
	• When	replacing a sub	mitted Context of Use	with a new Context of Use, the			
	Priorit	Numbers befo	ore and after the replace	cement does not have to match,			
	unless	they overlap w	ith the Context of Use	in the same context group. Also,			
	do not	provide the pri	orityNumber@update	Mode attribute even if the			
	Priorit	Numbers befo	ore and after replacem	ent do not match.			

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Element		Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
	a)	There are no b particular.	pusiness rules th	at should be followed	in addition to General above in
b) There are no business rules that should be followed in a particular.			in addition to General above in		
c) There are no business rules that sh particular.		at should be followed	in addition to General above in		

7.4.4 contextOfUse

The Context of Use defines the positioning of the document. The Context of Use is provided by the *contextOfUse* element, designates the positioning (CTD heading) in the application dossier through the *code* element under it, and designates 1 Document through the *documentReference* element. This defines which CTD heading the designated Document belongs to in the relevant application.

7.4.4.1 Place of description on XML

For the place to describe the *contextOfUse* element, refer to "9.2.6 Context of Use", etc., in the ICH IG.

7.4.4.2 XML snippet

An XML snippet of the *contextOfUse* element is shown below.

```
<component>

<priorityNumber value="1000"/>

<contextOfUse>

<id root="7c5c61fd-5b88-4018-8323-b21f1a731880"/>

<code code="ich_3.2.s.2.3" codeSystem="2.16.840.1.113883.3.989.2.2.1.1.2"/>

<statusCode code="active"/>

... [Partially omitted] ...

</contextOfUse>

</component>
```

7.4.4.3 XML elements and attributes

The contextOfUse element and the elements under it as well as their attributes are as follows.

	Element	Attribute	Cardinality	Value(s) Allowed	Description
				Example of value	
co	ntextOfUse		[11]		This element stores the
					information to associate the
					document submitted to the
					regulatory authority with the
					CTD heading.
	id		[11]		Follow the description of ICH
					IG.
		root	[11]	Valid UUID	Follow the description of ICH
					IG.
				Example:	
				root="7c5c61fd-	
				5b88-4018-8323-	
				b21f1a731880"	
	code		[01]		Follow the description of ICH
					IG.

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Element	Attribute	Cardinality	Value(s) Allowed	Description
			Example of value	
	code	[11]	Text Example: code=" ich_3.2.s.2.3"	Follow the description of ICH IG. Select the corresponding code from "ICH Context of Use" of ICH CV or "JP Context of Use" of JP CV to provide it.
	codeSystem	[11]	Valid OID <i>Example:</i> <i>codeSystem="2.16.</i> 840.1.113883.3.989. 2.2.1.1.1"	Follow the description of ICH IG. Provide OID of "ICH Context of Use" of ICH CV or OID of "JP Context of Use" of JP CV.
originalText		[01]		Follow the description of ICH IG.
	Value	[11]	Text Example: code=" ich_3.2.P.8.3-1"	Follow the description of ICH IG.
statusCode		[11]		Follow the description of ICH IG.
	code	[11]	Single-byte alphabets <i>Example:</i> code="active", code="suspended"	Follow the description of ICH IG. If the relevant Context of Use is valid, then provide "active", and if deleted, then provide "suspended".
replacementOf		[0*]		This element stores the <i>relatedContextOfUse</i> element. For details of the <i>relatedContextOfUse</i> element, refer to 7.4.5 of this document.
	typeCode	[11]	Fixed typeCode="RPLC"	This attribute is a structural attribute required to use the <i>replacementOf</i> element.
derivedFrom		[01]		This element stores the <i>documentReference</i> element. For details of the <i>documentReference</i> element, refer to 7.4.6 of this document.
referencedBy		[0*]		This element stores the <i>keyword</i> element. For details of the <i>keyword</i> element, refer to 7.4.7 of this document.
	typeCode	[11]	Fixed typeCode="REFR"	This attribute is a structural attribute required to use the <i>referencedBy</i> element.

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Element		Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description	
Submission rules for elements and attributes		 If the <i>contextOfUse.statusCode@code</i> attribute value is "active" and if the <i>priorityNumber</i> element does not contain the <i>updateMode</i> attribute, then the following is required. <i>code@code</i> <i>code@codeSystem</i> <i>derivedFrom</i> When the <i>contextOfUse.statusCode@code</i> attribute value is "suspended" or the <i>priorityNumber@updateMode</i> attribute value is provided, the Submission Unit containing any of the following information is rejected. <i>code@codeSystem</i> <i>code@code</i> <				
Business Rules	General	assigned to applied. In addition applied. The Surejected The Surejected	the Context of to the business bmission Unit, d. he code.original he statusCode@ uspended". he updateMode ontext of Use, v uspended", at th he statusCode@ ovided for the f bmission of the hen submitting ovided. hen submitting ntaining the de the time of reve e Context of Us uspended". provide the con s the replaced or the replaced or t of Use.	<u>Use, refer to 7.4.7 of</u> rules provided in ICH which falls under any <i>IText@value</i> attribute <i>code</i> attribute value is attribute is provided for whose <i>statusCode@co</i> he same time. <i>Code</i> attribute value of first time throughout the first version is "suspect the first version, the <i>r</i> <i>rivedFrom</i> element is vision, the <i>replacemen</i> se, whose <i>statusCode@</i> <i>ntextOfUse</i> element wo or deleted Context of Us	this document. I IG, the following will be of the following, will be value is 129 characters or more. s neither "active" nor for the Priority Number of the de attribute value is of the contextOfUse element he life cycle including the ended". replacementOf element is contextOfUse element not provided. tOf element is provided under @code attribute value is rith the same id@root attribute Jse. If applicants want to re- se, resubmit it as the new	
	b)	particular. If the CTD hea Section 3 of M	ding indicated	by the <i>code@code</i> attr bmission Unit will be	ribute value does not belong to rejected.	

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Element	Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
c)	There are no b particular.	usiness rules th	at should be followed	in addition to General above in

7.4.5 relatedContextOfUse

The *relatedContextOfUse* element is used when replacing the already submitted Context of Use with a new Context of Use. *relatedContextOfUse* element is submitted as a child element of the new Context of Use and specifies the Context of Use to be replaced by the *id* element.

7.4.5.1 Place of description on XML

For the place to describe the *relatedContextOfUse* element, refer to "9.2.7 Related Context of Use (Context of Use Life Cycle)", etc., in the ICH IG.

7.4.5.2 XML snippet

An XML snippet of the *relatedContextOfUse* element is shown below.

```
<replacementOf typeCode="RPLC">
<relatedContextOfUse>
<id root="d981c6a9-d57a-43cc-a71b-a8e35a34a39a"/>
</relatedContextOfUse>
</replacementOf>
```

7.4.5.3 XML elements and attributes

The *relatedContextOfUse* element and the elements under it as well as their attributes are as follows.

	Element	Attribute	Cardinality	Value(s) Allowed	Description		
re	latedContextOfUse		[1 1]	Example of value	This element stores the		
10	undeomexicjese		[11]		information on the Context of		
					Use to be replaced.		
	id		[11]		Follow the description of ICH		
					IG.		
		root	[11]	Valid UUID	Follow the description of ICH		
					IG.		
				Example:			
				root="d981c6a9-			
				d57a-43cc-a71b-			
				a8e35a34a39a"			
Submission rules for		> When the <i>contextOfUse.statusCode@code</i> attribute value is "suspended" or the					
elements and		priorityNu	mber@updateN	<i>Iode</i> attribute value is	s provided, the Submission Unit		
attributes		containing the following information will be rejected.					
		• related	ContextOfUse				

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Element		Attribute	Cardinality	Value(s) Allowed Example of value	Description
Business Rules	General	 In addition applied. The Surejected The Sureje	to the business bmission Unit, d. he Context of U different contex he Context of U the relevant Su he Context of U rovided through CTD reception to he Context of U eleted or replace e same eCTD r	rules provided in ICH which falls under any Use indicated by the <i>id</i> at group. Use indicated by the <i>id</i> ubmission Unit. Use indicated by the <i>id</i> the past submission on number. Use indicated by the <i>id</i> ed through the past sul eception number.	I IG, the following will be of the following, will be @ <i>root</i> attribute value belongs to @ <i>root</i> attribute value is provided @ <i>root</i> attribute value is not of the application with the same @ <i>root</i> attribute value has been pomission of the application with
	a) b) c)	There are no b particular. There are no b particular. There are no b particular.	usiness rules th usiness rules th usiness rules th	at should be followed at should be followed at should be followed	in addition to General above in in addition to General above in in addition to General above in

7.4.6 documentReference

The *documentReference* element designates the document. The *documentReference* element designated by Document Reference is associated with the positioning in the application dossier designated by the *code* element of *contextOfUse* element, which is the parent element.

7.4.6.1 Place of description on XML

For the place to describe the *documentReference* element, refer to "9.2.8 Document Reference", etc., in the ICH IG.

7.4.6.2 XML snippet

```
<derivedFrom>

<documentReference>

<id root="a17b06a2-a040-431d-8e5b-1f678c83af3c"/>

</documentReference>

</derivedFrom>
```

7.4.6.3 XML elements and attributes

The *documentReference* element and the elements under it as well as their attributes are as follows.

Element	Attribute	Cardinality	Value(s) Allowed	Description
			Example of value	
documentReference		[11]		This element stores the
				identifier of the Document to be
				associated with the Context of
				Use.
id		[11]		Follow the description of ICH
				IG.

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Element		Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
Submission elements an attributes	n rules for nd	 root ➢ If the content priorityNut following i docum 	[11] extOfUse.status mber element d s required. entBafarance	Valid UUID Example: root="a17b06a2- a040-431d-8e5b- 1f678c83af3c" Code@code attribute loes not contain the up	Follow the description of ICH IG. value is "active" and if the <i>pdateMode</i> attribute, then the
		 <i>accumentReference</i> If the attribute of <i>contextOfUse.statusCode@code</i> is "suspended" or the attribute of <i>priorityNumber@updateMode</i> is provided, the submission unit including the information below will be rejected. <i>documentReference</i> 			
Business Rules General ➤ In addition to the business rules provided in ICH IG, the following applied. • The Submission Unit, which falls under any of the following rejected. ◆ The Document indicated by the <i>id@root</i> attribute value in either the relevant Submission Unit or the database of authority*. ◆ When submitting the first version, the <i>contextOfUse</i> elecontaining the <i>documentReference</i> element is provided. * The regulatory authority stores the Documents submitted using eC database for the period of time specified by the administrative docummanagement rules of the Ministry of Health, Labor and Welfare (here to as the "prescribed retention period") unless the relevant applicatio a) There are no business rules that should be followed in addition to Generational context of the specified by the administrative docummanagement rules of the ministry of Health, Labor and Welfare (here to as the "prescribed retention period") unless the relevant application			H IG, the following will be of the following, will be of attribute value does not exist or the database of the regulatory contextOfUse element not ement is provided.		
			bmitted using eCTD v4.0 in the ninistrative document and Welfare (hereinafter referred elevant application is withdrawn. in addition to General above in		
	b)	There are no b particular. There are no b particular.	usiness rules th usiness rules th	at should be followed at should be followed	in addition to General above in in addition to General above in

7.4.7 Context of Use keyword

The keyword assigned to the Context of Use (hereinafter referred to as "CoU Keyword") provides the additional information for the CTD heading indicated by the Context of Use. The CoU Keyword is provided by the *keyword* element under the *contextOfUse* element, and has the following 2 major types.

- 1) The one whose keyword type and value are determined by ICH or the regulatory authority. Example: ICH Document Type, JP Analysis Type, etc.
- 2) The one whose keyword type is determined by ICH or the regulatory authority, and whose value is determined by the applicant arbitrarily.

Example: indication, substance, group title, etc.

When assigning the keyword of 2) above, define its value using the Keyword Definition in the relevant application. For details of the Keyword Definition, refer to 7.4.18 of this document.

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^{*} This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

7.4.7.1 Place of description on XML

For the place to describe the *keyword* element to be assigned to the Context of Use, refer to "9.2.9 Context of Use Keyword", etc., in the ICH IG.

7.4.7.2 XML snippet

An XML snippet of the *keyword* element to be assigned to the Context of Use is shown below. Example of 1) above

```
<referencedBy typeCode="REFR">
<keyword>
<code code="ich_document_type_65" codeSystem="2.16.840.1.113883.3.989.2.2.1.3.2"/>
</keyword>
</ referencedBy>
```

```
<keyword>
<code code="jp_cdisc_single" codeSystem="2.16.840.1.113883.3.989.5.1.3.3.1.10.1"/>
</keyword>
</ referencedBy>
```

```
Example of 2) above
<referencedBy typeCode="REFR">
   <keyword>
      <code code="MANU001" codeSystem="My list 001"/>
   </keyword>
</ referencedBy>
<referencedBy typeCode="REFR">
   <keyword>
      <code code="SUB001" codeSystem="My list 001 "/>
   </keyword>
</ referencedBy>
<referencedBy typeCode="REFR">
   <keyword>
      <code code="SDTMDATE" codeSystem="SDTMVer001 "/>
   </keyword>
</referencedBy>
```

Note: In case of 2) above, submit the definition of the keyword as Keyword Definition. For details, refer to 7.4.18 of this document.

7.4.7.3 XML elements and attributes

The *keyword* element to be assigned to the Context of Use and the elements under it as well as their attributes are as follows.

	Element	Attribute	Cardinality	Value(s) Allowed	Description
				Example of value	
ke	eyword		[11]		This element stores the
					information to specify
					additional information of the
					Context of Use.
	code		[11]		Follow the description of ICH
					IG.

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Element	Attribute	Cardinality	Value(s) Allowed Example of value	Description
	code	[11]	Text	Follow the description of ICH IG.
			Example: code="ich_route_1", code="MANU001"	
	codeSystem	[11]	Text	Follow the description of ICH IG.
			Example: codeSystem="My list 001"	
Submission rules for elements and attributes	There are no s the above-men	ubmission rules tioned "Cardin	s that should be followe ality", "Value(s) Allowe	d in addition to the contents of ed" and "Description".
Business Rules General A	 In addition applied. In case applica CoU K different case of Keyword drug provide the survey of the survey of	to the business that there are nation (multiple eyword) and de nee using the C an application ord should be as roducts can be of bmission Unit, d. keyword is pro- se" of ICH CV the Context of the Context of the Context of the Context of the Context of Use" fultiple CoU Key ne keyword req ontext of Use" fultiple CoU Key se. ne ICH Study Ca study title Key ny of the follow hich does not re JP Study Da JP Analysis JP Terminol JP Terminol ne JP Study Da se, which refers ne text.descript ferenced by the eyword that ince usiness rules th	a rules provided in ICH is multiple drug products a values exist in the releva- ocuments are submitted boU Keyword of the releva- to UKeyword of the releva- to UKeyword of the releva- signed and multiple 3.2 distinguished in the CTI which falls under any of ovided that is not permit or "JP Context of Use" Use referring to the ele- words in 2) of 11 of this uired by "ICH Context of JP CV is not assigned eywords of the same typ Group Order Keyword h yword has not been assi- ving keywords is assign effer to the electronic stu- ta Category Type ogy(Tabulation) ogy(Analysis) ta Category Keyword is s to the electronic study <i>ion</i> element is not provi- e Context of Use assigned licates data other than "d data on clinical pharmac- nat should be followed in	IG, the following will be and indications in the relevant ant application for one type of for each, clearly point out the evant type. (Example: In the lrug products, the product 2.P should be listed so that the D heading.) of the following, will be ted by either "ICH Context of of JP CV (however, in the case ctronic study data , with the s document). of Use" of ICH CV or "JP d. be are assigned to 1 Context of as been assigned, but the study gned. ed for the Context of Use, dy data. not assigned for the Context of data. ided in the Document ed with the JP Analysys Type clinical study data that are not cology" (Non-CP). n addition to General above in

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Element		Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description		
	b)	If the JP Study Data Category Keyword is not provided, the Submission Unit will be rejected.					
	c)	If the JP Stud rejected.	ly Data Categor	ry Keyword is provided,	, the Submission Unit will be		

7.4.8 sequenceNumber

The Sequence Number is provided by the *sequenceNumber* element and provides the submission sequence number indicating the submission order and time series of the Submission Units in the same application. The information provided through the Submission Unit to be submitted for application will be revised through the Submission Unit additionally submitted in the review process. The Sequence Number is a number assigned for each Submission Unit and increased for each submission.

7.4.8.1 Place of description on XML

For the place to describe the sequenceNumber element, refer to "9.2.12 Sequence Number", etc., in the ICH IG.

7.4.8.2 XML snippet

An XML snippet of the *sequenceNumber* element is shown below.

```
<componentOf1>
   <sequenceNumber value="1"/>
   <submission>
   ...[Partially omitted]...
```

</componentOf1>

7.4.8.3 XML elements and attributes

The *sequenceNumber* element and the elements under it as well as their attributes are as follows.

Element	Attribute	Cardinality	Value(s) Allowed	Description
			Example of value	
sequenceNumber		[11]		This element stores the
				information indicating the
				submission order and time
				series of the Submission Units
				in the same application.
	value	[11]	Single-byte	Follow the description of ICH
			numbers	IG.
			Example:	
			value="1"	
Submission rules for	There are no s	ubmission rules	s that should be follow	ved in addition to the contents of
elements and	the above-men	tioned "Cardin	ality", "Value(s) Allow	wed" and "Description".
attributes				_

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^{*} This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

Element		Attribute	Cardinality	Value(s) Allowed Example of value	Description	
Business Rules	General	 application at the time of subvalue obtained by adding 1 to this case, upon identifying th maximum Sequence Number value does not matter. The Submission Unit, which A value other than an int "9999999" is provided as The Sequence Number a When submitting the first rules a), b) and c) is provided at the time of revision, t At the time of revision, a provided at the time of revision, a provided 		sequence numbers alr submission of the revis 1 to the maximum value the already submitted ber, distinction of the second falls under any of t integer of single-byte as the Sequence Number and the second layer first version, a value n rovided as the Sequence n, the Sequence Number n, an already submitted	ready submitted in the same sed version, provide the numeric ue as the sequence number. In a Submission Unit having the submissionUnit.code@code he following, will be rejected. Arabic numerals "1" through ber. folder name do not match. ot conforming to the business ce Number. er is not incremented by "1". d Sequence Number value is	
a) > Th > W th re-		 The Seque: When re-is the Sequen re-issued o 	nce Number of suing or re-sub ce Number of t r re-submitted.	a) when submitting th mitting submissionuni he same value as (that	e first version shall be "1". (t.xml submitted once, provide of) the submissionunit.xml to be	
	b)	 b) > The Sequence Number of b) when submitting the first version shall b > To re-issue or re-submit b) once submitted, the Sequence Number shall always set to "1". 				
	c)	 The Sequer To re-issue always set 	nce Number of or re-submit c) to "2".	c) when submitting th) once submitted, the S	e first version shall be "2". Sequence Number shall be	

7.4.9 submission

Submission is provided by the *submission* element and provides the information on the product item contained in the relevant application. Submission is distinguished by the eCTD reception number, and 1 submission can contain information on one or more product items. The Submission Unit related to the product item provided by Submission is associated as a lower concept of the relevant Submission, but on the eCTD v4.0 XML message, the *submission* element exists as a lower element of the *submissionUnit* element. The *submissionUnit* element provides the information on the Submission associated with itself as a *submission* element.

7.4.9.1 Place of description on XML

On the eCTD v4.0 XML message, the submission element is placed as follows.

• controlActProcess >> subject >> submissionUnit >> componentOf1 >> submission

7.4.9.2 XML snippet

An XML snippet of the *submission* element is shown below.

```
<componentOf1>
<sequenceNumber value="1"/>
<submission>
<id>
<item root="c4550245-fa32-444e-8433-702fbba7a8d4" extension="20160505001"/>
</id>
</id>
```

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...[Partially omitted]... </submission> </componentOf1>

7.4.9.3 XML elements and attributes

The submission element and the elements under it as well as their attributes are as follows.

Element	Attribute	Cardinality	Value(s) Allowed	Description
			Example of value	
submission		[11]		This element stores the product item information provided in association with the relevant Submission Unit.
id		[11]		This element stores the identifier of the relevant eCTD application.
item		[11]		This element stores the identifier of the relevant eCTD application.
	root	[11]	Valid UUID <i>Example:</i> root="c4550245- fa32-444e-8433- 702fbba7a8d4"	UUID of this submission A number is issued by the applicant according to the algorithm based on the standard specifications provided in ICH IG.
	extension	[11]	Single-byte alphanumeric characters <i>Example:</i> <i>extension="201605</i> 05001"	eCTD reception number
code		[11]		This element stores the positioning of the relevant eCTD application (submission of the original, submission of references, etc.).
	code	[11]	Text Example: code="jp_original"	The code value indicating the positioning of the relevant eCTD application is held as a value. Select the code value from the "JP Submission" code list of JP CV.
	codeSystem	[11]	Valid OID <i>Example:</i> <i>codeSystem="2.16.</i> 840.1.113883.3.989. 5.1.3.3.1.5.1"	OID of the "JP Submission" code list

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Element		Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description	
subject2			[0*]		This element stores the <i>review</i> element. For details of the <i>review</i> element, refer to 7.4.10 of this document.	
component	Of		[11]		This element stores the <i>application</i> element. For details of the <i>application</i> element, refer to 7.4.15 of this document.	
Submission ru elements and attributes	Submission rules for elements and attributes			existing Review, provide a tion. For details of Review, refer		
Business General Rules General Code@code id.item@extension id.item@code code@code code@code code@codeSystem* * The version number included at the end of the OID indiccode@codeSystem attribute does not have to match. > The id.item@root attribute value shall be a UUID that can uniquel				te throughout the application <i>ubmission</i> in principle. If it is gulatory authority in advance. d of the OID indicated by the to match. JID that can uniquely identify this		
		 The Submission Unit, which falls under the following, will be rejected. The <i>id.item@extension</i> attribute value is different from the eCTD reception number of the relevant application. 				
	a)	 If the <i>subject2</i> element is not provided at the time of initial submission, the Submission Unit will be rejected. 				
	b)	 b) must not included in 	t contain the <i>su</i> b), that Submi	<i>bject2</i> element. Also, ssion Unit will be reje	if the <i>subject2</i> element is ected.	
	c)	 If the subje 	ct2 element is 1	not provided, the Subi	nission Unit will be rejected.	

7.4.10 review

The *review* element provides the product item information. The one *subject2* element is provided for each product, and the one *review* element is provided for each *subject2* element.

7.4.10.1 Place of description on XML

The *review* element is described in the following place on the eCTD v4.0 XML message.

controlActProcess >> subject >> submissionUnit >> componentOf1 >> submission >> subject2 >> review

7.4.10.2 XML snippet

An XML snippet of the *review* element is shown below.

<subject2>

<review>

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```
<id root="c2a664fc-4b41-4425-8631-46b7bf1f58a6"/>
<statusCode code="active"/>
<subject1>
    ...[Partially omitted]...
</subject1>
<holder>
    ...[Partially omitted]...
</holder>
<subject2>
    ...[Partially omitted]...
</subject2>
</review>
</subject2>
```

7.4.10.3 XML elements and attributes

The *review* element and the elements under it as well as their attributes are as follows.

Element		Attribute	Cardinality	Value(s) Allowed	Description
				Example of value	
re	view		[11]		This element stores the product item information.
	id		[11]		This element stores the identifier of the relevant <i>review</i> element.
		root	[11]	Valid UUID Example: root="c2a664fc- 4b41-4425-8631- 46b7bf1f58a6"	UUID of this Review. A number is issued by the applicant according to the algorithm described in ICH IG.
	statusCode		[11]		This element stores the information indicating the state of the application for the relevant product item.
		code	[11]	Single-byte alphabets <i>Example:</i> code="active", code="suspended"	The code indicating the state of the application When withdrawing only part of eCTD containing more than one application, provide "suspended" for the relevant Review to be withdrawn in the revision immediately after that. In any other case, provide "active".
	subject1		[01]		This element stores the <i>manufacturedProduct</i> element. For details of the <i>manufacturedProduct</i> element, refer to 7.4.11 of this document.

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	holder		[01]		This element stores the		
			[0.11]		<i>applicant</i> element.		
					For details of the <i>annlicant</i>		
					element, refer to 7.4.13 of this		
					document.		
	subiect2		[0*]		This element stores the		
	~		[0.1.]		productCategory element.		
					For details of the		
					<i>productCategory</i> element, refer		
					to 7.4.14 of this document.		
Su	ibmission rules for	> When subr	nitting the first	version, all of the abo	ve-mentioned elements and		
el	ements and	attributes a	re required.	, e roroni, u n or une u oo			
at	tributes	\rightarrow At the time	of revision. if	the <i>statusCode@code</i>	attribute value is "active", all of		
		the above-	mentioned elem	ents and attributes are	e required.		
		\rightarrow At the time	of revision. if	the <i>stautsCode@code</i>	attribute value is "suspended".		
		the Submis	sion Unit conta	ining any of the follo	wing will be rejected.		
		subject	t1	and any of the folio	wing win be rejected.		
		holder	-				
		subject	t2				
		The subject	<i>ect2</i> element mi	ist provide for each ar	oplication category.		
B	usiness General	 The Submi 	ssion Unit whi	ch falls under any of t	the following will be rejected		
R	nles	• The statusCode@code attribute value of the review element provided for the					
		first time throughout the life cycle including submission of the first version					
		is not "	active"	ne me cycle melading	submission of the first version		
		• The re	view statusCod	e@code attribute value	e is neither "active" nor		
		"suspended".					
		• As a result of providing the status Code@code attribute value of the review					
		element with "suspended" the <i>review</i> element with the <i>statusCode@code</i>					
		attribute value of "active" no longer exists in the application					
		The <i>id@root</i> attribute value shall be a UUID that can uniquely identify this					
		Review					
		NOVICW. Do not include the <i>review</i> element in which the approval application has not					
		been withdrawn at the time of revision or the content has not been changed					
		\geq Do not pro	vide the <i>review</i>	element with the sam	e <i>id@root</i> attribute value as a		
		review that	has become in	valid due to withdraw	al of the application. If you want		
		to reactivat	the Review the	at was once invalidat	ed by withdrawing an		
		application	resubmit it as	the new Review	ed by whildrawing an		
			, resublint it us				
a)		There are no b	usiness rules th	at should be followed	in addition to General above in		
		particular.	astricts rules th				
	h)	\rightarrow b) must not	t contain the re	view element Also if	the <i>review</i> element is included in		
		b), the Sub	mission Unit w	ill be rejected.	and a content to mended in		
		\rightarrow There are r	o business rule	s that should be follow	wed in addition to General above		
	()	in particula	ir	5 mar bilouid oc 10110v	to Seneral above		

7.4.11 manufacturedProduct

The *manufacturedProduct* element provides the product information. 1 *manufacturedProduct* element is provided for each *review* element. The *manufacturedProduct* element has a *manufacturedProduct* element of the same name under it. In this document, the former is called the *manufacturedProduct* element, and the latter is called the *manufacturedProduct.manufacturedProduct* element.

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7.4.11.1 Place of description on XML

The *manufacturedProduct* element is described in the following place on the eCTD v4.0 XML message.

controlActProcess >> subject >> submissionUnit >> componentOf1 >> submission >> subject2 >> review >> subject1 >> manufacturedProduct

7.4.11.2 XML snippet

An XML snippet of the *manufacturedProduct* element is shown below.

```
<subject1>

<manufacturedProduct>

<manufacturedProduct>

<manufacturedProduct>

<manufacturedProduct>

<manufacturedProduct>

<manufacturedProduct>

</manufacturedProduct>

</manufacturedProduct>

</manufacturedProduct>

</manufacturedProduct>

</manufacturedProduct>

</manufacturedProduct>
```

7.4.11.3 XML elements and attributes

The *manufacturedProduct* element and the elements under it as well as their attributes are as follows.

		E	lement	Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
m	anu	fac	turedProduct		[11]		This element stores the product information.
	ma uci	ınu t	facturedProd		[11]		This element stores the product information.
		na	me		[11]		This element stores the brand name.
			part		[11]		This element stores the brand name.
				value	[11]	Text	The brand name of the drug product.
						Example:	
						value="Seiyakukyol	
						tablets 10mg"	
		ing	gredient		[1*]		This element stores the
							ingredientSubstance element.
							For details of the
							ingredientSubstance element,
							refer to 7.4.12 of this
							document.
				classCode	[11]	Fixed	This attribute is a structural
							attribute required to use the
						classCode="INGR"	ingredient element.
Submission rules for		ion rules for	An ingredi	<i>ent</i> element mu	st be provided for each	active ingredient contained in	
el	eme	ents	and	the relevant	t product.		
at	trib	oute	S				

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Element		Attribute	Cardinality	Value(s) Allowed Example of value	Description			
Business Rules	General	 The <i>part@value</i> attribute value must match the brand name described in the application form. The Submission Unit, which falls under the following, will be rejected. The <i>part@value</i> attribute value is 241 characters or more. 						
	a)	There are no b particular.	usiness rules th	at should be followed ir	addition to General above in			
 b) b) must not contain the <i>manufacturedProduct</i> element. Also, if <i>manufacturedProduct</i> element is included in b), the Submission rejected. 					ment. Also, if the he Submission Unit will be			
	c)	c) There are no business rules that should be followed in addition to General particular.						

7.4.12 ingredientSubstance

The *ingredientSubstance* element provides the name of the active ingredient. 1 *ingredientSubstance* element is provided for each *ingredient* element.

7.4.12.1 Place of description on XML

The *ingredientSubstance* element is described in the following place on the eCTD v4.0 XML message.

controlActProcess >> subject >> submissionUnit >> componentOf1 >> submission >> subject2 >> review >> subject1 >> manufacturedProduct >>manufacturedProduct >>ingredient
 >>ingredientSubstance

7.4.12.2 XML snippet

An XML snippet of the *ingredientSubstance* element is shown below.

```
<ingredient classCode="INGR">
<ingredientSubstance>
<name>
<part value="E I hydrochloride" code="jp_jan" codeSystem= "
2.16.840.1.113883.3.989.5.1.3.3.1.7.1"/>
</name>
</ingredientSubstance>
</ingredientSubstance>
```

7.4.12.3 XML elements and attributes

The *ingredientSubstance* element and the elements under it as well as their attributes are as follows.

Element		Attribute	Cardinality	Value(s) Allowed	Description
			[1 1]	Example of value	This shares at stars the many of
ın	greatentSubstance		[11]		This element stores the name of
					the active ingredient.
	name		[11]		This element stores the name of
					the active ingredient.
	part		[11]		This element stores the name of
					the active ingredient.
		value	[11]	Text	The name of the active
					ingredient.
				<i>Example: value="E</i>	
				I hydrochloride"	

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1 1 1							
		code	[11]	Text	The code indicating the type of		
					the name of the active		
				Example:	ingredient To be selected from		
				code="jp_jan"	the "JP Substance Name Type"		
					code list of JP CV		
		codeSystem	[11]	Valid OID	OID of the "JP Substance Name		
					Type" code list		
				Example:			
				code="2.16.840.1.1			
				13883.3.989.5.1.3.3			
				.1.7.1"			
Submission	n rules for	There are no submission rules that should be followed in addition to the contents of					
elements a	nd	the above-mentioned "Cardinality", "Value(s) Allowed" and "Description".					
attributes							
Business	General	In principle	e, the <i>part@val</i>	ue attribute value mus	t match the non-proprietary		
Rules		name stated	l in the application	tion.			
		➤ The Submit	ssion Unit, whi	ch falls under the follo	owing, will be rejected.		
		• The <i>pa</i>	<i>rt@value</i> attrib	oute valueis 241 charac	cters of more.		
	a)	There are no b	usiness rules th	at should be followed	in addition to General above in		
		particular.					
b) > b) must not			contain the ing	gredientSubstance ele	ement. Also, if the		
		ingredientS	Substance elem	nent is included in b),	the Submission Unit will be		
		rejected.					
	<u>c</u>)	There are no b	usiness rules th	at should be followed	in addition to General above in		
		particular.					

7.4.13 applicant

The *applicant* element provides the applicant information. 1 *applicant* element is provided for each *review* element.

7.4.13.1 Place of description on XML

The *applicant* element is described in the following place on the eCTD v4.0 XML message.

controlActProcess >> subject >> submissionUnit >> componentOf1 >> submission >> subject2 >> review >> holder >> applicant

7.4.13.2 XML snippet

An XML snippet of the *applicant* element is shown below.

```
<holder>
<applicant>
<sponsorOrganization>
<a hoise constraints and the second state of the second state o
```

</holder>

7.4.13.3 XML elements and attributes

The *applicant* element and the elements under it as well as their attributes are as follows.

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^{*} This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.
		El	ement	Attribute	Cardinality	Value(s) Allowed Example of value	Description		
ap	plio	cant			[11]		This element stores the		
							applicant name.		
	spe	onso	rOrganizati		[11]		This element stores the		
	on						applicant name.		
		nan	ne		[11]		This element stores the		
		F					applicant name.		
		1	part		[11]		This element stores the		
							applicant name.		
				value	[11]	Text	The name of the applicant of		
							the relevant application.		
						Example:			
						value="PMDA			
						Pharmaceutical			
						Co., Ltd."			
Sı	ıbn	nissi	on rules for	There are no submission rules that should be followed in addition to the contents of					
el	eme	ents	and	the above-mentioned "Cardinality", "Value(s) Allowed" and "Description".					
at	trik	oute	5						
B	usir	iess	General	> The <i>part@value</i> attribute value must match the applicant name stated in the					
R	ules	5		application					
			> The Submission Unit, which falls under the following, will be rejected.						
			• The <i>part@value</i> attribute value is 241 characters or more.						
a)		a)	There are no business rules that should be followed in addition to General above in						
				particular.					
b) > b) must not contain the <i>applicant</i> element. Also, if the <i>applicant</i> elem			, if the <i>applicant</i> element is						
				included in	b), the Submis	sion Unit will be reject	cted.		
				There are no b	usiness rules th	at should be followed	in addition to General above in		
				particular.					

7.4.14 productCategory

The *productCategory* element provides the application category. 1 or more *subject2* (element)s are provided for each *review* element, and the *productCategory* element is provided for each *subject2* element. As 1 *productCategory* element always has 1 application category, in case of an application with more than one application category, the same number of *subject2* elements as the number of application categories is provided.

7.4.14.1 Place of description on XML

The *productCategory* element is described in the following place on the eCTD v4.0 XML message.

controlActProcess >> subject >> submissionUnit >> componentOf1 >> submission >> subject2
 > review >> subject2 >> productCategory

7.4.14.2 XML snippet

An XML snippet of the *productCategory* element is shown below.

```
<subject2>
<productCategory>
<code code="jp_1_1" codeSystem="2.16.840.1.113883.3.989.5.1.3.3.1.6.1"/>
</productCategory>
</subject2>
```

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^{*} This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

7.4.14.3 XML elements and attributes

The	productCategory	element an	d the elements	under it as well	l as their attrib	outes are as follows
-----	-----------------	------------	----------------	------------------	-------------------	----------------------

	Elen	nent	Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description		
pr	oductCat	egory		[11]		This element stores the		
						application category.		
	code			[11]		This element stores the		
						application category.		
			code	[11]	Text	The code indicating the		
						application category. Select the		
					Example:	application category described		
					code="jp_1_1"	in the marketing application		
						form from the "JP Product		
					Category" code list of JP CV.			
		codeSystem	[11]	Valid OID	OID of the "JP Product			
						Category" code list.		
					Example:			
					codeSystem="2.16.			
					840.1.113883.3.989.			
					5.1.3.3.1.6.1"			
Sı	ıbmissior	rules for	There are no submission rules that should be followed in addition to the contents of					
el	ements ai	nd	the above-mentioned "Cardinality", "Value(s) Allowed" and "Description".					
at	tributes							
B	usiness	General	> The application category indicated by the <i>code</i> @ <i>code</i> attribute value must much					
Rules			the application category described in the application.					
a)		There are no bu	siness rules th	at should be followed	in addition to General above in			
particular.			particular.					
		b)	b) must not contain the <i>productCategory</i> element. Also, if the <i>productCategory</i>					
			element is in	ncluded in b),	the Submission Unit w	vill be rejected.		
		c)	There are no bu	siness rules th	at should be followed	in addition to General above in		
			particular.					

7.4.15 application

The Application is provided by the *application* element and provides the definition of the information provided by the relevant application and the information related to the entity of the document. The one *submission* element always contains the one *application* element.

7.4.15.1 Place of description on XML

The *application* element is described in the following place on the eCTD v4.0 XML message.

controlActProcess >> subject >> submissionUnit >> componentOf1 >> submission >> componentOf >> application

7.4.15.2 XML snippet

An XML snippet of the *application* element is shown below.

```
<componentOf>
<application>
<id>
<item root="492462f7-81bf-46e0-9b59-b677a86c88a4" extension="sender-specified value"/>
```

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^{*} This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

```
</id>
</id>

</id>

<code code="jp_nda" codeSystem="2.16.840.1.113883.3.989.5.1.3.3.1.8.1"/>

<reference>

...[Partially omitted]...

</reference>

<component>

...[Partially omitted]...

</component>

<referencedBy>

...[Partially omitted]...

</referencedBy>

</application>
```

7.4.15.3 XML elements and attributes

The *application* element and the elements under it as well as their attributes are as follows.

Element		Element	Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
application		cation		[11]		This element stores the information on the Application provided in association with the relevant SubmissionUnit.
	Id			[11]		This element stores the identifier of the relevant eCTD application.
		item		[11]		This element stores the identifier of the relevant eCTD application.
			root	[11]	Valid UUID Example: root="492462f7- 81bf-46e0-9b59- b677a86c88a4"	UUID of this Application A number is issued by the applicant according to the algorithm described in ICH IG.
			extension	[01]	Text Example: extension="sender- specified value"	Any value assigned for the purpose of the applicant managing the application
	co	de		[11]		This element stores the type of the relevant eCTD application.
			code	[11]	Text Example: code="jp_ nda"	The code indicating the type of the relevant eCTD application Select the code value from the "JP Application" code list of JP CV.

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Element	Attribute	Cardinality	Value(s) Allowed Example of value	Description
	codeSystem	[11]	Valid OID <i>Example:</i> <i>codeSystem="2.16.84</i> 0.1.113883.3.989.5.1. 3.3.1.8.1"	OID of the "JP Application" code list
reference		[0*]		This element stores the <i>applicationReference</i> element. For details of the <i>applicationReference</i> element, refer to 7.4.16 of this document.
component		[0*]		This element stores the <i>document</i> element. For details of the <i>document</i> element, refer to 7.4.17 of this document.
referencedBy		[0*]		This element stores the <i>keywordDefinition</i> element. For details of the <i>keywordDefinition</i> element, refer to 7.4.18 of this document.
Submission rules for elements and attributes	 If there are referred to related app Unit. For d If there are Unit, provi Document, If new Key provide a <i>r</i> Keyword I 	f there are other applications related to the relevant application (hereinafter eferred to as the "related applications"), provide a <i>reference</i> element for each elated application. Also, provide all the related applications for each Submission Jnit. For details of the related application, refer to 7.4.16 of this document. f there are new Documents to be provided through the relevant Submission Jnit, provide a <i>component</i> element for each Document. For details of the Document, refer to 7.4.17 of this document. f new Keyword Definitions to be used for the relevant application are provided, provide a <i>referencedBy</i> element for each Keyword Definition. For details of the Keyword Definition, refer to 7.4.18 of this document.		

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^{*} This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

Element		Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description	
Business Rules	 Societal > Trovide the same value for the following attribute throughout the appregardless of change of the information under <i>application</i> in princip necessary to change these values, consult the regulatory authority in <i>id.item@root</i> <i>code@code</i> <i>code@codeSystem*</i> * The version number included at the end of the OID indicated by <i>code@codeSystem</i> attribute does not have to match. > The <i>id@root</i> attribute value shall be a UUID that can uniquely ider Application. > The <i>id.item@extension</i> attribute is intended to be used by the applic attribute may be included in the eCTD v4.0 XML message submitted regulatory authority, but the regulatory authority does not use this at In addition, the type of the value of this attribute is not limited to the types specified in 2.5 [The character types that can be used as a text document. > The <i>id.item@extension</i> attribute following, will be reject • The <i>id.item@extension</i> attribute value is 1001 characters or more interval. 				throughout the application <i>lication</i> in principle. If it is latory authority in advance. OID indicated by the natch. t can uniquely identify this used by the applicant. This message submitted to the loes not use this attribute value. s not limited to the character n be used as a text type] in this ving, will be rejected.	
	a)	 a) There are no business rules that should be followed in addition above in particular. b) There are no business rules that should be followed in addition to C in particular. 				
	b)					
	c)	There are no b particular.	usiness rules th	at should be followed in	n addition to General above in	

7.4.16 applicationReference

The *applicationReference* element provides the information on the related application. For example, it can be used when referring to the application for the already approved product item at the time of partial change approval application. In this case, the related application must have been made with eCTD v3.2.2 or v4.0 as the original. You may refer to the eCTD reception number of the application using eCTD v3.2.2 from the *applicationReference* element using eCTD v4.0. If there is no related eCTD application, it is not necessary to provide the *applicationReference* element, but if provided, 1 *application* element can have 1 or more *applicationReference* elements. If there are multiple related eCTD applications, describe the *applicationReference* element for each related eCTD application.

7.4.16.1 Place of description on XML

The *applicationReference* element is described in the following place on the eCTD v4.0 XML message.

controlActProcess >> subject >> submissionUnit >> componentOf1 >> submission >> componentOf >> application >> reference >> applicationReference

7.4.16.2 XML snippet

An XML snippet of the *applicationReference* element is shown below. <reference> <applicationReference> <id root="20160103001"/> <reasonCode> <item code="jp_pca" codeSystem="2.16.840.1.113883.3.989.5.1.3.3.1.9.1"/> </reasonCode>

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</applicationReference>

7.4.16.3 XML elements and attributes

The *applicationReference* element and the elements under it as well as their attributes are as follows.

Element		Element	Attribute	Cardinality	Value(s) Allowed	Description
					Example of value	
ap	plie	cationReference		[11]		This element stores the related
						application information.
id				[11]		This element stores the
						identifier of the related
						application.
			root	[11]	Single-byte	eCTD reception number of the
					alphanumeric	related application
					characters	
					Example:	
					root="20160103001	
					"	
reasonCode		isonCode		[11]		This element stores the type of
						relationship.
		item		[1*]		This element stores the type of
						relationship.
			code	[11]	Text	The code indicating the type of
						relationship with the related
					Example:	application indicated by
					code="jp_pca"	applicationReference.id@root.
						Select the code value from the
						"JP Application Reference
						Reason" code list of JP CV.
			codeSystem	[11]	Valid OID	OID of the "JP Application
						Reference Reason" code list
					Example:	
					codeSystem="2.16.	
					840.1.113883.3.989.	
					5.1.3.3.1.9.1"	
Sı	ıbn	nission rules for	\succ If 1 related	application has	s more than one type,	provide a <i>reasonCode.item</i>
el	eme	ents and	element for	each related ty	pe under 1 application	nReference element.
at	trit	outes				

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^{*} This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

Element		Attribute	Cardinality	Value(s) Allowed Example of value	Description	
Business Rules	General	 Provide all Submission first version subsequent submitting The Submission The Submission The Submission The Submission The application Multiplication Multiplication Multiplication The example 	the related app unit. For exam was submitted submission, it the first version ssion Unit, whi TD reception re ed in the releval plication having e does not exis plication having e was withdraw le <i>applicationR</i> re contained in le <i>reasonCode</i> . <i>Code.item@cod</i> <i>applicationRe</i> er, even if the v d by the <i>reason</i> formation mate <i>Code.item@cod</i> TD reception re <i>proot</i> attribute v ady approved a approval appli	lications as of the time nple, if 2 related appli is interpreted as havin a. ch falls under any of t number indicated by the nt Submission Unit. g the eCTD reception t in the database of the g the eCTD reception t in the database of the g the eCTD reception vn in the past. <i>Reference</i> elements havin 1 Submission Unit an <i>item</i> elements with the <i>de</i> and <i>reasonCode.item</i> <i>eference</i> element. <i>rersion</i> number include <i>nCode.item@codeSyste</i> ches, the combination <i>leSystem</i> will regarded number of an unapprovidable application to be submication as the related ty	e of submission of each cations were submitted when the cations were not described in the g lost the relevance after he following, will be rejected. he <i>id@root</i> attribute value is number indicated by the <i>id@root</i> e regulatory authority. number indicated by the <i>id@root</i> e regulatory authority. number indicated by the <i>id@root</i> wing the same <i>id@root</i> attribute id provided. e same combination of <i>cm@codeSystem</i> * are provided ed at the end of the OID <i>tem</i> attribute does not match, if of <i>reasonCode.item@code</i> and d as identical. ved application is provided for <i>nReference</i> element indicating itted at the time of partial /pe.	
	a)	 a) There are no business rules that should be followed in addition to General ab particular. b) There are no business rules that should be followed in addition to General should be				
	c)	particular. There are no b particular.	usiness rules th	at should be followed	in addition to General above in	

7.4.17 document

The Document provides the information on the file to be submitted. The Document is provided by the *document* element. The applicant can provide 0 to multiple *document* elements through 1 Submission Unit. 1 *component* element is provided for each file to be submitted, and 1 *document* element is provided for each *component* element.

7.4.17.1 Place of description on XML

For the place to describe the *document* element, refer to "9.2.15 Document", etc., in the ICH IG.

7.4.17.2 XML snippet

An XML snippet of the *document* element is shown below.

```
<component>
```

<document>

<id root="8505a8b2-7035-47cf-81ec-e8176e1d87be"/><title value="General information"/><text integrityCheckAlgorithm="SHA256">

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```
<reference value="m3/32-prod/manuf-process-and-controls.pdf"/>
<integrityCheck>c0d5623550c997a70b62717d95fca1cada201754d1ed9fbbbbfa97bfd64c
8ea4</integrityCheck>
</text>
</document>
</component>
```

7.4.17.3 XML elements and attributes

The *document* element and the elements under it as well as their attributes are as follows.

Element	Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
document		[11]		This element stores the information on the file to be submitted to the regulatory authority.
id		[11]		Follow the description of ICH IG.
	root	[11]	Valid UUID	Follow the description of ICH IG.
			Example: root="8505a8b2-7035- 47cf-81ec-e8176e1d87be"	
title		[11]		Follow the description of ICH IG.
	value	[11]	Text Example: value="General information"	Follow the description of ICH IG.
	updateMode	[01]	Fixed updateMode="R"	When updating the title of the Document, specify "R".
text		[01]		Follow the description of ICH IG.
	integrityChe ckAlgorithm	[11]	Fixed integrityCheckAlgorithm=" SHA256"	Follow the description of ICH IG.

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^{*} This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

Element	Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
	charset	[01]	Text Example: charset="jp_utf8"	This indicates the character code of the Japanese data included in the electronic study data in the Document that references the electronic study data. If the electronic study data to be referenced is in SAS XPORT format (.xpt), select the appropriate code from JP CV "JP Japanese Character Code".
reference		[11]		Follow the description of ICH IG.
	value	[11]	Text Example: value="/1/m3/32- bodydata/32s-	Specify the location of the file in the relative path format from submissionunit.xml which includes this
integrityCheck		[11]	Single-byte alphanumeric characters <i>Example:</i> <integritycheck>c0d56235 50c997a70b62717d95fca1c ada201754d1ed9fbbbbfa97 bfd64c 8ea4<integritycheck></integritycheck></integritycheck>	Follow the description of ICH IG.
thumbnail		[01]	Text Example: value="26145c7a-3dc7- 404d-91c1-6e0e5c71f8f6"	Follow the description of ICH IG. Follow the description of ICH IG.
description	value	[01]	Text <i>Example: value="</i> Dataset for PK analysis (ADaM format)"	Follow the description of ICH IG. This is an explanation of the contents of the electronic study data to be referenced in the case of the Document that references the electronic study data in the clinical pharmacology area.

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 Submission rules for elements and attributes The <i>text</i> element is required except when updating the Document title The <i>title@updateMode</i> attribute is required when updating the <i>title@u</i> attribute value of a submitted Document. The Submission Units containing text elements will be rejected when <i>title@updateMode</i> attribute value is provided. The following attributes are described in ICH IG, but even though a S Unit is submitted with these included, they are not considered to have provided for the regulatory authority. <i>text@language</i> <i>text@mediaTyne</i>
• text@updateMode
Business General > In addition to the business rules provided in ICH IG, the following will applied. • The Submission Unit, which falls under any of the following, will rejected. > The titl@@uplue attribute value has 1001 characters or more. • The titl@@uplue@uplue attribute value has 1001 characters or more. > The titl@@uplue@uplue attribute value has 1001 characters or or the title@upluteMode attribute value has 1001 characters or the title@upluteMode attribute value is provided on the doc element that is provided for the first time through its lifecycl including initial submission. • The title@uplateMode attribute value is provided, but the titl attribute value is not updated. > Although the title@uplateMode attribute value is not provided id@root attribute value is the same as the id@root attribute value is most provided. • A document element not referred to from the Context of Use same Submission Unit is provided. > The file path that includes a first layer folder name that does the eCTD reception number of the relevant eCTD is specifier reference@value attribute value. • The text@charset attribute value. > The text@charset attribute value. • The text@charset attribute is not provided under the docume that references SAS XPORT format (xpt) files. • The text.description element is not provided under the docume element reference from the Context of Use with JP Analysis Keyword indicating other than "non clinical pharmacology of CP). • The text.description element. > The text.description element.text.thumbnail@ • The tequalary authority does not use the docume
a) There are no business rules that should be followed in addition to Genera

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Element	Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description			
b	 The Submit The plate to store 	 The Submission Unit, which falls under the following, will be rejected. The place indicated by the <i>reference@value</i> attribute value is not the to store the electronic study data. 					
c	 The Submi The pl store the 	ssion Unit, wh ace indicated b ne electronic st	ich falls under the following, by the <i>reference@value</i> attribuudy data.	will be rejected. ate value is the place to			

7.4.18 keywordDefinition

Keyword Definition provides the definition of the keyword. The *contextOfUse* elements can have a keyword under them, but the *keyword* element only specifies the code, and it does not indicate the contents indicated by that code. Each code is defined in (one of) the following 2 methods.

- (1) The code and the contents are defined by ICH or the regulatory authority.
- (2) The applicant defines the code and the contents.

When assigning the Keyword falling under (1) above to the Context of Use, the corresponding Keyword Definition must not be provided. When assigning the Keyword falling under (2) above to the Context of Use, the corresponding Keyword Definition needs to be provided for the regulatory authority.

7.4.18.1 Place of description on XML

For the place to describe the *keywordDefinition* element, refer to "9.2.18 Keyword Definition", etc., in the ICH IG.

7.4.18.2 XML snippet

An XML snippet of the keywordDefinition element is shown below.

```
<referencedBy>
</keywordDefinition>
</code code="ich_keyword_type_3" codeSystem="2.16.840.1.113883.3.989.2.2.1.5.2"/>
</statusCode code="active"/>
</statusCode code="active"/>
</value>
</item code="MANU001" codeSystem="My list 001">
</displayName value="Big Manufacturer"/>
</item>
</value>
</keywordDefinition>
</referencedBy>
```

7.4.18.3 XML elements and attributes

The *keywordDefinition* element and the elements under it as well as their attributes are as follows.

Element		Attribute	Cardinality	Value(s) Allowed	Description
				Example of value	
keywordDefinition			[11]		This element stores the
					definition of the keyword.
	code		[11]		Follow the description of ICH
					IG.

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^{*} This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

Element	Attribute	Cardinality	Value(s) Allowed	Description	
			Example of value		
	code	[11]	Text	Follow the description of ICH	
				IG. Select the corresponding	
			Example:	code from "ICH Keyword	
			code="ich_keyword	Definition Type" of ICH CV or	
			_type_1"	"JP Keyword Definition Type"	
				of JP CV.	
	codeSystem	[11]	Valid OID	Follow the description of ICH	
	-			IG. Provide the OID of "ICH	
			Example:	Keyword Definition Type" of	
			codeSystem = "2.16.	ICH CV or OID of "JP	
			840.1.113883.3.989.	Keyword Definition Type" of	
			2.2.1.5.2"	JP CV.	
statusCode		[11]		Follow the description of ICH	
				IG.	
	code	[11]	Fixed	Follow the description of ICH	
		[]		IG	
			code="active"		
value		[11]		Follow the description of ICH	
				IG.	
item		[11]		Follow the description of ICH	
				IG.	
	code	[11]	Text	Follow the description of ICH	
				IG.	
			Example:	Any code value specified by the	
			code="MANU001"	applicant	
	codeSystem	[11]	Text	Follow the description of ICH	
		[]		IG.	
			Example:	The identifier of the code list.	
			codeSystem="My	which is specified by the	
			list 001"	applicant arbitrarily	
displayName		[1 1]	1001 001	Follow the description of ICH	
aispiayivanie		[11]		IG	
	value	[1 1]	Text	Follow the description of ICH	
	, and	[1.1.1]	Tent	IG	
			Frample	The display name of the	
			value-"Rig	keyword which is specified by	
			Manufacturer"	the applicant arbitrarily	
	undateMode	[0, 1]	Fixed	Follow the description of ICP	
	apunicinione	[0.1]	TIACU	IG When undating the display	
			undateMode-"P"	name of the Keyword specify	
			npuulembae – K	"R"	
Submission rules for	When undating the displayName@value attribute value of the Keyword				
elements and	Definition already submitted the following is required				
attributes	displayName@updateMode				
elements and	Definition already submitted, the following is required. • displayName@updateMode				

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Element		Attribute	Cardinality	Value(s) Allowed Example of value	Description
Business Rules	General	• In addi applied • The Su rejecte \diamond T \diamond T \diamond T \diamond T \diamond T ka th \diamond A is \diamond T at su	ition to the busi ition to the busi ibmission Unit, d. he value.item@ he value.item@ he displayName eywordDefinited troughout the lift t the time of rev provided, but the he combination tribute values is ibmitted in the provided	ness rules provided in which falls under any <i>code</i> attribute value h <i>codeSystem</i> attribute <i>e@value</i> attribute value <i>e@updateMode</i> attribute on element that is prov fe cycle including the vision, the <i>displayName</i> <i>displayName@value</i> of the <i>value.item@co</i> s the same as (that of) past in the same applice	ICH IG, the following will be of the following, will be as 129 characters or more. value has 257 characters or he has 1001 characters or more. he walue is provided under the vided for the first time first version submission. he@updateMode attribute value he attribute value is not updated. de and value.item@codeSsytem the Keyword Definition cation, but the heap of provided
	a)	There are no b	pusiness rules th	at should be followed	in addition to General above in
	b)	 The Keywork provided in The Subministry will be reif 	ord Definition, 1 b). Ission Unit with ected.	which defines the Key the <i>displayName@up</i>	word to be used in b), shall be <i>odateMode</i> attribute contained
	c)	 The Keyward Submitted in Sector of the Submitted in Submitted in Sector of the Sector of the	ord Definition t in b) in advance Keyword to be supporting b) o ission Unit with ected.	o define the Keyword e. used in b) is also to be nly. the <i>displayName@up</i>	to be used in c) may be used in c), provide the Keyword <i>odateMode</i> attribute contained

7.4.19 categoryEvent

The *categoryEvent* element indicates the timing of submitting the relevant Submission Unit to the regulatory authority and the type for first version submission. The types for first version submission refer to a), b) and c) indicated in 3.3.1 of this document. 1 Submission Unit has 1 *categoryEvent* element.

7.4.19.1 Place of description on XML

The *categoryEvent* element is described in the following place on the eCTD v4.0 XML message.

• controlActProcess >> subject >> submissionUnit >> componentOf2 >> categoryEvent

7.4.19.2 XML snippet

An XML snippet of the *categoryEvent* element is shown below.

<componentOf2> <categoryEvent> <code code="jp_initial" codeSystem="2.16.840.1.113883.3.989.5.1.3.3.1.2.1"/> <component> <categoryEvent> <code code="jp_initial_a" codeSystem="2.16.840.1.113883.3.989.5.1.3.3.1.3.1"/> </categoryEvent>

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</component> </categoryEvent> </componentOf2>

7.4.19.3 XML elements and attributes

The *categoryEvent* element and the elements under it as well as their attributes are as follows.

Element	Attribute	Cardinality	Value(s) Allowed	Description
			Example of value	
categoryEvent		[11]		This element stores the timing
				of submitting the relevant
				Submission Unit and the type
landa		[1 1]		This element stores the timing
coae		[11]		of submitting the relevant
				Submission Unit
	aada	[1 1]	Toxt	The code indicating at what
	coae	[11]	Text	timing of the review the
			Frampla	relevant Submission Unit was
			Example:	submitted Select the code
			couejp_initiai	submitted Select the code
				Event" and list of IP CV
	andaSustam	[1 1]	Valid OID	OID of the "IP Category
	couesystem	[11]	valid OID	Event" code list
			Frample	Event code list
			codeSystem="2 16 84	
			0 1 113883 3 080 5 1	
			3 3 1 2 1"	
component		[01]		This element stores the
				positioning of the relevant
				Submission Unit when
				submitting the first version.
categoryEvent		[11]		This element stores the
				positioning of the relevant
				Submission Unit when
				submitting the first version.
code		[11]		This element stores the
				positioning of the relevant
				Submission Unit when
				submitting the first version.
	code	[11]	Text	The code indicating the type
				of the relevant Submission
			Example:	Unit for first version
			code="jp_initial_a"	submission Select the code
				value from the "JP Initial
				Submission Type" code list of IP CV
1 I I I	L	1	1	

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Element		Attribute	Cardinality	Value(s) Allowed	Description				
					l ·	Example of value	•		
				codeSystem	[11]	Valid OID	OID of the "JP Initial		
							Submission Type" code list		
						Example:			
						codeSystem="2.16.84			
						0.1.113883.3.989.5.1.			
						3.3.1.3.1"			
Submission rules for		ion rules for	\succ When sub-	➤ When submitting the first version, the <i>component</i> element is required for any of					
elements and			and	a), b) and	a), b) and c) indicated in 3.3.1 of this document.				
attributes			S	\succ At the time	At the time of revision, the <i>component</i> element must not be provided.				
B	Business General		General	\succ The <i>comp</i>	The componentOf2.categoryEvent.code@code attribute value indicating "first				
R	Rules			version submission", "for expert discussion "or" for the subcommittee" is					
				provided of	provided only once throughout the life cycle in principle. If it is necessary to				
				provide an	provide any value for multiple times in 1 eCTD application, consult the				
			regulatory	regulatory authority in advance. However, for submissions by method 2 shown in 3.3.1 of this document, the <i>componentOf2.categoryEvent.code@code</i>					
			in 3.3.1 of						
				attribute v	alue indicating '	'first version submission	n" is provided twice throughout		
				the lifecyc	le.				
			a)	If the Sub	nission Unit to	be submitted when subr	nitting the first version is a),		
				the <i>compo</i>	nentOf2.catego	ryEvent.code@code att	ribute value must be the code		
				indicating	a).				
			b)	If the Sub	nission Unit to	be submitted is b), the			
				componen	tOf2.categoryE	<i>vent.code@code</i> attribu	te value must be the code		
				indicating	b).				
			c)	\succ If the Sub	nission Unit to	be submitted is c), the			
				componen	tOf2.categoryE	<i>vent.code@code</i> attribu	te value must be the code		
				indicating	c).				

8. Reuse

8.1 Document Reuse

In an application using eCTD v4.0, you may reuse the Document submitted in the past. For how to reuse the Document, refer to "9.2.17.1 Document Reuse", etc., in the ICH IG. The Document may be reused at the applicant's discretion in principle. When reusing the Document, either 1) or 2) must be satisfied in addition to the conditions described in ICH IG.

- 1) Both the Submission Unit definining the Document to be reused and the Submission Unit that contains the *documentReference* element that references the Document to be reused belong to the same application.
- 2) All of the following conditions shall be satisfied:
 - The application defining the Document to be reused has already been approved.
 - Both the application defining the Document to be reused and the application containing the *documentReference* element referencing the Document to be reused are submitted as original in accordance with the eCTD v4.0 specifications.
 - The application dossier defining the Document to be reused is subject to document retention by the regulatory authority and is within the prescribed retention period.

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^{*} This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

8.2 File Reuse

In an application using eCTD v4.0, you may reuse the file submitted in the past. For how to reuse the file, refer to "9.2.17.3 File Reuse", etc., in the ICH IG. The file may be reused at the applicant's discretion in principle. To reuse a file, in addition to (satisfying) the conditions provided in ICH IG, the Submission Unit, in which the file to be reused was submitted, and the submission unit containing the *document* element, which refers to the file to be reused, must belong to the same application. Therefore, do not specify a path that includes the first layer folder name (eCTD reception number) in the *reference@value* attribute value of the document element.

9. Handling of the group title Keyword

If the group title Keyword is used for the eCTD v4.0 XML message submitted to the regulatory authority, it will be displayed as the node with the *displayName@value* attribute value of the relevant group title as a label (hereinafter referred to as the "group title node") on the CTD tree display screen in the review environment. The group title node will be displayed at the level between the CTD heading of the Context of Use, to which the relevant group title is assigned, and the title of the Document referred to by the relevant Context of Use.



Note that the group title is also one of the keywords that make up the context group. That is, even in case of a Context of Use to which the same group title Keyword is assigned, if another keyword is different, the context group will be different; therefore, multiple group title nodes of the same value will be displayed.

10. Life cycle management

10.1 Overview

Life cycle management for eCTD in Japan manages addition, change, etc. of application dossier in an individual application but does not collectively manage the new approval application, partial change approval application, etc. for one product. In an individual application, the submission sequence number folder ("1", "2"...) is placed under the eCTD reception number folder, and the application dossier are stored in the folders for Module 1 through Module 5 of the CTD to be placed under that ("m1", "m2", "m3", "m4" and"m5"). The purpose of life cycle management is to manage which file is valid as application dossier for each file according to its attribute information when adding, changing or deleting any file that constitutes the application dossier.

In life cycle management of eCTD v4.0, the differential submission method is adopted for the eCTD v4.0 XML messages and files in principle. In an eCTD submission (package) after submitting the first version, the applicant shall submit the information on new submission or change to the existing information only. However, keep in mind that there is a case where unchanged information must also be submitted each time in terms of the nature of the information or the specification of the standards. For details, refer to 10.3 of this document.

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^{*} This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

10.2 Requirements for submission of the first version of eCTD

10.2.1 Folder structure for submission of the first version

Create folder structure referring to 5 of this document.

10.2.2 File for first version submission

The following files must submit:

- eCTD v4.0 XML Message (submissionunit.xml)
- Checksum file (sha256.txt)
- Files to be submitted with the first version*
 - * In the case of submission by method 2 shown in 3.3.1 of this document, the files to be submitted for the first version should be submitted separately for type b) and c). For type b), only the electronic study data should be submitted, and for type c), only the data specified by the CTD notification should be submitted.

10.2.3 eCTD v4.0 XML message structure for first version submission

When submitting the first version, submit Type a) if submitted in the submission method 1 indicated in 3.3.1 of this document, and Types b) and c) if submitted in the method 2. This section shows the basic structure of the eCTD v4.0 XML message for the first version. For details of each element and attribute, refer to 7 of this document.

10.2.3.1 Submission of the first version using Method 1

This section shows an example of a description for submitting the first version using "Method 1" indicated in 3.3.1 of this document.

1) Example of description from the *submissionUnit* element to the *categoryEvent* element

```
<submissionUnit>
<submissionUnit>
<id root="A"/>
<code code="B" codeSystem="C"/>
------ (For the Context of Use and Submission, refer to 2) and 3) of this section, respectively.)------
<componentOf2>
<categoryEvent>
<code code="D" codeSystem="E"/>
<categoryEvent>
<categoryEvent>
<categoryEvent>
<categoryEvent>
<categoryEvent>
</categoryEvent>
</categoryEve
```

<u>A:</u> UUID of this Submission Unit

- B: The code indicating the type of this Submission Unit (Refer to "JP Submission Unit" of JP CV)
- <u>C:</u> OID of the code list defining the code of this Submission Unit (above B:)
- <u>D:</u> The code indicating at what timing in the review this Submission Unit was submitted (Refer to "JP Category Event" of JP CV)
- <u>E:</u> OID of the code list defining the code of this Category Event (above D:)

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^{*} This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

- <u>F:</u> The code indicating that this Submission Unit is a) indicated in 3.3.1 of this document (Refer to "JP Initial Submission Type" of JP CV)
- <u>G:</u> OID of the code list defining the code of this Category Event (above F:)
- 2) Example of description of the *contextOfUse* element

```
<component>
   <priorityNumber value="H"/>
   <contextOfUse>
        <id root="I"/>
        <code code="J" codeSystem="K"/>
        <statusCode code="L"/>
        <derivedFrom>
            <documentReference>
                 <id root="M"/>
            </documentReference>
        </derivedFrom>
        <referencedBy typeCode="N">
            <keyword>
                 <code code="<u>O</u>" codeSystem="<u>P</u>"/>
            </keyword>
        </referencedBy>
------ (To provide more than one keyword, repeat referencedBy)------
   </contextOfUse>
</component>
------ (To provide more than one Context of Use, repeat component)------
```

- <u>H:</u> The value to specify the display order if there are multiple context groups (Also describe it even if there are not more than one.)
- <u>I:</u> UUID of this Context of Use
- <u>J:</u> The code indicating the CTD heading to assign the Document specified by this Context of Use (Refer to "ICH Context of Use" of ICH CV or "JP Context of Use" of JP CV)
- K: OID of the code list defining the code of this Context of Use (above J:)
- L: Status of this Context of Use
- <u>M:</u> The *id@root* attribute value of the Document referred to by this Context of Use
- <u>N:</u> Structural attribute required to use the referencedBy element. The value must be "REFR".
- <u>O:</u> Code of the keyword assigned to this Context of Use
- <u>P:</u> OID of the code list defining the keyword assigned to this Context of Use or any value specified in Keyword Definition
- 3) Example of description of the *submission* element

```
<componentOf1>
<sequenceNumber value="Q"/>
<submission>
<id>
<item root="<u>R</u>" extension="<u>S</u>"/>
</id>
<code code="<u>T</u>" codeSystem="<u>U</u>"/>
<subject2>
```

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```
<review>
                  <id root="V"/>
                  <statusCode code="W"/>
                  <subject1>
                       <manufacturedProduct>
                            <manufacturedProduct>
                                <name>
                                     <part value="X"/>
                                </name>
                                <ingredient classCode="Y">
                                     <ingredientSubstance>
                                          <name>
                                              <part value="Z" code="AA" codeSystem="AB" />
                                          </name>
                                     </ingredientSubstance>
                                </ingredient>
----- (To provide more than one Ingredient Substance, repeat ingredient)------
                           </manufacturedProduct>
                       </manufacturedProduct>
                  </subject1>
                  <holder>
                       <applicant>
                            <sponsorOrganization>
                                <name>
                                     <part value="AC"/>
                                </name>
                           </sponsorOrganization>
                       </applicant>
                  </holder>
                  <subject2>
                       cproductCategory>
                           <code code="<u>AD</u>" codeSystem="<u>AE</u>"/>
                       </productCategory>
                  </subject2>
             </review>
------ (To provide more than one Review, repeat subject2)------
        </subject2>
----- (For Application, refer to 4) below) ------
   </submission>
</componentOf1>
<u>Q:</u> Submission sequence number of this Submission Unit ("1" for first version application)
R: UUID of the submission which this Submission Unit is associated with
   eCTD reception number
<u>S:</u>
```

<u>T:</u> The code indicating the positioning of this Submission (Example: Submission of the original, submission of references, etc.) (Refer to "JP Submission" of JP CV)

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^{*} This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

- <u>U:</u> OID of the code list defining the code of this Submission (above T:)
- <u>V:</u> UUID of this Review.
- W: Status of this Review ("active" for first version submission)
- X: Brand name
- Y: Structural attribute required to use the ingredient element. The value must be "INGR".
- <u>Z:</u> Active ingredient name

AA: The code indicating the type of active ingredient name (Refer to JP CV "JP Substance Name Type")

- AB: OID of the code list that defines the Substance Name Type code (above AA:)
- AC: Applicant name
- AD: The code indicating the application category (Refer to JP CV "JP Product Category")
- AE: OID of the code list defining the code of this Product Category (aboveAD:)
- 4) Example of description of the *application* element

```
<componentOf>
<application>
<id>
<item root="<u>AF</u>" extension="<u>AG</u>"/>
</id>
<code code="<u>AH</u>" codeSystem="<u>AI</u>"/>
<reference>
<applicationReference>
<id root="<u>AJ</u>"/>
<reasonCode>
<item code="<u>AK</u>" codeSystem="<u>AL</u>"/>
</reasonCode>
</reference>
```

------ (To provide more than one Application Reference, repeat *reference*. As for the related applications, include all the related application as of that point of time for each submission, not limited to the first version or the revised version.)------

------ (For *document* and *keywordDefinition*, refer to 5) and 6) of this section, respectively.)------

</application>

</componentOf>

- <u>AF:</u> UUID of this Application
- AG: Any value (specified) by the applicant
- <u>AH:</u> The code indicating the type of this Application (marketing approval application, etc.) (Refer to JP CV "JP Application")
- AI: OID of the code list defining the code of this Application (aboveAH:)
- <u>AJ:</u> eCTD reception number of the application related to this Application (partial change approval application, etc.)
- <u>AK:</u> The code indicating the type of the relationship of the related application indicated in AJ:above (Refer to JP CV "JP Application Reference Reason")
- AL: OID of the code list defining the code of the type of relationship (aboveAK:)

5) Example of description of the *document* element

<component> <document>

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```
<id root="<u>AM</u>"/>
<text integrityCheckAlgorithm="<u>AN</u> ">
<reference value="<u>AO</u>"/>
<integrityCheck><u>AP</u></integrityCheck>
</text>
</document>
</component>
```

------ (To provide more than one Document, repeat *component*.) ------

<u>AM:</u>UUID of this Document

- <u>AN:</u> Calculation algorithm for the checksum of the file referred to by this Document. The value must be "sha256".
- <u>AO:</u> The path of the file referred to by this Document. The path must be a relative path based on submissionunit.xml.
- <u>AP:</u> The checksum of the file referred to by this Document. The value must be in the sha256 format.
- 6) Example of description of the *keywordDefinition* element

```
<referencedBy>
<keywordDefinition>
<code code="<u>AQ</u>" codeSystem=<u>AR</u>"/>
<statusCode cd="<u>AS</u>"/>
<value>
<item code="<u>AT</u>" codeSystem="<u>AU</u>">
<displayName value="<u>AU</u>">
</item>
</value>
</keywordDefinition>
</referencedBy>
```

```
------ (To provide more than one keywordDefinition, repeat referencedBy.)------
```

- <u>AQ</u>: The code indicating the type of the Keyword defined by this Keyword Definition (Example: indication, product item name, manufacturer, etc.) (Refer to "ICH Keyword Definition Type" of ICH CV or "JP Keyword Definition Type" of JP CV)
- <u>AR:</u> OID of the code list defining the code indicating the type of the Keyword defined by this Keyword Definition (aboveAQ:)
- AS: Status of this Keyword Definition The value must be "active".
- <u>AT:</u> Any code (specified) by the applicant, which indicates the contents of the Keyword defined by this Keyword Definition (name of the indication, name of the drug product, etc.)
- <u>AU:</u> The identifier of the code list defining the code arbitrarily specified by the applicant, which indicates the contents of the Keyword defined by this Keyword Definition (aboveAT:) As the relevant code list shall be possessed by the applicant, any format will do as long as the information can be identified (Example: OID, applicant's arbitrary text).
- <u>AV:</u> The displayed characters corresponding to the code arbitrarily specified by the applicant, which indicates the contents of the Keyword defined by this Keyword Definition

10.2.3.2 Submission of the first version using Method 2

This section shows an example of description for submitting the first version using Method 2 indicated in 3.3.1 of this document.

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^{*} This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

10.2.3.2.1. Submission of the first version of the eCTD Type b)

This section shows an example of description of eCTD Type b) when submitting the first version using Method 2 indicated in 3.3.1 of this document.

1) Example of description from the *submissionUnit* element to the *categoryEvent* element

```
<submissionUnit>
<id root="<u>AW</u>"/>
<code code="<u>AX</u>" codeSystem="<u>AY</u>"/>
------ (For contextOfUse and submission, refer to 2) and 3) of this section, respectively) -------
<componentOf2>
<categoryEvent>
<code code="<u>AZ</u>" codeSystem="<u>BA</u>"/>
<code code="<u>AZ</u>" codeSystem="<u>BA</u>"/>
<code code="<u>BB</u>" codeSystem="<u>BC</u>"/>
</categoryEvent>
</categoryEvent>
</categoryEvent>
</categoryEvent>
</categoryEvent>
</categoryEvent>
</categoryEvent>
</categoryEvent>
</categoryEvent>
```

AW: UUID of this Submission Unit

- AX: The code indicating the type of this Submission Unit (Refer to "JP Submission Unit" of JP CV)
- AY: OID of the code list defining the code of this Submission Unit (aboveAX:)
- <u>AZ:</u> The code indicating at what timing in this review this Submission Unit was submitted (Refer to "JP Category Event" of JP CV)
- BA: OID of the code list defining the code of this Category Event (aboveAZ:)
- <u>BB:</u> The code indicating that this Submission Unit is b) indicated in 3.3.1 of this document (Refer to "JP Initial Submission Type" of JP CV)
- BC: OID of the code list defining the code of this Category Event (aboveBB:)

2) Example of description of the *contextOfUse* element

```
<component>
   <priorityNumber value="BD"/>
   <contextOfUse>
        <id root="BE"/>
        <code code="BF" codeSystem="BG"/>
        <statusCode code="BH"/>
        <derivedFrom>
            <documentReference>
                 <id root="BI"/>
            </documentReference>
        </derivedFrom>
        <referencedBy typeCode="BJ">
            <keyword>
                 <code code="<u>BK</u>" codeSystem="<u>BL</u>"/>
            </keyword>
        </referencedBy>
```

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^{*} This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

------ (To provide more than one keyword, repeat *referencedBy*)------

```
</contextOfUse>
```

</component>

------ (To provide more than one Context of Use, repeat component)------

- <u>BD:</u> The value to specify the display order if there are multiple context groups (Also describe it even if there are not more than one.)
- BE: UUID of this Context of Use.
- <u>BF:</u> The code indicating the CTD heading to assign the Document specified by this Context of Use (Refer to "ICH Context of Use" of ICH CV or "JP Context of Use" of JP CV)
- BG: OID of the code list defining the code of this Context of Use (aboveBF:)
- <u>BH:</u> Status of this Context of Use
- <u>BI:</u> The *id*@*root* attribute value of the Document referred to by this Context of Use
- BJ: Attribute required when using the *referencedBy* element. The value must be "REFR".
- BK: Code of the keyword assigned to this Context of Use
- <u>BL:</u> OID of the code list defining the keyword assigned to this Context of Use or any value specified in Keyword Definition
- 3) Example of description of the *submission* element

```
<componentOf1>
<sequenceNumber value="<u>BM</u>"/>
<submission>
<id>
<item root="<u>BN</u>" extension="<u>BO</u>"/>
</id>
<code code="<u>BP</u>" codeSystem="<u>BQ</u>"/>
```

----- (For *application*, refer to 4) below) ------

</submission>

</componentOf1>

BM: Submission sequence number of this Submission Unit ("1" for first version application)

- BN: UUID of this submission
- BO: eCTD reception number
- <u>BP:</u> The code indicating the positioning of this Submission (Example: Submission of the original, submission of references, etc.) (Refer to "JP Submission" of JP CV)
- BQ: OID of the code list defining the code of this Submission (aboveBP:).

4) Example of description of the *application* element

```
<componentOf>
<application>
<id>
<id>
<id>
<item root="BR" extension="BS"/>
</id>
</id>
</code code="BT" codeSystem="BU"/>
</code code="CodeSystem="BU"/>
</code code="CodeSystem="BU"/>
</codeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSystem="CodeSyste
```

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^{*} This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

- BR: UUID of this Application
- BS: Any value (specified) by the applicant
- <u>BT:</u> The code indicating the type of this Application (marketing approval application, etc.) (Refer to JP CV "JP Application")

BU: OID of the code list defining the code of this Application (aboveBT:)

5) Example of description of the *document* element

```
<component>
<document>
<id root="<u>BV</u>"/>
<text integrityCheckAlgorithm="<u>BW</u>">
<reference value="<u>BX</u>"/>
<integrityCheck><u>BY</u></integrityCheck>
</text>
</document>
</component>
```

------ (To provide more than one Document, repeat *component*.) ------

<u>BV</u>: UUID of this Document

- <u>BW:</u>Calculation algorithm for the checksum of the file referred to by this Document. The value must be "sha256".
- <u>BX:</u> The path of the file referred to by this Document. The path must be a relative path based on submissionunit.xml.
- BY: The checksum of the file referred to by this Document. The value must be in the sha256 format.

6) Example of description of the *keywordDefinition* element

```
<referencedBy>
<keywordDefinition>
<code code="<u>BZ</u>" codeSystem="<u>CA</u>"/>
<statusCode code="<u>CB</u>"/>
<value>
<item code="<u>CC</u>" codeSystem="<u>CD</u>">
<displayName value="<u>CE</u>"/>
</item>
</value>
</keywordDefinition>
</referencedBy>
```

------ (To provide more than one *keywordDefinition*, repeat *referencedBy*.)------

- <u>BZ:</u> The code indicating the type of the Keyword defined by this Keyword Definition (Example: indication, product item name, manufacturer, etc.) (Refer to "ICH Keyword Definition Type" of ICH CV or "JP Keyword Definition Type" of JP CV)
- <u>CA:</u> OID of the code list defining the code indicating the type of the Keyword defined by this Keyword Definition (aboveBZ:)
- CB: Status of this Keyword Definition The value must be "active".
- <u>CC:</u> Any code (specified) by the applicant, which indicates the contents of the Keyword defined by this Keyword Definition (name of the indication, name of the drug product, etc.)
- <u>CD:</u> The identifier of the code list defining the code arbitrarily specified by the applicant, which indicates the contents of the Keyword defined by this Keyword Definition (aboveCC:) As the

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relevant code list shall be possessed by the applicant, any format will do as long as the information can be identified (Example: OID, applicant's arbitrary text).

<u>CE:</u> The displayed characters corresponding to the code arbitrarily specified by the applicant, which indicates the contents of the Keyword defined by this Keyword Definition

10.2.3.2.2. Submission of the first version of the eCTD Type c)

The structure of eCTD Type c) for submitting the first version using Method 2 indicated in 3.3.1 of this document is not different from the structure of Type a) indicated in 10.2.3.1 of this document except for the following. Keep the following 2 points in your mind to refer to 10.2.3.1 of this document.

- <u>F:</u> The code indicating that this Submission Unit is c) indicated in 3.3.1 of this document (Refer to "JP Initial Submission Type" of JP CV).
- <u>Q:</u> Submission sequence number of this Submission Unit ("2" for first version application)

10.3 Requirements for eCTD revision

10.3.1 Folder structure for revision

At the time of revision, create the following folders by referring to 5 of this document.

- First layer folder (the folder with the eCTD reception number as the folder name)
- Second layer folder (the folder whose folder name is the submission sequence number of the relevant revision)
- The folder storing the files to be submitted for the relevant revision and its upper folder(s)

10.3.2 Files for revision

The following files must be submitted.

- eCTD v4.0 XML message (submissionunit.xml)
- Checksum file (sha256.txt)
- The files to be submitted for the relevant revision

10.3.3 eCTD v4.0 XML message structure for revision

For eCTD for revision, use Type a) indicated in 3.3.1 of this document regardless of the submission package. At the time of revision, create an eCTD v4.0 XML message according to ICH IG for the basic structure. This section shows the basic structure of the eCTD v4.0 XML message for the revised version. For details of each element and attribute, refer to 7 of this document.

1) Example of description from the *submissionUnit* element to *categoryEvent* element



</submissionUnit>

<u>CF:</u> UUID of this Submission Unit as the UUID of Submission Unit is assigned for each submission, it does not overlap with the Submission Unit submitted in the past.

<u>CG</u>: The code indicating the type of this Submission Unit (Refer to "JP Submission Unit" of JP CV) <u>CH</u>: OID of the code list defining the code of this Submission Unit (aboveCG:)

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^{*} This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

- <u>CI:</u> The code indicating at what timing in review this Submission Unit was submitted (Refer to "JP Category Event" of JP CV)
- <u>CJ:</u> OID of the code list defining the code of this Category Event (aboveCI:)

2) Example of description of the *contextOfUse* element

- The method to describe the Context of Use to be newly provided at the time of revision is not different from the method to describe it for the first version. Refer to 2) of 10.2.3.1 of this document.
- You cannot add, replace or delete any CoU Keyword for the already submitted Context of Use. As for an already submitted Document, if you want to associate it with a different context group, delete the existing Context of Use, which refers to the relevant Document, and provide a new Context of Use. For the relevant new Context of Use, either the already submitted Document or file can be reused or the same file can be re-submitted to refer to this as a new Document.
- An example of description for deleting the Context of Use for the purpose of deleting a document submitted in the past is shown below.

<component>

```
<priorityNumber value="<u>CK</u>"/>
<contextOfUse>
<id root="<u>CL</u>"/>
<statusCode code="<u>CM</u>"/>
</contextOfUse>
```

</component>

- <u>CK</u>: The value to specify the display order if there are multiple context groups (Also describe it even if there are not more than one.). It is desirable to be the same value as the Priority Number of the Context of Use to be deleted. Even though any other value is provided, the relevant value is not considered to have been provided for the regulatory authority. The Priority Number of the Context of Use deleted will be available in the same Submission Unit and later.
- CL: UUID of the Context of Use to be deleted
- <u>CM:</u> Status of this Context of Use When deleting the Context of Use, provide "suspended" for this attribute value.
- When replacing the Context of Use for the purpose of replacing the document at the time of revision, the following 4 situations are possible.
 - (1) Replace 1 file with 1 file.
 - (2) Replace 1 file with multiple files.
 - (3) Replace multiple files with 1 file.
 - (4) Replace multiple files with multiple files.

(An example of description) for each of the above is shown below.

(1) Replace 1 file with 1 file.

```
<component>
<priorityNumber value="<u>CN</u>"/>
<contextOfUse>
<id root="<u>CO</u>"/>
<code code="<u>CP</u>" codeSystem="<u>CQ</u>"/>
<statusCode code="<u>CR</u>"/>
<replacementOf typeCode="<u>CS</u>">
<relatedContextOfUse>
<id root="<u>CT</u>">
</relatedContextOfUse>
```

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</replacementOf> <derivedFrom> <documentReference> <id root="<u>CU</u>"/> </documentReference> </derivedFrom>

------ (If a Keyword is assigned to the Context of Use before replacement, describe the said Keyword here. As the Keyword description method is not different from (the method of) description for the first version, refer to 10.2.3 of this document. Note that the number of the Keywords and the code must be the same between the Contexts of Use before and after replacement.)------

</contextOfUse>

</component>

- <u>CN:</u> The value to specify the display order if there are multiple context groups (Also describe it even if there are not more than one.) Describe the Priority Number to be assigned to the new Context of Use. As long as it does not overlap with any Context of Use in the same context group, it does not matter if the Priority Numbers of the Contexts of Use before and after replacement are the same or different. Also, even though the Priority Numbers are different before and after replacement, do not provide any *priorityNumber@updateMode* attribute.
- CO: UUID of the new Context of Use.
- <u>CP:</u> The code indicating the CTD heading to assign the Document specified by the new Context of Use (Refer to "ICH Context of Use" of ICH CV or "JP Context of Use" of JP CV). This value must be the same between the Contexts of Use before and after replacement.
- <u>CQ</u>: OID of the code list defining the code of this Context of Use (aboveCP:). This value must be the same between the Contexts of Use before and after replacement. (The version number included at the end of the OID indicated by the *code@codeSystem* attribute does not have to match.)
- <u>CR:</u> Status of the new Context of Use The value must be "active".
- CS: Structural attribute required to use the *replacementOf* element. The value must be "RPLC".
- CT: UUID of the old Context of Use
- CU: The id@root attribute value of the Document referred to by the new CoU

(2) Replace 1 file with multiple files.

<component></component>
<prioritynumber value="<u>CV</u>"></prioritynumber>
<contextofuse></contextofuse>
<id root="<u>CW</u>"></id>
<code code="<u>CX</u>" codesystem="<u>CY</u>"></code>
<statuscode code="<u>CZ</u>"></statuscode>
<replacementof typecode="DA"></replacementof>
<relatedcontextofuse></relatedcontextofuse>
<id root="<u>DB</u>"></id>
<derivedfrom></derivedfrom>
<documentreference></documentreference>
<id root="<u>DC</u>"></id>

------ (If a Keyword is assigned to the Context of Use before replacement, describe the said Keyword here. As the Keyword description method is not different from (the method of) description for

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^{*} This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

the first version, refer to 10.2.3 of this document. Note that the number of the Keywords and the code must be the same between the Contexts of Use before and after replacement.)------

```
</contextOfUse>
</component>
<component>
   <priorityNumber value="DD"/>
   <contextOfUse>
       <id root="DE"/>
       <code code="DF" codeSystem="DG"/>
       <statusCode code="DH"/>
       <replacementOf typeCode="DI">
            <relatedContextOfUse>
                <id root="DJ">
            </relatedContextOfUse>
       </replacementOf>
       <derivedFrom>
            <documentReference>
                <id root="DK"/>
            </documentReference>
       </derivedFrom>
```

------ (If a Keyword is assigned to the Context of Use before replacement, describe the said Keyword here. As the Keyword description method is not different from (the method of) description for the first version, refer to 10.2.3 of this document. Note that the number of the Keywords and the code must be the same between the Contexts of Use before and after replacement.)------

</contextOfUse> </component>

------ (In this example of description, 2 Contexts of Use replace 1 Context of Use. When more Contexts of Use replace 1 Context of Use, repeat the *component* element for the number of the new Contexts of Use.)

<u>CV:</u> The value to specify the display order if there are multiple context groups (Also describe it even if there are not more than one.) Describe the Priority Number to be assigned to the new Context of Use. As long as it does not overlap with any Context of Use in the same context group, it does not matter if the Priority Numbers of the Contexts of Use before and after replacement are the same or different. Also, even though the Priority Numbers are different before and after replacement, do not provide any *priorityNumber@updateMode* attribute. When multiple Contexts of Use replace 1 Context of Use, only one of the new Contexts of Use can have the same Priority Number as that of the old Context of Use.

```
CW: UUID of the new Context of Use
```

- <u>CX:</u> The code indicating the CTD heading to assign the Document specified by the new Context of Use (Refer to "ICH Context of Use" of ICH CV or "JP Context of Use" of JP CV). This value must be the same between the Contexts of Use before and after replacement.
- <u>CY:</u> OID of the code list defining the code of this Context of Use (aboveCP:). This value must be the same between the Contexts of Use before and after replacement. (The version number included at the end of the OID indicated by the *code@codeSystem* attribute does not have to match.)
- CZ: Status of the new Context of Use The value must be "active".
- DA: Structural attribute required to use the *replacementOf* element. The value must be "RPLC".

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- <u>DB:</u> UUID of the old Context of Use If multiple Contexts of Use replace 1 Context of Use, this attribute value of multiple new Contexts of Use will be the same. In this example of description, the values of DB:and DJ:are the same.
- DC: The id@root attribute value of the Document referred to by the new CoU
- DD: Same as CV:
- DE: Same as CW:
- DF: Same as CX:
- DG: Same as CY:
- DH: Same as CZ:
- DI: Same as DA:
- DJ: Same as DB:
- DK: Same as DC:

(3) Replace multiple files with 1 file.

```
<component>
   <priorityNumber value="DL"/>
   <contextOfUse>
       <id root="DM"/>
       <code code="DN" codeSystem="DO"/>
       <statusCode code="DP"/>
       <replacementOf typeCode="DQ">
            <relatedContextOfUse>
                <id root="DR">
            </relatedContextOfUse>
       </replacementOf>
       <replacementOf typeCode="DS">
            <relatedContextOfUse>
                <id root="DT">
            </relatedContextOfUse>
       </replacementOf>
       <replacementOf typeCode="DU">
            <relatedContextOfUse>
                <id root="DV">
            </relatedContextOfUse>
       </replacementOf>
       <derivedFrom>
            <documentReference>
                <id root="DW"/>
            </documentReference>
       </derivedFrom>
```

------ (If a Keyword is assigned to the Context of Use before replacement, describe the said Keyword here. As the Keyword description method is not different from (the method of) description for the first version, refer to 10.2.3 of this document. Note that the number of the Keywords and the code must be the same between the Contexts of Use before and after replacement.)------

</contextOfUse> </component>

<u>DL:</u> The value to specify the display order if there are multiple context groups (Also describe it even if there are not more than one.) Describe the Priority Number to be assigned to the new Context of Use. As long as it does not overlap with any Context of Use in the same context group, it

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does not matter if the Priority Numbers of the Contexts of Use before and after replacement are the same or different. Also, even though the Priority Numbers are different before and after replacement, do not provide any *priorityNumber@updateMode* attribute.

- DM: UUID of the new Context of Use.
- <u>DN:</u> The code indicating the CTD heading to assign the Document specified by the new Context of Use (Refer to "ICH Context of Use" of ICH CV or "JP Context of Use" of JP CV). This value must be the same between the Contexts of Use before and after replacement.
- <u>DO:</u> OID of the code list defining the code of this Context of Use (aboveDN:). This value must be the same between the Contexts of Use before and after replacement. (The version number included at the end of the OID indicated by the *code@codeSystem* attribute does not have to match.)
- DP: Status of the new Context of Use The value must be "active".
- DQ: Structural attribute required to use the *replacementOf* element. The value must be "RPLC".
- <u>DR:</u> UUID of the old Context of Use If there are multiple old Contexts of Use, all the old Contexts of Use will be enumerated together with the *replacementOf* element.
- DS: Same as DQ:
- DT: Same as DR:
- DU: Same as DQ:
- DV: Same as DR:

DW: The *id@root* attribute value of the Document referred to by the new CoU

(4) Replace multiple files with multiple files.

<component>

<prioritynumber value="DX"></prioritynumber>
<contextofuse></contextofuse>
<id root="DY"></id>
<code code="DZ" codesystem="EA"></code>
<statuscode code="<u>EB</u>"></statuscode>
<replacementof typecode="<u>EC</u>"></replacementof>
<relatedcontextofuse></relatedcontextofuse>
<id root="ED"></id>
<replacementof typecode="<u>EE</u>"></replacementof>
<relatedcontextofuse></relatedcontextofuse>
<id root="<u>EF</u>"></id>
<derivedfrom></derivedfrom>
<documentreference></documentreference>
<id root="<u>EG</u>"></id>

------ (If a Keyword is assigned to the Context of Use before replacement, describe the said Keyword here. As the Keyword description method is not different from (the method of) description for the first version, refer to 10.2.3 of this document. Note that the number of the Keywords and the code must be the same between the Contexts of Use before and after replacement.)------

```
</contextOfUse>
</component>
<component>
```

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^{*} This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

```
<priorityNumber value="EH"/>
<contextOfUse>
    <id root="EI"/>
    <code code="EJ" codeSystem="EK"/>
    <statusCode code="EL"/>
    <replacementOf typeCode="EM">
         <relatedContextOfUse>
             <id root="EN">
        </relatedContextOfUse>
    </replacementOf>
    <replacementOf typeCode="EO">
         <relatedContextOfUse>
             <id root="EP">
        </relatedContextOfUse>
    </replacementOf>
    <derivedFrom>
        <documentReference>
             <id root="EO"/>
         </documentReference>
    </derivedFrom>
```

------ (If a Keyword is assigned to the Context of Use before replacement, describe the said Keyword here. As the Keyword description method is not different from (the method of) description for the first version, refer to 10.2.3 of this document. Note that the number of the Keywords and the code must be the same between the Contexts of Use before and after replacement.)------

</contextOfUse> </component>

- <u>DX:</u> The value to specify the display order if there are multiple context groups (Also describe it even if there are not more than one.) Describe the Priority Number to be assigned to the new Context of Use. As long as it does not overlap with any Context of Use in the same context group, it does not matter if the Priority Numbers of the Contexts of Use before and after replacement are the same or different. Also, even though the Priority Numbers are different before and after replacement, do not provide any *priorityNumber@updateMode* attribute.
- DY: UUID of the new Context of Use
- <u>DZ</u>: The code indicating the CTD heading to assign the Document specified by the new Context of Use (Refer to "ICH Context of Use" of ICH CV or "JP Context of Use" of JP CV). This value must be the same between the Contexts of Use before and after replacement.
- <u>EA:</u> OID of the code list defining the code of this Context of Use (aboveDZ:). This value must be the same between the Contexts of Use before and after replacement. (The version number included at the end of the OID indicated by the *code@codeSystem* attribute does not have to match.)
- EB: Status of the new Context of Use The value must be "active".
- EC: Structural attribute required to use the *replacementOf* element. The value must be "RPLC".
- <u>ED:</u> UUID of the old Context of Use If there are multiple old Contexts of Use, all the old Contexts of Use will be enumerated together with the *replacementOf* element.
- EE: Same as EB:
- EF: Same as ED:
- EG: The *id@root* attribute value of the Document referred to by the new CoU
- EH: Same as DX:
- EI: Same as DY:
- EJ: Same as EZ:
- EK: Same as EA:

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- EL: Same as EB: EM: Same as EC: EN: Same as ED: EO: Same as EC: EP: Same as ED: EQ: Same as EG:
- If you intend to replace the document at the time of revision, replace the Context of Use by using any of the above-mentioned methods in principle. It is not appropriate to delete the Context of Use and provide a new Context of Use while you intend to replace the document. As for the Context of Use that should be replaced, note that if it is judged as a result of the action taken through deletion and new submission that there is an impact on the review, you may be requested to re-submit the Submission Unit.
- 3) Example of description of the *submission* element
 - At the time of revision, if no change is made to the product item information, provide only the minimum-required information under the *submission* element as shown below.

```
<componentOf1>
<sequenceNumber value="<u>ER</u>"/>
<submission>
<id>
<item root="<u>ES</u>" extension="<u>ET</u>"/>
</id>
<code code="<u>EU</u>" codeSystem="<u>EV</u>"/>
```

----- (For Application, refer to 4) of this section) ------

</submission>

</componentOf1>

- <u>ER:</u> Submission sequence number of this Submission Unit (The numeric value obtained by adding 1 to the *sequenceNumber@value* attribute value stated in the Submission Unit received just before it)
- <u>ES:</u> UUID of the submission which this Submission Unit is associated with. It must be the same value as the *submission.id.item@root* attribute value of the first version.
- ET: eCTD reception number It must be the same value as the eCTD reception number stated in the first version.
- <u>EU:</u> The code indicating the positioning of this Submission (Example: Submission of the original, submission of references, etc.) (Refer to "JP Submission" of JP CV). It must be the same value as the *code@code* attribute value stated in the first version.
- <u>EV:</u> OID of the code list defining the code of this Submission (aboveEU:). It must be the same value as the *code@codeSystem* attribute value stated in the first version.
- At the time of revision, if a new product item is added, provide a description under the *submission* element as follows.

```
<componentOf1>
<sequenceNumber value="<u>EW</u>"/>
<submission>
<id>
<item root="<u>EX</u>" extension="<u>EY</u>"/>
</id>
<code code="<u>EZ</u>" codeSystem="<u>FA</u>/>
<subject2>
```

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```
<review>
<id root="<u>FB</u>"/>
<statusCode code="<u>FC</u>"/>
</review>
</subject2>
```

------ (Describe the Review related to the newly added product item, and provide the *statusCode* attribute value as "active".)------

----- (Do not include any Review that is neither withdrawn nor changed.)------

```
</submission>
```

</componentOf1>

- <u>EW:</u> Submission sequence number of this Submission Unit (The numeric value obtained by adding 1 to the *sequenceNumber@value* attribute value stated in the Submission Unit received just before it)
- EX: UUID of the submission which this Submission Unit is associated with. It must be the same value as the *submission.id.item@root* attribute value stated in the first version.
- $\underline{EY:}$ eCTD reception number It must be the same value as the eCTD reception number stated in the first version.
- <u>EZ:</u> The code indicating the positioning of this Submission (Example: Submission of the original, submission of references, etc.) (Refer to "JP Submission" of JP CV). It must be the same value as the *code@code* attribute value stated in the first version.
- <u>FA:</u> OID of the code list defining the code of this Submission (aboveEZ:). It must be the same value as the *code@codeSystem* attribute value stated in the first version.
- FB: UUID of the Review related to the newly added product item
- <u>FC:</u> Status of this Review. This attribute value of the Review related to the newly added product item must be "active".
- In the eCTD application containing more than one product item, to withdraw only some product items of the marketing application in the review process, provide a description under the *submission* element as follows at the time of the earliest revision after submitting a withdrawal request. You cannot withdraw any product item of the marketing application only by submitting eCTD. Also, to withdraw all the product items of the marketing application contained in eCTD, you do not need to submit eCTD after submitting a withdrawal request.

```
<componentOf1>
<sequenceNumber value="FD"/>
<submission>
<id>
<item root="FE" extension="FF"/>
</id>
<code code="FG" codeSystem="FH"/>
<subject2>
<review>
<id root="FI"/>
<statusCode code="FJ"/>
</review>
</subject2>
```

------ (If multiple product items are withdrawn, provide each review together with the *subject2* element, and provide the *statusCode* attribute value as "suspended" similarly to the above.)------

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^{*} This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

----- (Do not include any Review that is neither withdrawn nor changed.)------

```
</submission>
```

</componentOf1>

- <u>FD:</u> Submission sequence number of this Submission Unit (The numeric value obtained by adding 1 to the *sequenceNumber@value* attribute value stated in the Submission Unit received just before it)
- <u>FE:</u> UUID of the submission which this Submission Unit is associated with. It must be the same value as the *submission.id.item@root* attribute value stated in the first version.
- <u>FF:</u> eCTD reception number It must be the same value as the eCTD reception number stated in the first version.
- <u>FG:</u> The code indicating the positioning of this Submission (Example: Submission of the original, submission of references, etc.) (Refer to "JP Submission" of JP CV). It must be the same value as the *code@code* attribute value stated in the first version.
- <u>FH:</u> OID of the code list defining the code of this Submission (aboveFG:). It must be the same value as the *code@codeSystem* attribute value stated in the first version.
- FI: UUID of the Review related to the withdrawn product item
- <u>FJ:</u> Status of this Review. This attribute value of the Review related to the withdrawn product item must be "suspended".
- To change the product item information at the time of revision, provide a description under the submission element as follows.

```
<componentOf1>
<sequenceNumber value="<u>FK</u>/>
<submission>
<id>
<id>
</id>
</id>
<code code="<u>FN</u>" codeSystem="<u>FM</u>"/>
<subject2>
<review>
<id root="<u>FP</u>"/>
<statusCode code="<u>FQ</u>"/>
<subject1>
```

------ (Provide all the elements and attributes submitted in the first version under the *subject1* element and state the value after a change in the change part. If there are multiple change parts in the same product item, reflect all the changes under the same *subject1* element. Do not include *updateMode* in the change part.)------

</subject1> </review> </subject2>

------ (If information on more than one product item is changed, describe all the reviews related to the changed product items.)------

----- (Do not include any Review that is neither withdrawn nor changed.)------

</submission> </componentOf1>

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^{*} This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

- <u>FK:</u> Submission sequence number of this Submission Unit (The numeric value obtained by adding 1 to the *sequenceNumber@value* attribute value stated in the Submission Unit received just before it)
- <u>FL:</u> UUID of the submission which this Submission Unit is associated with. It must be the same value as the *submission.id.item@root* attribute value of the first version.
- <u>FM:</u> eCTD reception number It must be the same value as the eCTD reception number stated in the first version.
- <u>FN:</u> The code indicating the positioning of this Submission (Example: Submission of the original, submission of references, etc.) (Refer to "JP Submission" of JP CV). It must be the same value as the *code@code* attribute value stated in the first version.
- <u>FO:</u> OID of the code list defining the code of this Submission (aboveFN:). It must be the same value as the *code@codeSystem* attribute value stated in the first version.
- FP: UUID of the Review related to the product item containing changes.
- <u>FQ:</u> Status of this Review. This attribute value of the Review related to the product item containing changes must be "active".

4) Example of description of the *application* element

```
<componentOf>
<application>
<id>
<id>
<item root="FR" extension="FS"/>
</id>
<code code="FT" codeSystem="FU"/>
<reference>
<applicationReference>
<id root="FV"/>
<reasonCode>
<item code="FW" codeSystem="FX"/>
</reasonCode>
<item code="FW" codeSystem="FX"/>
</reasonCode>
</reference>
```

------ (To provide more than one Application Reference, repeat *reference*. As for the related applications, include all the related application as of that point of time for each submission, not limited to the first version or the revised version.)------

------ (For *document* and *keywordDefinition*, refer to 5) and 6) of this section, respectively.)------

</application>

</componentOf>

- FR: UUID of this Application
- FS: Any value (specified) by the applicant
- <u>FT:</u> The code indicating the type of this Application (marketing approval application, etc.) (Refer to JP CV "JP Application"). It must be the same value as the *code@code* attribute value stated in the first version.
- <u>FU:</u> OID of the code list defining the code indicating the type of this Application (aboveFT:). It must be the same value as the *code@codeSystem* attribute value stated in the first version.
- <u>FV:</u> eCTD reception number of the related application of this Application
- <u>FW:</u> The code indicating the type of the relationship of the related application indicated in FV:above (Refer to JP CV "JP Application Reference Reason")
- FX: OID of the code list defining the code of the type of relationship (aboveFW:)

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^{*} This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

- 5) Example of description of the *document* element
 - The method to describe the Document to be newly provided at the time of revision is not different from the method to describe it for the first version. Refer to 10.2.3 of this document.
 - You cannot change or delete the once submitted Document throughout the life cycle of eCTD except to correct the typo in the title. For how to correct the typo in the title, refer to10.3.4.2.
- 6) Example of description of the *keywordDefinition* element
 - The method to describe the Keyword Definition to be newly provided at the time of revision is not different from the method to describe it for the first version. Refer to 10.2.3 of this document.
 - You cannot change or delete the once submitted Keyword Definition throughout the life cycle of eCTD except to modify the notation of the displayed character string indicated by the *displayName@value* attribute. For how to modify the notation of the displayed character string, refer to10.3.4.3.

10.3.4 Information update

At the time of revision, the following information can be updated.

- 1) Change the display order of the Context of Use in the context group
- 2) Correct the typo in the Document title
- 3) Modify the notation of the Keyword display character string

However, do not revise eCTD for the purpose of updating the information only in principle.

10.3.4.1 Change the display order of the Context of Use in the context group

The Context of Use display order in the context group is determined by the *priorityNumber@value* attribute value, but the display order can be changed by changing the relevant attribute value when revising the eCTD. For how to change the display order of the Context of Use, refer to "9.2.5 Priority Number for Context of Use", etc., in the ICH IG.

10.3.4.2 Correct the typo in the Document title.

If there is a typo in the title of the Document indicated by the *document.title@value* attribute value, it can be corrected by changing the relevant attribute value when revising the eCTD. For how to correct the typo in the Document title, refer to "9.2.17.2.1 Document Title Updates", etc., in the ICH IG. Update of the Document title is interpreted as having an intention to apply to all the Submission Units (including the Submission Units of another application) which refer to the same *document.id@root* value. If you have an intention to apply the update only in a certain Submission Unit, provide a new Document having the *document.id@root* value. If it falls under any of the following, you are not allowed to update the Document title.

- Update the Document title of another application.
- Updating the title changes the positioning of the document instead of correction of the typo.

10.3.4.3 Modify the notation of the Keyword display character string.

If it is necessary to modify the display character string of the keyword indicated by the *displayName@value* attribute value of the Keyword Definition, it can be corrected by changing the relevant attribute value when revising the eCTD. For how to modify the notation of the keyword display character string, refer to "9.2.18.6 Keyword Definition display name change", etc., in the ICH IG. Modification of the notation of the Keyword display character string is interpreted as having an intention to apply to all the Submission Units submitted in the past in the same application as well. To modify the notation of the Keyword Definition. Note that modification of the notation as well. To modify the notation of the the notation of the notation of

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10.3.5 Migration from eCTD v3.2.2

If eCTD v3.2.2 is used when submitting the first version, you cannot make a revision using eCTD v4.0 during the review time period. Use the same version of eCTD from submission of the first version to completion of the life cycle. You are not allowed to inquire the leaf ID, etc. of the document submitted using the version of v3.2.2 or earlier from an application using the version of v4.0 or later.

10.3.6 Important notes for revision

Multiple operations* must not be performed simultaneously within the same Submission Unit for one Context of Use/Review/Document specified by UUID and one Keyword Definition specified by a combination of code and codeSystem attribute values. For example, for one Context of Use, the *contextOfUse* element for remove and the *contextOfUse* element for updating the display order must not be provided in the same Submission Unit at the same time.

* New submissions and replacements, removals and updates, etc.



11. Important notes for referring to the electronic study data from the eCTD v4.0 XML message

As the XML description method is not distinguished according to the file to refer to in eCTD v4.0, create an eCTD v4.0 XML message by referring to 7 of this document in principle. However, the electronic study data must conform to the Technical Conformance Guide, even if the electronic study data is referenced from the eCTD v4.0 XML message and submitted. Therefore, note that there are points of difference in the business rules between when referencing the electronic study data from the eCTD v4.0 XML message and referencing other files. Important notes for referring to the electronic study data are provided below.

1) 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 the same as the name of the study ID folder in which the relevant electronic study data is stored. However, it is not necessary to match uppercase and lowercase letters.

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Scope	Code list	Code
All the electronic study data	JP Study Data Category	Appropriate code
	JP Analysis Type	Appropriate code
SDTM data set (Files under "sdtm" and "sdtm_j" folders)	JP Terminology (Tabulation)	Appropriate code
ADaM data set (Files under "adam" and "adam_j" folders)	JP Terminology (Analysis)	Appropriate code

2) Assign the CoU Keyword to the Context of Use, which refers to the electronic study data, as follows.

3) The following elements/attributes should be provided in the Document that refers to the electronic study data.

Scope	Element/Attribute	Value
Electronic study data in the	document.text.description@	Description of the file
clinical pharmacology	value	contents
Electronic study data in SAS	document.text@charset	Select the appropriate code
XPORT format (.xpt)		from JP CV "JP Japanese
		Character Code"

- 4) The ICH Document Type Keyword does not need to be assigned to the Context of Use that refers to the electronic study data. Even if it is assigned, the assigned ICH Document Type Keyword does not need to be the same between the Context of Use that refers to the electronic study data and the Context of Use that refers to the corresponding clinical study report.
- 5) The following conditions 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.
 - 5)-1 The *code*@*code* and *code*@*codeSystem* attribute values of the study id_study title Keyword shall be the same between them.
 - 5)-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^{*1}, including the presence or absence of the information:
 - The *code@code* and *code@codeSystem* attribute values of Context of Use^{*2}
 - The CoU Keyword *code@code* and *code@codeSystem* attribute values below:
 - ICH Study Group Order*2
 - ➢ indication
 - *1For example, if there are multiple reports corresponding to the electronic study data and each exists under a different CTD heading, only one of the Context of Use that references those reports needs to match the above information with the Context of Use that references the electronic study data.

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^{*} This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

*²The 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 does not need to match.

However, the Context of Use that references the corresponding clinical study report is not submitted at the time of submitting eCTD type b) when submitting the first version by "Method 2" shown in 3.3.1 of this document. Therefore, the above conditions 5)-1 and 5)-2 don't need to be met at the time of submitting eCTD type b) but need to be met at the time of submitting the eCTD type c) instead.

- 6) If the corresponding electronic study data is common among multiple reports with different study ID* within the application, create study ID folders corresponding to each report and submit them by one of the following methods.
 - Store the same electronic study data in each study ID folder.
 - Store the electronic study data in one study ID folder, and store a document wrriten to refer to the study ID folder in the "misc" folder under the other study ID folder.

*The study ID indicated by the study id part of the study id_study title Keyword assigned to the Context of Use that references the clinical study report.

- 7) It is necessary that the file path after "m5/datasets" in each electronic study data must be unique because the file to be validated for the electronic study data is uniquely identified. Therefore, keep the following in mind for revision.
 - When submitting new electronic study data
 - A valid Context of Use referring to the same file in the same path under m5/datasets folder as a newly submitting Context of Use refers to, must not be happened at the time of this submission sequence of lifecycle. It means that a newly submitting Context of Use can be happened with the same file of same path under m5/datasets folder as the deleted Content of Use referred to from the Submission Unit.
 - When replacing previously submitted electronic study data
 - 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 must match.
- 8) When reusing a Document that references electronic study data, all of the following conditions must be met in addition to 8.1 of this document. The file reuse shown in 8.2 of this document is not permitted in the electronic study data.
 - A valid Context of Use referring to a reused Document must not be existed two or more times at the time of this submission sequence of lifecycle.
 - 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 be existed at the time of this submission sequence of lifecycle.

If the Document that references the electronic study data is reused, the file name of the file referenced by the reused Document and the folder structure information under the "m5" folder where it is stored will be inherited even after reuse. For example, if a Document that references a file under the "misc" folder is reused, the file referenced by the Document is treated as a file under the "misc" folder even after being reused.

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- 9) As for the Document and Context of Use, which refer to the electronic study data, the following information will not be utilized by the regulatory authority.
 - priorityNumber@value
 - priorityNumber@updateMode
 - document.title@value
 - document.title@updateMode

12. Other considerations

12.1 CoU Keyword to be assigned to the clinical study report

For the Context of Use that refers to clinical study reports included in Module 5 of CTD, assign the ICH CV "ICH Document Type" as follows.

When submitting the clinical study report in one file:

Assign "ich_document_type_2" to the Context of Use, which refers to the relevant file.

When submitting the clinical study report consisting of multiple files:

For the Context of Use that refers to each file, assign an appropriate one of the Codes with the item number of the clinical study report provided in the column of "E3-Reference".

12.2 Handling of the Context Group

A Context Group consists of one or more Contexts of Use and Document referenced by those Contexts of Use. One context group is configured for each combination of the values of the code attribute and the codeSystem attribute of both the Context of Use and the Keyword assigned to the Context of Use. If the codeSystem attribute indicates the OID of the ICH CV or JP CV codelist, even if the version number included at the end of the OID is different, if other information matches, combinations of values for the code and codeSystem attributes are considered identical. Therefore, for example, Contexts of Use having the following Context of Use codes are judged to belong to the same context group.

	Context of Use 1	Context of Use 2
contextOfUse @code	jp_m1.1	jp_m1.1
contextOfUse @codeSystem	2.16.840.1.113883.3.989.2.2.1.1. <u>1</u>	2.16.840.1.113883.3.989.2.2.1.1. <u>2</u>

12.3 How to express attachment numbers

In order to facilitate the identification of each document and study, it is possible to assign a finer granularity number (e.g., 3.2.s.2.3-1) to each document and study than the CTD number prescribed in the M4 Granularity Document and JP CV "JP Context of Use". The number can be granted by Document title having it or ether one below.

1) Document Label (*contextOfUse.code.originalText@value* attribute)

The *code.originalText*@*value* attribute of the Context of Use provides an arbitrary abbreviation (Document Label) of the Document referenced by the relevant Context of Use. It is possible to assign an attachment number for each document by providing an arbitrary character string as the Document Label. An example of Document Label is shown below.

contextOfUse>

<id root="7c5c61fd-5b88-4018-8323-b21f1a731880"/>

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```
<code code="ich_3.2.s.2.3" codeSystem="2.16.840.1.113883.3.989.2.2.1.1.2">
</originalText value="3.2.s.2.3-1"/>
</code>
<statusCode code="active"/>
...[Partially omitted]...
</contextOfUse>
```

2) ICH Study Group Order Keyword

The ICH Study Group Order Keyword is a Keyword for defining the display order between context groups that include the study id_study title Keyword. The ICH Study Group Order Keyword can be used to assign attachment numbers to multiple documents by study ID unit. The ICH Study Group Order Keyword and Document Label can be used together. An example of a Context of Use description with an ICH Study Group Order Keyword is shown below. <contextOfUse>

```
<id root="7c5c61fd-5b88-4018-8323-b21f1a731880"/>
   <code code="ich_5.3.1.1" codeSystem="2.16.840.1.113883.3.989.2.2.1.1.2"/>
   <statusCode code="active"/>
       <referencedBy typeCode="REFR"/>
          <keyword>
             <code code="ich_study_group_order_1" codeSystem="2.16.840.1.113883.3.98"
9.2.2.1.12.1"/>
          </keyword>
      </referencedBy>
      <referencedBy typeCode="REFR"/>
          <keyword>
             <code code="STUDYID_TITLE001" codeSystem="StudyID list 001"/>
          </keyword>
      </referencedBy>
...[Partially omitted]...
</contextOfUse>
```

13. Validation rules

In addition to the validation rules provided in ICH IG, the business rules, etc., described in this document apply to the validation rules for eCTD application in Japan. For more specific details of validation for eCTD applications in Japan, refer to the list of check items published on the PMDA website (https://www.pmda.go.jp/) and the operation manual, etc., for the eCTD v4.0 verification tool.

14. Inquiry

If you have any question, etc. about operation of eCTD v4.0, contact us at the below email address. However, submit any (question about a) general matter through an industry organization such as Japan Pharmaceutical Manufacturers Association (JPMA) so that the response to it will spread to the entire industry as it is not desirable to respond to it only for one company. This does not apply to any question about a specific product item. We will receive it at the below email address.

ectd@pmda.go.jp

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15. Appendix 1: Module 1 creation guidelines

15.1 Overview

To make an eCTD application using eCTD v4.0, include all of Module 1 through Module 5 of CTD in 1 eCTD v4.0 XML message. The data of Module 1 will be associated with the CTD heading by the code of the Context of Use similarly to the data of other Modules, and included in the same eCTD v4.0 XML message as (that of) the Context of Use, which refers to the data of other Modules, and submitted.

15.2 Folder structure and folder naming rules

The folder structure and folder naming for Module 1 shall be the following folder structure in principle.



The applicant may create folders under the "jp" folder as necessary. However, do not change the hierarchy up to "m1/jp".

15.3 File naming in Module 1

Set up a file in Module 1 referring to the following file name. Note that the following file name is a reference and the applicant may provide any name.

Document type	File name	Remarks
1.1-1 Table of contents of the application dossier containing Module 1	m1-01-01.pdf	In eCTD application, submission shall be optional.
1.1-2 Outline table	m1-01-02.pdf	
1.2 Marketing application form (copy)	m1-02-XX.pdf	
1.3 Certification documents	m1-03-XX.pdf	
1.4 Patent status	m1-04-01.pdf	
1.5 Origin or history of discovery and history of development	m1-05-01.pdf	
1.6 Data on usage conditions in foreign countries	m1-06-01.pdf	
1.7 List of equieffective products of the same kind	m1-07-01.pdf	
1.8 Instructions for use (drafts)	m1-08-01.pdf	
1.9 Document on the generic name	m1-09-01.pdf	
1.10 Summary of designated review data for poisonous drugs, powerful drugs, etc.	m1-10-01.pdf	
1.11 Pharmaceutical product risk management plans (draft)	m1-11-01.pdf	
1.12-1 Attached submission data list (PDF)	m1-12-01.pdf	
1.12-2 Attached submission data list (MS Excel)	m1-12-02.xlsx	
1.13.1-1 Copy of the approval document	m1-13-01-01.pdf	It can be submitted by referring to it as a related application. For details, refer to 15.4 of this document.

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Document type	File name	Remarks
1.13.1-2 Review report	m1-13-01-02.pdf	It can be submitted by
		referring to it as a related
		application. For details, refer
		to 15.4 of this document.
1.13.1-3 Overview of the data	m1-13-01-03.pdf	It can be submitted by
		referring to it as a related
		application. For details, refer
		to 15.4 of this document.
1.13.1-4 Attached submission data list	m1-13-01-04.pdf	It can be submitted by
		referring to it as a related
		application. For details, refer
		to 15.4 of this document.
1.13.2 Clinical study consultation records	m1-13-02-XX.pdf	
(copy)		
1.13.3 Inquiries (copy) and responses to the	m1-13-03-XX.pdf	
inquiries (copy)		
1.13.4.1.1 List of target values / setting values,	m1-13-04-01-01.pdf	
etc. in the manufacturing process		
column on the marketing application	1 12 0 1 01 02	
1.13.4.1.2-1 List of submission data on new	m1-13-04-01-02-	
additives	01.pdf	
1.13.4.1.2-2 Individual review product item	m1-13-04-01-02-	
	02.pdf	
1.13.4.1.2-3 Marketing application (copy)	$m_{1-1,3-0,4-0,1-0,2-}$	
1 12 4 1 2 4 Overview of new additions	03.pdf m1 12 04 01 02	
1.13.4.1.2-4 Overview of new additives	1111-13-04-01-02-	
1 12 4 1 2 VV Data on now additive Attached	04.pdf m1 12 04 01 02	
1.15.4.1.2 AX Data on new additives: Attached	1111-15-04-01-02- XV ndf	
submission data AA	AA.pul	
1.1.3.4.1.3 で ツノ1世	1111-13-04-01-03.DdI	1

1.13.4.2 Data submitted to the Ministry of Health, Labour and Welfare

15.4 How to submit the data related to the already approved pharmaceutical products

Of the documents related to already approved drugs to be included in Module 1 of the CTD, "copy of approval document" and "related documents related to already approved matters (review report, data equivalent to Module 2 (Common Technical Document Summaries) and the attached submission data list))" can be submitted in one of the following ways. However, you are not allowed to change the submission method in the middle of the life cycle in principle.

m1-13-04-01-03.pdf

m1-13-4-2.pdf

- Include the relevant files in the "m1/jp" folder, get them referred to from the Document, and 1) associate them with the corresponding CTD headings using the Context of Use.
- Reuse the Document of the approved application to associate it with the corresponding CTD 2) heading using the Context of Use.
- 3) Include the eCTD reception number of the relevant already approved application in the id@root attribute of Application Reference.

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If the method of 3) above is adopted, any data related to the same already approved pharmaceutical product must not be included in Module 1 of CTD by 1) or 2).

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eCTD recep	otion number		
Submission	sequence		
number			
Application	category		
Application	date		
Name	Generic Name		
	Brand name		
Modules, et	c. to be included	□ Module 1	
in this submission		\Box The response to the inquiry is included.	
(Check the corresponding		\square Module 2	
module, etc	.)	\square Module 3	
		\square Module 4	
		\square Module 5	
	Electronic study data are included.		
Type of the electronic			
medium			
Number of submitted media			
Size (for each submitted			
medium)			
Statement regarding virus			
check			
Checksum of	of		
submission	unit.xml		
Operation c	onfirmation	OS:	
environmen	ıt	PDF Version:	
Contact		(Name of the regulatory representative)	Tel:
			Email:
		(Name of the technical representative)	Tel:
			Email:
Remarks			

We submit electronic application dossier for approval of manufacturing and marketing for a prescription drug according to the above.

(Date)

(Applicant) Address Name

To the Minister of Health, Labour and Welfare