

**ICH Electronic Common Technical Document (eCTD) v4.0 Implementation
Guide in Japan v1.2.0**

Provisional Translation (as of December 2017) *

DOCUMENT CHANGE HISTORY

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TABLE OF CONTENTS

1.	Purpose	8
2.	Definitions of terms, notations, symbols, etc.....	8
2.1	Terminology	8
2.2	Character notation	9
2.3	Symbol in the place of description.....	9
2.4	Color of the characters in XML snippets	9
2.5	XML element and attribute table	9
3.	General matters.....	11
3.1	Components that should be included for eCTD application.....	11
3.2	Components not to be included in eCTD to be submitted to the regulatory authority	11
3.3	Matters related to submission	11
3.3.1	Submission method via the electronic study data system	11
3.3.2	Method to deliver to the reception of PMDA	12
3.4	Operation requirements.....	12
3.5	Requirements for using eCTD.....	13
3.6	Handling of electronic signatures	13
3.7	Controlled vocabulary	13
4.	Security	13
4.1	Checksums	13
4.2	Security settings for each file:	13
5.	Requirements for the folder structure and file path contained in eCTD.....	14
5.1	Basic folder structure.....	14
5.2	Naming Conventions	15
5.3	The maximum path length.....	15
6.	Requirements for the format of the file included in eCTD.....	15
7.	Requirements for the eCTD v4.0 XML message	15
7.1	Character encode	15
7.2	Message header	15
7.3	Handling of the elements and attributes not having any value	16
7.4	How to use the XML elements and attributes included in the payload.....	16
7.4.1	Required elements (controlActProcess)	16
7.4.2	submissionUnit.....	16
7.4.2.1	Place of description on XML	16
7.4.2.2	XML snippet.....	16
7.4.2.3	XML elements and attributes	16
7.4.3	priorityNumber for contextOfUse	18
7.4.3.1	Place of description on XML	18
7.4.3.2	XML snippet.....	18
7.4.3.3	XML elements and attributes	19
7.4.4	contextOfUse.....	19
7.4.4.1	Place of description on XML	20
7.4.4.2	XML snippet.....	20
7.4.4.3	XML elements and attributes	20
7.4.5	relatedContextOfUse.....	22
7.4.5.1	Place of description on XML	22

Provisional Translation (as of December 2017) *

7.4.5.2	XML snippet.....	22
7.4.5.3	XML elements and attributes	22
7.4.6	documentReference.....	23
7.4.6.1	Place of description on XML	23
7.4.6.2	XML snippet.....	23
7.4.6.3	XML elements and attributes	24
7.4.7	Context of Use keyword.....	25
7.4.7.1	Place of description on XML	25
7.4.7.2	XML snippet.....	25
7.4.7.3	XML elements and attributes	26
7.4.8	sequenceNumber.....	27
7.4.8.1	Place of description on XML	27
7.4.8.2	XML snippet.....	28
7.4.8.3	XML elements and attributes	28
7.4.9	submission	29
7.4.9.1	Place of description on XML	29
7.4.9.2	XML snippet.....	29
7.4.9.3	XML elements and attributes	29
7.4.10	review.....	31
7.4.10.1	Place of description on XML	31
7.4.10.2	XML snippet.....	31
7.4.10.3	XML elements and attributes	32
7.4.11	manufacturedProduct.....	33
7.4.11.1	Place of description on XML	33
7.4.11.2	XML snippet.....	33
7.4.11.3	XML elements and attributes	34
7.4.12	ingredientSubstance	34
7.4.12.1	Place of description on XML	34
7.4.12.2	XML snippet.....	35
7.4.12.3	XML elements and attributes	35
7.4.13	applicant.....	36
7.4.13.1	Place of description on XML	36
7.4.13.2	XML snippet.....	36
7.4.13.3	XML elements and attributes	36
7.4.14	productCategory.....	37
7.4.14.1	Place of description on XML	37
7.4.14.2	XML snippet.....	37
7.4.14.3	XML elements and attributes	37
7.4.15	application	38
7.4.15.1	Place of description on XML	38
7.4.15.2	XML snippet.....	38
7.4.15.3	XML elements and attributes	39
7.4.16	applicationReference	41
7.4.16.1	Place of description on XML	41
7.4.16.2	XML snippet.....	41
7.4.16.3	XML elements and attributes	41

Provisional Translation (as of December 2017) *

7.4.17	document.....	43
7.4.17.1	Place of description on XML	43
7.4.17.2	XML snippet.....	43
7.4.17.3	XML elements and attributes	43
7.4.18	keywordDefinition.....	45
7.4.18.1	Place of description on XML	46
7.4.18.2	XML snippet.....	46
7.4.18.3	XML elements and attributes	46
7.4.19	categoryEvent	48
7.4.19.1	Place of description on XML	48
7.4.19.2	XML snippet.....	48
7.4.19.3	XML elements and attributes	49
8.	Reuse.....	50
8.1	Document Reuse.....	50
8.2	File Reuse.....	51
9.	Handling of the group title Keyword	51
10.	Life cycle management.....	51
10.1	Overview	51
10.2	Application life cycle and response life cycle	52
10.3	Requirements for submission of the first version of eCTD	54
10.3.1	Folder structure for submission of the first version.....	54
10.3.2	File for first version submission.....	54
10.3.3	eCTD v4.0 XML message structure for first version submission.....	54
10.3.3.1	Submission of the first version using Method 1	54
10.3.3.2	Submission of the first version using Method 2	59
10.3.3.3	Submission of the first version of the eCTD Type b)	59
10.3.3.4	Submission of the first version of the eCTD Type c)	62
10.4	Requirements for eCTD revision	62
10.4.1	Folder structure for revision	62
10.4.2	Files for revision	62
10.4.3	eCTD v4.0 XML message structure for revision.....	62
10.4.4	Information update	73
10.4.4.1	Change the display order of the Context of Use in the context group.....	73
10.4.4.2	Correct the typo in the Document title.....	73
10.4.4.3	Modify the notation of the Keyword display character string.	73
10.4.5	Migration from eCTD v3.2.2.....	73
11.	Important notes for referring to the electronic study data from the eCTD v4.0 XML message	74
12.	CoU Keyword to be assigned to the clinical study report	74
13.	Validation rules	75
14.	Inquiry	75
15.	Appendix 1: Module 1 creation guidelines	76
15.1	Overview	76
15.2	Folder structure and folder naming rules	76
15.3	File naming in Module 1	76
15.4	How to submit the data related to the already approved pharmaceutical products.....	77

Provisional Translation (as of December 2017) *

15.5 Handling of the electronic study data included in the inquiries (copy) and the responses to the inquiries (copy)	77
16. Appendix 2: Important points for utilizing eCTD v4.0 for the response to the inquiry.....	78
16.1 Overview	78
16.2 Folder structure and folder naming rules	78
16.3 Requirements for the response eCTD v4.0 XM message	78
16.3.1 Required elements (controlActProcess)	79
16.3.2 submissionUnit.....	79
16.3.2.1 XML elements and attributes	79
16.3.3 priorityNumber for contextOfUse	80
16.3.3.1 XML elements and attributes	81
16.3.4 contextOfUse.....	81
16.3.4.1 XML elements and attributes	81
16.3.5 relatedContextOfUse.....	83
16.3.5.1 XML elements and attributes	83
16.3.6 documentReference.....	84
16.3.6.1 XML elements and attributes	84
16.3.7 Context of Use keyword.....	85
16.3.7.1 XML elements and attributes	85
16.3.8 sequenceNumber.....	86
16.3.8.1 XML elements and attributes	86
16.3.9 submission	87
16.3.9.1 XML elements and attributes	87
16.3.10 application	88
16.3.10.1 XML elements and attributes	89
16.3.11 document.....	90
16.3.11.1 XML elements and attributes	90
16.3.12 keywordDefinition.....	92
16.3.12.1 XML elements and attributes	92
16.4 Reuse in the response eCTD	94
Format 1 (Cover letter for eCTD).....	95

Provisional Translation (as of December 2017) *

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Provisional Translation (as of December 2017) *

1. Purpose

This document describes handling of Appendix 3 “ICH electronic common technical document (eCTD) v4.0 Implementation guide v1.2” (hereinafter referred to as “ICH IG”) in Japan upon implementing eCTD. As a requirement for creating eCTD v4.0 XML messages and other components, it describes how the applicant should electronically submit 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 difference between the description of this document and the description of ICH IG, the description of this document shall take precedence.

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

2.1 Terminology

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

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
Electronic study data (Study dataset files)	Electronic clinical study results and associated documents
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”.

Provisional Translation (as of December 2017) *

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 in the place of description

Legends of the symbol in the place of description in 7 of this document are provided below.

Symbol	Description
>>	The element described on the right to this symbol is a child 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: <i>root</i> , <i>extension</i>
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 attributes				
Business Rules	General			
	a)			
	b)			
	c)			
	Response eCTD			

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

Attribute: It indicates the name of the attribute.

Provisional Translation (as of December 2017) *

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 multiplicity 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 Allowed 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 alphabets: Only single-byte alphabetic characters (from a to z and from A to Z) can be used.
- Single-byte numbers: Single-byte Arabic numerals (from 0 to 9) can only be used.
- Single-byte alphanumeric characters: Only single-byte alphabets and single-byte numbers can be used.

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 “multiplicity”, “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 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 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 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 of this document in addition to “business rules - General” above are shown.

Business Rules

Response eCTD: Of the business rules that should be followed upon providing the relevant element or attribute, the rules to be applied when submitting response eCTD indicated in 10.2 of this document are shown.

Provisional Translation (as of December 2017) *

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 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 Practical Operations of Electronic Study Data Submissions (About practical matters related to electronic data submission for approval application)” (PFSB/ELD Notification 0427 No.1 as of April 27, 2015 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 “Notification on Practical Operations”), 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 Practical Operations and “Technical Conformance Guide on Electronic Study Data Submissions” (PMDA/AREDPG Notification No. 0427001 as of April 27, 2015 Notification by the Director of the Advanced Review with Electronic Data Promotion Group, 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 instance among a) above.

Provisional Translation (as of December 2017) *

- 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, submit it only through 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 it 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 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 delivered to the reception of PMDA, PMDA will confirm the submission data, and if it is judged acceptable, then a seal of receipt will be affixed on the output paper of the cover letter for eCTD. The applicant shall deem reception confirmation to have been made with this seal of receipt.

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 1 eCTD, then representative application information will do.

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

3.4 Operation requirements

When making an eCTD application, you must guarantee that the functions (display, link, etc.) required by the eCTD notification will work considering the standard environment for review to be announced by the regulatory authority. Notify the regulatory authority of the environment whose operation has been confirmed via the electronic study data system in principle.

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, and the time clock during that time shall be on the applicant side. 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 web site of the regulatory authority 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.

When responding the inquiries from the regulatory authority in the review process of the eCTD application, if draft electronic study data are submitted by the applicant to the regulatory authority, then use eCTD according to this document. In this case, you cannot use eCTD to submit anything other than electronic study data (Example: The responses themselves, electronic files other than the electronic study data to be attached to the responses).

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 this and points of attention. Include an electronic file of this document in Section 13 of Module 1.

Note that you must not submit an eCTD intended for bidirectional communication described in ICH IG, the life cycle of management and submission of application data, an application associated with more than one submission and upper 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. In this case, the time clock for the time required for replacement of the data in association with removal of the electronic signature shall be on the applicant side.

3.7 Controlled vocabulary

Use the controlled vocabulary specific to Japan (hereinafter referred to as “JP CV”) in addition to the controlled vocabulary specified by ICH (hereinafter referred to as “ICH CV”). JP CV will be separately specified.

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 ICH IG.

4.2 Security settings for each file:

The applicant must not apply any file-level security settings or password protection to individual files of eCTD in principle. As an exception, there will be no problem even though other security settings (printing, document change, etc.) are applied to the references contained in Module 3, Module 4 and Module 5 if it is possible to peruse the contents of the files without the regulatory authority entering such information as the

Provisional Translation (as of December 2017) *

password and certificate. Also, if any reference is contained in Module 1, handle it similarly. Prepare a printable file so that it can be immediately submitted upon request from the regulatory authority after the application is received.

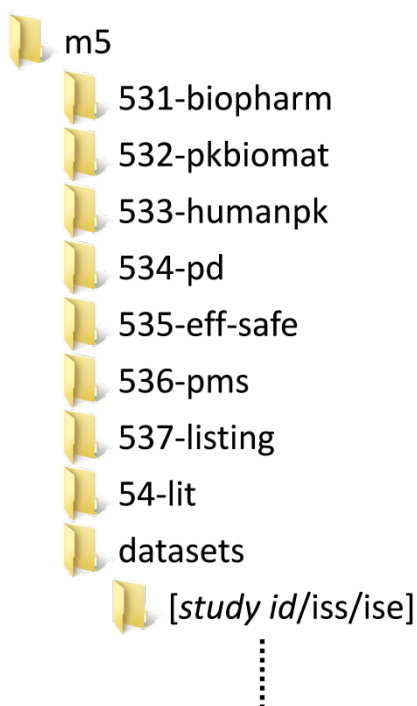
5. Requirements for the folder structure and file path contained in eCTD

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.
- The folder to store the study report of Module 5 shall have the same name as the study ID folder for the corresponding electronic study data. For the folder name for the electronic study data, refer to the technical conformance guide. The study ID, which will be the name of the study ID folder for the study report, shall be the same value as the study id part of the study id_study title Keyword to be added to the Context of Use, which refers to the relevant study report.
- As for the folder to store the study report of Module 5, if the corresponding electronic study data are divided into more than one study ID folder though there is only one report, then the study ID folder for the electronic study data and the study ID folder for the study report shall have the same structure and name. In this case, consult the review team in charge in advance about the structure of the submission package considering the browsability such as storing the same study report in each folder or storing a document stating that the report under the other study ID folder is referred to under one study ID folder. In this case, if the Document or file is reused, the structure will be different between the study ID folder for the electronic study data and the study ID folder for the study report; therefore, the reuse of neither one is permitted.
- Place the electronic study data indicated in the practical notification and the technical conformance guide 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.

Provisional Translation (as of December 2017) *



(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

For instructions to write the message / header, follow ICH IG. For the time being, the regulatory authority is not going to use the availability or value of *receiver.device.id.item@root* and *receiver.device.id.item@identifierName* for judgment about whether or not to accept it or for review.

Provisional Translation (as of December 2017) *

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.

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]...
    </component>
    <componentOf1>
      ...[Partially omitted]...
    </componentOf1>
    <componentOf2>
      ...[Partially omitted]...
    </componentOf2>
  </submissionUnit>
</subject>
```

7.4.2.3 XML elements and attributes

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

Provisional Translation (as of December 2017) *

Element	Attribute	Cardinality	Value(s) Allowed Example of value	Description
submissionUnit		[1..1]		This element stores the documents and pieces of information to be provided for the regulatory authority.
id		[1..1]		Follow the description of ICH IG.
	root	[1..1]	Valid UUID Example: root="c64abdbd-c052-439a-bbcc-e00198139790"	Follow the description of ICH IG.
code		[1..1]		Follow the description of ICH IG.
	code	[1..1]	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	[1..1]	Valid OID Example: codeSystem="2.16.840.1.113883.3.989.5.1.3.3.1.1.1"	OID of the “JP Submission Unit” code list of JP CV
title		[0..1]		Follow the description of ICH IG.
	value	[1..1]	Text Example: value="First version"	Follow the description of ICH IG.
component		[0..*]		This element stores the contextOfUse element. For details of the contextOfUse element, refer to 7.4.4 of this document.
componentOf1		[1..1]		This element stores the sequenceNumber element and the submission element. For details of the sequenceNumber element, refer to 7.4.8 of this document. For details of the submission element, refer to 7.4.9.

Provisional Translation (as of December 2017) *

Element		Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
	componentOf2		[1..1]		This element stores the categoryEvent element. For details of the categoryEvent element, refer to 7.4.19 of this document.
Submission rules for elements and attributes		<ul style="list-style-type: none"> ➤ The applicant shall determine whether to provide the submissionUnit.title element arbitrarily. ➤ If the submissionUnit.title element is provided, the following is required. <ul style="list-style-type: none"> • title@value 			
Business Rules	General	<ul style="list-style-type: none"> ➤ In addition to the business rules provided in ICH IG, the following will be applied. <ul style="list-style-type: none"> • The Submission Unit, which falls under any of the following, will be rejected. <ul style="list-style-type: none"> ✧ Multiple submissionUnit elements are provided. ✧ The submissionUnit element is not provided. ✧ The title@value attribute value has 129 characters or more. ✧ When submitting the first version, the component element is not provided. • At the time of revision, if there is no contextOfUse element to be provided, then the component element will not be provided. • The submissionUnit.statusCode element is not used. To withdraw the Submission Unit, consult the regulatory authority. • The regulatory authority does not use the submissionUnit.title@value attribute in principle. 			
	a)	There are no business rules that should be followed in addition to General above in particular.			
	b)	There are no business rules that should be followed in addition to General above in particular.			
	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 in the context group. The Context of Use will be displayed in ascending order of the Priority Number for each context group. The electronic study data will be displayed in ascending order of the folder name or the file name at the regulatory authority. The Priority Number is provided by the **priorityNumber** element.

7.4.3.1 Place of description on XML

For the place to describe the **priorityNumber** element, refer to 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>
    ...[Partially omitted]...
  </contextOfUse>
</component>
```

Provisional Translation (as of December 2017) *

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 <i>Example of value</i>	Description
priorityNumber			[1..1]		This element stores the information indicating the display order of the Contexts of Use in the context group.
		value	[1..1]	Single-byte numbers Example: <i>value="1000"</i>	Specify the integer to be used for display ordering of the Context of Use element.
		updateMode	[0..1]	Fixed <i>updateMode="R"</i>	When updating the Priority Number, specify "R".
Submission rules for elements and attributes		<ul style="list-style-type: none"> ➤ If the contextOfUse element is provided, the following is required. <ul style="list-style-type: none"> • priorityNumber@value ➤ When updating the priorityNumber@value attribute value of the already submitted Context of Use, the following is required. <ul style="list-style-type: none"> • priorityNumber@updateMode 			
Business Rules	General	<ul style="list-style-type: none"> ➤ In addition to the business rules provided in ICH IG, the following will be applied. <ul style="list-style-type: none"> • The Submission Unit, which falls under any of the following, will be rejected. <ul style="list-style-type: none"> ✧ In the same application, multiple Contexts of Use, which belong to 1 context group, have the same (value of the) Priority Number. ✧ When submitting the first version, the priorityNumber@updateMode attribute value is provided. ✧ At the time of revision, the priorityNumber@updateMode attribute value is provided, but the priorityNumber@value attribute value is not updated. • The Priority Number assigned to the Context of Use, which refers to the electronic study data, does not affect the display order of the electronic study data at the regulatory authority. 			
	a)	There are no business rules that should be followed in addition to General above in particular.			
	b)	There are no business rules that should be followed in addition to General above in particular.			
	c)	There are no business rules that should be followed in addition to General above in particular.			

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 data 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.

Provisional Translation (as of December 2017) *

7.4.4.1 Place of description on XML

For the place to describe the *contextOfUse* element, refer to 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="2.16.840.1.113883.3.989.2.2.1.1.1"/>
    <statusCode value="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 Example of value	Description
<i>contextOfUse</i>		[0..*]		This element stores the information to associate the document submitted to the regulatory authority with the CTD heading.
<i>id</i>		[1..1]		Follow the description of ICH IG.
	<i>root</i>	[1..1]	Valid UUID Example: root="7c5c61fd-5b88-4018-8323-b21f1a731880"	Follow the description of ICH IG.
<i>code</i>		[0..1]		Follow the description of ICH IG.
	<i>code</i>	[1..1]	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.
	<i>codeSystem</i>	[1..1]	Valid OID Example: codeSystem="2.16.840.1.113883.3.989.2.2.1.1.1"	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.
<i>statusCode</i>		[1..1]		Follow the description of ICH IG.

Provisional Translation (as of December 2017) *

Element	Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
	<i>code</i>	[1..1]	Single-byte alphabets <i>Example:</i> <i>code="active",</i> <i>code="suspended"</i>	Follow the description of ICH IG. If the relevant Context of Use is valid, then provide “active”, and if deleted, then provide “suspended”.
<i>replacementOf</i>		[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.
	<i>typeCode</i>	[1..1]	Fixed <i>typeCode="RPLC"</i>	This attribute is a structural attribute required to use the <i>replacementOf</i> element.
<i>derivedFrom</i>		[0..1]		This element stores the <i>documentReference</i> element. For details of the <i>documentReference</i> element, refer to 7.4.6 of this document.
<i>referencedBy</i>		[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.
	<i>typeCode</i>	[1..1]	Fixed <i>typeCode="REFR"</i>	This attribute is a structural attribute required to use the <i>referencedBy</i> element.
Submission rules for elements and attributes	<p>➤ 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.</p> <ul style="list-style-type: none"> • <i>code@code</i> • <i>code@codeSystem</i> • <i>derivedFrom</i> 			

Provisional Translation (as of December 2017) *

Element		Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
Business Rules	General	➤ In addition to the business rules provided in ICH IG, the following will be applied. <ul style="list-style-type: none"> The Submission Unit, which falls under any of the following, will be rejected. <ul style="list-style-type: none"> ✧ The <i>statusCode@code</i> attribute value is neither "active" nor "suspended". ✧ The <i>updateMode</i> attribute is provided for the Priority Number of the Context of Use, whose <i>statusCode@code</i> attribute value is "suspended", at the same time. ✧ When submitting the first version, the <i>statusCode@code</i> attribute value is "suspended". ✧ When submitting the first version, the <i>replacementOf</i> element is provided. ✧ When submitting the first version, the <i>contextOfUse</i> element not containing the <i>derivedFrom</i> element is provided. ✧ At the time of revision, the <i>replacementOf</i> element is provided under the Context of Use, whose <i>statusCode@code</i> attribute value is "suspended". 			
	a)	There are no business rules that should be followed in addition to General above in particular.			
	b)	➤ The Submission Unit, which falls under the following, will be rejected. <ul style="list-style-type: none"> The CTD heading indicated by the <i>code@code</i> attribute value does not belong to Section 3 of Module 5. 			
	c)	There are no business rules that should be followed in addition to General above in particular.			

7.4.5 relatedContextOfUse

The *relatedContextOfUse* element is used when replacing the already submitted Context of Use with a new Context of Use. *relatedContextOfUse* 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 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.

Provisional Translation (as of December 2017) *

Element	Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
<i>relatedContextOfUse</i>		[1..1]		This element stores the information on the Context of Use to be replaced.
<i>id</i>		[1..1]		Follow the description of ICH IG.
	<i>root</i>	[1..1]	Valid UUID <i>Example:</i> <i>root="d981c6a9-d57a-43cc-a71b-a8e35a34a39a"</i>	Follow the description of ICH IG.
Submission rules for elements and attributes		There are no submission rules that should be followed in addition to the contents of the above-mentioned “Cardinality”, “Value(s) Allowed” and “Description”.		
Business Rules	General	<p>➤ In addition to the business rules provided in ICH IG, the following will be applied.</p> <ul style="list-style-type: none"> The Submission Unit, which falls under any of the following, will be rejected. <ul style="list-style-type: none"> ✧ The <i>relatedContextOfUse</i> element is provided under the <i>contextOfUse</i> element whose <i>statusCode@code</i> attribute value is "suspended". ✧ The Context of Use indicated by the <i>id@root</i> attribute value belongs to a different context group. ✧ The Context of Use indicated by the <i>id@root</i> attribute value is provided in the relevant Submission Unit. ✧ The Context of Use indicated by the <i>id@root</i> attribute value is not provided through the past submission of the application with the same eCTD reception number. ✧ The Context of Use indicated by the <i>id@root</i> attribute value is deleted through the past submission of the application with the same eCTD reception number. 		
	a)	There are no business rules that should be followed in addition to General above in particular.		
	b)	There are no business rules that should be followed in addition to General above in particular.		
	c)	There are no business rules that should be followed in addition to General above in particular.		

7.4.6 documentReference

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

7.4.6.1 Place of description on XML

For the place to describe the *documentReference* element, refer to ICH IG.

7.4.6.2 XML snippet

```
<derivedFrom>
  <documentReference>
```

Provisional Translation (as of December 2017) *

```
<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.

The <i>documentReference</i> 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
<i>documentReference</i>			[1..1]		This element stores the identifier of the Document to be associated with the Context of Use.
	<i>id</i>		[1..1]		Follow the description of ICH IG.
		<i>root</i>	[1..1]	Valid UUID <i>Example:</i> <i>root="a17b06a2-a040-431d-8e5b-1f678c83af3c"</i>	Follow the description of ICH IG.
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>documentReference</i>			
Business Rules	General	➤ In addition to the business rules provided in ICH IG, the following will be applied. • The Submission Unit, which falls under any of the following, will be rejected. ✧ The Document indicated by the <i>id@root</i> attribute value does not exist in either the relevant Submission Unit or the database of the regulatory authority*. ✧ The Document indicated by the <i>id@root</i> attribute value is the Document provided through the response eCTD indicated in 10.2 of this document. ✧ When submitting the first version, the <i>contextOfUse</i> element not containing the <i>documentReference</i> element is provided. ✧ At the time of revision, the <i>documentReference</i> element is provided under the <i>contextOfUse</i> element whose <i>statusCode@code</i> attribute value is "suspended". * The regulatory authority stores the Documents submitted using eCTD v4.0 for the period of time specified by the administrative document management rules of the Ministry of Health, Labor and Welfare unless the relevant application is withdrawn.			
		a)	There are no business rules that should be followed in addition to General above in particular.		
		b)	There are no business rules that should be followed in addition to General above in particular.		
		c)	There are no business rules that should be followed in addition to General above in particular.		

Provisional Translation (as of December 2017) *

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, terminology (tabulation), 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.

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 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>
```

```
<referencedBy typeCode="REFR"/>
  <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.

Provisional Translation (as of December 2017) *

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 <i>Example of value</i>	Description
keyword		[1..1]		This element stores the information to specify additional information of the Context of Use.
code		[1..1]		Follow the description of ICH IG.
	code	[1..1]	Text <i>Example:</i> <i>code="ich_route_1",</i> <i>code="MANU001"</i>	Follow the description of ICH IG.
	codeSystem	[1..1]	Text <i>Example:</i> <i>codeSystem="My list 001"</i>	Follow the description of ICH IG.
Submission rules for elements and attributes	There are no submission rules that should be followed in addition to the contents of the above-mentioned "Cardinality", "Value(s) Allowed" and "Description".			

Provisional Translation (as of December 2017) *

Element		Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
Business Rules	General	<p>➤ In addition to the business rules provided in ICH IG, the following will be applied.</p> <ul style="list-style-type: none"> When assigning multiple keywords to 1 Context of Use, assign multiple referencedBy elements to provide the keyword element for each referencedBy element. The Submission Unit, which falls under any of the following, will be rejected. <ul style="list-style-type: none"> ✧ A keyword is provided for the CTD heading not permitted to assign any keyword by “ICH Context of Use” of ICH CV or “JP Context of Use” of JP CV. ✧ The keyword required by “ICH Context of Use” of ICH CV or “JP Context of Use” of JP CV is not assigned. ✧ Multiple CoU Keywords of the same type are assigned to 1 Context of Use. ✧ In case that there are multiple values in the relevant application for 1 type of CoU Keyword and a document is submitted for each of them, their distinction is not clearly indicated using the relevant type of CoU Keyword. (Example: In an application containing more than one drug product, multiple sections of 3.2.P are provided, but no product keyword is provided; therefore, the drug products cannot be distinguished on the CTD heading.) ✧ Any of the following keywords is provided for the Context of Use, which does not refer to the electronic study data. <ul style="list-style-type: none"> ✓ JP Study Data Category ✓ JP Analysis Type ✓ JP Japanese Character Code ✧ The JP Study Data Category Keyword is not provided for the Context of Use, which refers to the electronic study data. ✧ Only one of the JP Analysis Type Keyword and the JP Keyword Definition Type Keyword’s <code>jp_keyword_type_1</code> is provided. 			
	a)	There are no business rules that should be followed in addition to General above in particular.			
	b)	There are no business rules that should be followed in addition to General above in particular.			
	c)	There are no business rules that should be followed in addition to General above in particular.			

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 ICH IG.

Provisional Translation (as of December 2017) *

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 <i>Example of value</i>	Description
<i>sequenceNumber</i>			[1..1]		This element stores the information indicating the submission order and time series of the Submission Units in the same application.
		<i>value</i>	[1..1]	Single-byte numbers <i>Example:</i> <i>value="1"</i>	Follow the description of ICH IG.
Submission rules for elements and attributes		There are no submission rules that should be followed in addition to the contents of the above-mentioned “Cardinality”, “Value(s) Allowed” and “Description”.			
Business Rules	General	<ul style="list-style-type: none"> ➤ To make a revision, of the sequence numbers already submitted in the same application at the time of submission of the revised version, provide the numeric value obtained by adding 1 to the maximum value as the sequence number. In this case, upon identifying the already submitted Submission Unit having the maximum Sequence Number, distinction of the <i>submissionUnit.code@code</i> value does not matter. ➤ The Submission Unit, which falls under any of the following, will be rejected. <ul style="list-style-type: none"> • A value other than an integer of single-byte Arabic numerals “1” through “999999” is provided as the Sequence Number. • When submitting the first version, a value not conforming to the business rules a), b) and c) is provided as the Sequence Number. • At the time of revision, the Sequence Number is not incremented by “1”. • At the time of revision, an already submitted Sequence Number value is provided. 			
	a)	<ul style="list-style-type: none"> ➤ The Sequence Number of a) when submitting the first version shall be “1”. ➤ When re-issuing or re-submitting submissionunit.xml submitted once, provide the Sequence Number of the same value as (that of) the submissionunit.xml to be re-issued or re-submitted. 			
	b)	<ul style="list-style-type: none"> ➤ The Sequence Number of b) when submitting the first version shall be “1”. ➤ To re-issue or re-submit b) once submitted, the Sequence Number shall be always set to “1”. 			
	c)	<ul style="list-style-type: none"> ➤ The Sequence Number of c) when submitting the first version shall be “2”. ➤ To re-issue or re-submit c) once submitted, the Sequence Number shall be always set to “2”. 			

Provisional Translation (as of December 2017) *

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* >> *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>
    <code code="jp_original" codeSystem="2.16.840.1.113883.3.989.5.1.3.3.1.5.1"/>
    ...[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 Example of value	Description
submission		[1..1]		This element stores the product item information provided in association with the relevant Submission Unit.
id		[1..1]		This element stores the identifier of the relevant eCTD application.
item		[1..1]		This element stores the identifier of the relevant eCTD application.
	root	[1..1]	Valid UUID Example: <i>root</i> ="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.

Provisional Translation (as of December 2017) *

Element			Attribute	Cardinality	Value(s) Allowed Example of value	Description
			<i>extension</i>	[1..1]	Text Example: <i>extension="20160505001"</i>	eCTD reception number
	<i>code</i>			[1..1]		This element stores the positioning of the relevant eCTD application (submission of the original, submission of references, etc.).
			<i>code</i>	[0..1]	Text Example: <i>code="jp_original"</i>	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.
			<i>codeSystem</i>	[0..1]	Valid OID Example: <i>codeSystem="2.16.840.1.113883.3.989.5.1.3.3.1.5.1"</i>	OID of the “JP Submission” code list
	<i>subject2</i>			[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.
	<i>componentOf</i>			[1..1]		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 rules for elements and attributes			➤ If a new <i>review</i> element is provided or if the information on the existing <i>review</i> element and lower is changed, then the <i>subject2</i> element is required. For submission of the <i>review</i> element, refer to 7.4.10 of this document.			
Business Rules		General	➤ Provide the same value for the following attribute throughout the application regardless of change of the information under <i>submission</i> in principle. If it is necessary to change these values, consult the regulatory authority in advance. <ul style="list-style-type: none">• <i>id.item@root</i>• <i>id.item@extension</i>• <i>code@code</i>• <i>code@codeSystem</i>			

Provisional Translation (as of December 2017) *

Element	Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
	a)	➤ The Submission Unit, which falls under any of the following, will be rejected. <ul style="list-style-type: none"> The <i>id.item@root</i> attribute value is not provided. The <i>id.item@extension</i> attribute value is not provided. The <i>id.item@extension</i> attribute value is different from the eCTD reception number of the relevant application. The <i>code@code</i> attribute value is not provided. The <i>code@codeSystem</i> attribute value is not provided. When submitting the first version, the <i>subject2</i> element is not provided. 		
	b)	➤ It is not necessary to include the <i>subject2</i> element in b). Also, if the <i>subject2</i> element is included in b), the information under it is not considered to have been provided for the regulatory authority. ➤ The information under the <i>code</i> element contained in b) is not considered to have been provided for the regulatory authority.		
	c)	➤ The Submission Unit, which falls under any of the following, will be rejected. <ul style="list-style-type: none"> The <i>id.item@root</i> attribute value is not provided. The <i>id.item@extension</i> attribute value is not provided. The <i>id.item@extension</i> attribute value is different from the eCTD reception number of the relevant application. The <i>code@code</i> attribute value is not provided. The <i>code@codeSystem</i> attribute value is not provided. The <i>subject2</i> element is not included. 		

7.4.10 review

The ***review*** element provides the product item information. 1 ***subject2*** element is provided for each application, and 1 ***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* >> *submissionUnit* >> *componentOf1* >> *submission* >> *subject2* >> *review*

7.4.10.2 XML snippet

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

```

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

```

Provisional Translation (as of December 2017) *

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 <i>Example of value</i>	Description
review		[1..1]		This element stores the product item information.
id		[1..1]		This element stores the identifier of the relevant review element.
	root	[1..1]	Valid UUID <i>Example:</i> <i>root="c2a664fc-4b41-4425-8631-46b7bf1f58a6"</i>	UUID of this Review. A number is issued by the applicant according to the algorithm described in ICH IG.
statusCode		[1..1]		This element stores the information indicating the state of the application for the relevant product item.
	code	[1..1]	Single-byte alphabets <i>Example:</i> <i>code="active",</i> <i>code="suspended"</i>	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		[0..1]		This element stores the manufacturedProduct element. For details of the manufacturedProduct element, refer to 7.4.11 of this document.
holder		[0..1]		This element stores the applicant element. For details of the applicant element, refer to 7.4.13 of this document.
subject2		[0..*]		This element stores the productCategory element. For details of the productCategory element, refer to 7.4.14 of this document.

Provisional Translation (as of December 2017) *

Submission rules for elements and attributes		<ul style="list-style-type: none"> ➤ When submitting the first version, all of the above-mentioned elements and attributes are required. ➤ At the time of revision, if the <i>statusCode@code</i> attribute value is "active", all of the above-mentioned elements and attributes are required. ➤ At the time of revision, if the <i>stautsCode@code</i> attribute value is "suspended", the Submission Unit containing any of the following will be rejected. <ul style="list-style-type: none"> • <i>subject1</i> • <i>holder</i> • <i>subject2</i>
Business Rules	General	<ul style="list-style-type: none"> ➤ The Submission Unit, which falls under any of the following, will be rejected. <ul style="list-style-type: none"> • The <i>statusCode@code</i> attribute value of the <i>review</i> element provided for the first time throughout the life cycle including submission of the first version is not "active". • The <i>review.statusCode@code</i> attribute value is neither "active" nor "suspended". ➤ Provide the <i>subject2</i> element for each application category.
	a)	There are no business rules that should be followed in addition to General above in particular.
	b)	➤ It is not necessary to include the <i>review</i> element in b). Also, if the <i>review</i> element is included in b), the information under it is not considered to have been provided for the regulatory authority.
	c)	➤ All of the above-mentioned elements and attributes are required.

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.

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* >> *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>
      <name>
        <part value="Seiyakukyol tables 10mg"/>
      </name>
      <ingredient classCode="INGR">
...[Partially omitted]...
      </ingredient>
    </manufacturedProduct>
  </manufacturedProduct>
</subject1>

```

Provisional Translation (as of December 2017) *

7.4.11.3 XML elements and attributes

The **manufacturedProduct** 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
manufacturedProduct		[1..1]		This element stores the product information.
manufacturedProduct		[1..1]		This element stores the product information.
name		[1..1]		This element stores the brand name.
part		[1..1]		This element stores the brand name.
	value	[1..1]	Text <i>Example: value="Seiyakukyo tablets 10mg"</i>	The brand name of the drug product.
ingredient		[1..*]		This element stores the ingredientSubstance element. For details of the ingredientSubstance element, refer to 7.4.12 of this document.
	classCode	[1..1]	Fixed <i>classCode="INGR"</i>	This attribute is a structural attribute required to use the ingredient element.
Submission rules for elements and attributes		➤ An ingredient element is provided for each active ingredient contained in the relevant product.		
Business Rules	General	➤ The Submission Unit, which falls under the following, will be rejected. <ul style="list-style-type: none"> The part@value attribute value does not agree with the brand name stated in the application. 		
	a)	There are no business rules that should be followed in addition to General above in particular.		
	b)	➤ It is not necessary to include the manufacturedProduct element in b). Also if the manufacturedProduct element is included in b), the information under it is not considered to have been provided for the regulatory authority.		
	c)	There are no business rules that should be followed in addition to General above in 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 >> submissionUnit >> componentOf1 >> submission >> subject2 >> review >> subject1 >> manufacturedProduct >> manufacturedProduct >> ingredient >> ingredientSubstance`

Provisional Translation (as of December 2017) *

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>
</ingredient>
```

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 <i>Example of value</i>	Description
<i>ingredientSubstance</i>		[1..1]		This element stores the name of the active ingredient.
<i>name</i>		[1..1]		This element stores the name of the active ingredient.
<i>part</i>		[1..1]		This element stores the name of the active ingredient.
	<i>value</i>	[1..1]	Text <i>Example: value="E I hydrochloride"</i>	The name of the active ingredient.
	<i>code</i>	[1..1]	Single-byte alphanumeric characters <i>Example: code="jp_jan"</i>	The code indicating the type of the name of the active ingredient To be selected from the “JP Substance Name Type” code list of JP CV
	<i>codeSystem</i>	[1..1]	Single-byte alphanumeric characters <i>Example: code="2.16.840.1.113883.3.989.5.1.3.3.1.7.1"</i>	OID of the “JP Substance Name Type” code list
Submission rules for elements and attributes		There are no submission rules that should be followed in addition to the contents of the above-mentioned “Cardinality”, “Value(s) Allowed” and “Description”.		
Business Rules	General	➤ The Submission Unit, which falls under the following, will be rejected. <ul style="list-style-type: none"> The <i>part@value</i> attribute value does not agree with the non-proprietary name stated in the application. 		
	a)	There are no business rules that should be followed in addition to General above in particular.		
	b)	➤ It is not necessary to include the <i>ingredientSubstance</i> element in b). Also, if the <i>ingredientSubstance</i> element is included in b), the information under it is not considered to have been provided for the regulatory authority.		

Provisional Translation (as of December 2017) *

	c)	There are no business rules that 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 >> 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>
      <name>
        <part value="PMDA Pharmaceutical Co., Ltd."/>
      </name>
    </sponsorOrganization>
  </applicant>
</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.

Element	Attribute	Cardinality	Value(s) Allowed Example of value	Description
applicant		[1..1]		This element stores the applicant name.
sponsorOrganization		[1..1]		This element stores the applicant name.
name		[1..1]		This element stores the applicant name.
part		[1..1]		This element stores the applicant name.
value		[1..1]	Text Example: value="PMDA Pharmaceutical Co., Ltd."	The name of the applicant of the relevant application.
Submission rules for elements and attributes		There are no submission rules that should be followed in addition to the contents of the above-mentioned "Cardinality", "Value(s) Allowed" and "Description".		
Business Rules	General	➤ The Submission Unit, which falls under the following, will be rejected. <ul style="list-style-type: none"> • The part@value attribute value does not agree with the applicant name stated in the application. 		

Provisional Translation (as of December 2017) *

Element	Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
	a)	There are no business rules that should be followed in addition to General above in particular.		
	b)	➤ It is not necessary to include the <i>applicant</i> element in b). Also, if the <i>applicant</i> element is included in b), the information under it is not considered to have been provided for the regulatory authority.		
	c)	There are no business rules that 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* >> *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>
```

7.4.14.3 XML elements and attributes

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

Provisional Translation (as of December 2017) *

Element	Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
productCategory		[1..1]		This element stores the application category.
code		[1..1]		This element stores the application category.
	code	[1..1]	Single-byte alphanumeric characters <i>Example:</i> <i>code="jp_1_1"</i>	The code indicating the application category. To be selected from the “JP Product Category” code list of JP CV.
	codeSystem	[1..1]	Valid OID <i>Example:</i> <i>codeSystem="2.16.840.1.113883.3.989.5.1.3.3.1.6.1"</i>	OID of the “JP Product Category” code list.
Submission rules for elements and attributes		There are no submission rules that should be followed in addition to the contents of the above-mentioned “Cardinality”, “Value(s) Allowed” and “Description”.		
Business Rules	General	➤ The Submission Unit, which falls under the following, will be rejected. <ul style="list-style-type: none"> The application category indicated by the code@code attribute value does not agree with the application category described in the application. 		
	a)	There are no business rules that should be followed in addition to General above in particular.		
	b)	➤ It is not necessary to include the productCategory element in b). Also, if the productCategory element is included in b), the information under it is not considered to have been provided for the regulatory authority.		
	c)	There are no business rules that should be followed in addition to General above in particular.		

7.4.15 application

The **application** element provides the definition of the information provided by the relevant application and the information related to the entity of the document. 1 **submission** element always contains 1 **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 >> 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"/>
    </id>
```

Provisional Translation (as of December 2017) *

```

<code code="jp_maa_nd" 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>
</componentOf>

```

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	Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
application		[1..1]		This element stores the information on the Application provided in association with the relevant SubmissionUnit.
id		[1..1]		This element stores the identifier of the relevant eCTD application.
item		[1..1]		This element stores the identifier of the relevant eCTD application.
	root	[1..1]	Valid UUID <i>Example:</i> <i>root="492462f7-81bf-46e0-9b59-b677a86c88a4"</i>	UUID of this Application A number is issued by the applicant according to the algorithm described in ICH IG.
	extension	[0..1]	Text <i>Example:</i> <i>extension="sender-specified value"</i>	Any value assigned for the purpose of the applicant managing the application
code		[1..1]		This element stores the type of the relevant eCTD application.
	code	[0..1]	Single-byte alphanumeric characters <i>Example:</i> <i>code="jp_maa_nd"</i>	The code indicating the type of the relevant eCTD application Select the code value from the “JP Application” code list of JP CV.

Provisional Translation (as of December 2017) *

Element		Attribute	Cardinality	Value(s) Allowed Example of value	Description
		codeSystem	[0..1]	Valid OID Example: <i>codeSystem="2.16.84 0.1.113883.3.989.5.1. 3.3.1.8.1"</i>	OID of the “JP Application” code list
	reference		[0..*]		This element stores the applicationReference element. For details of the applicationReference element, refer to 7.4.16 of this document.
	component		[0..*]		This element stores the document element. For details of the document element, refer to 7.4.17 of this document.
	referencedBy		[0..*]		This element stores the keywordDefinition element. For details of the keywordDefinition element, refer to 7.4.18 of this document.
Submission rules for elements and attributes		<p>➤ If there are other applications related to the relevant application (hereinafter referred to as the “related applications”), provide a reference element for each related application. Also, provide all the related applications for each Submission Unit. For details of the related application, refer to 7.4.16 of this document.</p> <p>➤ If there are new Documents to be provided through the relevant Submission Unit, provide a component element for each Document. For details of the Document, refer to 7.4.17 of this document.</p> <p>➤ If new Keyword Definitions to be used for the relevant application are provided, provide a referencedBy element for each Keyword Definition. For details of the Keyword Definition, refer to 7.4.18 of this document.</p>			
Business Rules	General	<p>➤ Provide the same value for the following attribute throughout the application regardless of change of the information under application in principle.</p> <ul style="list-style-type: none"> • id.item@root • code@code • code@codeSystem <p>Also, if it is necessary to change these values, then consult the regulatory authority in advance.</p> <p>➤ The id.item@extension attribute is intended to be used by the applicant. You may include this attribute in the eCTD v4.0 XML message to be submitted to the regulatory authority, but the relevant attribute value is not considered to have been provided for the regulatory authority.</p>			
	a)	<p>➤ The Submission Unit, which falls under any of the following, will be rejected.</p> <ul style="list-style-type: none"> • The id.item@root attribute value is not provided. • The code@code attribute value is not provided. • The code@codeSystem attribute value is not provided. 			

Provisional Translation (as of December 2017) *

Element	Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
	b)	<ul style="list-style-type: none"> ➤ It is not necessary to include the reference element in b). Also, if the reference element is included in b), the information under it is not considered to have been provided for the regulatory authority. ➤ If the code element is included in b), the information under it is not considered to have been provided for the regulatory authority. 		
	c)	There are no business rules that should be followed in addition to General above in particular.		

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 >> 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="201600103001"/>
    <reasonCode>
      <item>
        <code code="jp_pca" codeSystem="2.16.840.1.113883.3.989.5.1.3.3.1.9.1"/>
      </item>
    </reasonCode>
  </applicationReference>
</reference>
```

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	Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
applicationReference		[1..1]		This element stores the related application information.
id		[1..1]		This element stores the identifier of the related application.

Provisional Translation (as of December 2017) *

Element		Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
		<i>root</i>	[1..1]	Single-byte alphanumeric characters <i>Example: root="201600103001"</i>	eCTD reception number of the related application
	<i>reasonCode</i>		[1..1]		This element stores the type of relationship.
	<i>item</i>		[1..*]		This element stores the type of relationship.
		<i>code</i>	[1..1]	Single-byte alphanumeric characters <i>Example: code="jp_pca"</i>	The code indicating the type of relationship with the related application indicated by <i>applicationReference.id@root</i> . Select the code value from the “JP Application Reference Reason” code list of JP CV.
		<i>codeSystem</i>	[1..1]	Valid OID <i>Example: codeSystem="2.16.840.1.113883.3.989.5.1.3.3.1.9.1"</i>	OID of the “JP Application Reference Reason” code list
Submission rules for elements and attributes		➤ If 1 related application has more than one type, provide a <i>reasonCode.item</i> element for each related type under 1 <i>applicationReference</i> element.			
Business Rules	General	➤ Provide all the related applications as of the time of submission of each Submission Unit. For example, if 2 related applications were submitted when the first version was submitted and the related applications were not described in the subsequent submission, it is interpreted as having lost the relevance after submitting the first version. ➤ The Submission Unit, which falls under any of the following, will be rejected. <ul style="list-style-type: none">• The eCTD reception number indicated by the <i>id@root</i> attribute value is provided in the relevant Submission Unit.• The application having the eCTD reception number indicated by the <i>id@root</i> attribute does not exist in the database of the regulatory authority.• The application having the eCTD reception number indicated by the <i>id@root</i> attribute was withdrawn in the past.• Multiple <i>applicationReference</i> elements having the same <i>id@root</i> attribute value are contained in 1 Submission Unit and provided.• Multiple <i>reasonCode.item</i> elements with the same combination of <i>reasonCode.item@code</i> and <i>reasonCode.item@codeSystem</i> are provided under 1 <i>applicationReference</i> element.• The eCTD reception number of an unapproved application is provided for the <i>id@root</i> attribute value of the <i>applicationReference</i> element indicating the already approved application to be submitted at the time of partial change approval application as the related type.			

Provisional Translation (as of December 2017) *

Element	Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
	a)	There are no business rules that should be followed in addition to General above in particular.		
	b)	➤ It is not necessary to include the <i>applicationReference</i> element in b). Also, if the <i>applicationRederence</i> element is included in b), the information under it is not considered to have been provided for the regulatory authority.		
	c)	There are no business rules that should be followed in addition to General above in particular.		

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 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">
      <reference value="m3/32-prod/manuf-process-and-controls.pdf"/>
      <integrityCheck>c0d5623550c997a70b62717d95fca1cada201754d1ed9fbbbfba97bfd64c
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
<i>document</i>		[1..1]		This element stores the information on the file to be submitted to the regulatory authority.
<i>id</i>		[1..1]		Follow the description of ICH IG.
	<i>root</i>	[1..1]	Valid UUID <i>Example:</i> <i>root="8505a8b2-7035-47cf-81ec-e8176e1d87be"</i>	Follow the description of ICH IG.

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Element	Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
title		[1..1]		Follow the description of ICH IG.
	value	[1..1]	Text <i>Example: value="General information"</i>	Follow the description of ICH IG.
	updateMode	[0..1]	Fixed <i>updateMode="R"</i>	When updating the title of the Document, specify "R".
	text			Follow the description of ICH IG.
		[1..1]	Fixed <i>integrityCheckAlgorithm="SHA256"</i>	Follow the description of ICH IG.
	reference			Follow the description of ICH IG.
		[1..1]	Text <i>Example: value="../m3/32-bodydata/32s-drugsub/32s1-geninfo.pdf"</i>	Specify the location of the file in the relative path format from submissionunit.xml which includes this attribute.
	integrityCheck	[1..1]	Single-byte alphanumeric characters <i>Example: <integrityCheck>c0d5623550c997a70b62717d95fca1c ada201754d1ed9fbbbfafa97 bfd64c 8ea4<integrityCheck/></i>	Follow the description of ICH IG.
	description			Follow the description of ICH IG.
		[1..1]	Text <i>Example: value="26145c7a-3dc7-404d-91c1-6e0e5c71f8f6"</i>	Follow the description of ICH IG.

Provisional Translation (as of December 2017) *

Element		Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
Submission rules for elements and attributes					<ul style="list-style-type: none"> ➤ The text element is required except for the following cases. <ul style="list-style-type: none"> • The Document is reused. • The Document title is updated. ➤ The following attributes are described in ICH IG, but even though a Submission Unit is submitted with these included, they are not considered to have been provided for the regulatory authority. <ul style="list-style-type: none"> • text@language • text@mediaType • text@updateMode
Business Rules	General				<ul style="list-style-type: none"> ➤ In addition to the business rules provided in ICH IG, the following will be applied. <ul style="list-style-type: none"> • The Submission Unit, which falls under any of the following, will be rejected. <ul style="list-style-type: none"> ✧ The title@value attribute value has 129 characters or more. ✧ The following elements are provided under the document element for which the title@updateMode attribute value is provided. <ul style="list-style-type: none"> ✓ text ✓ referencedBy ✧ The title@updateMode attribute value is provided, but the title@value attribute value is not updated. ✧ Although the title@updateMode attribute value is not provided, the id@root attribute value is the same as the id@root attribute value of the Document submitted in the past. ✧ A document element not referred to from the Context of Use of the same Submission Unit is provided. ✧ The file corresponding to the location indicated by the reference@value attribute value does not exist. ✧ The checksum indicated by the contents of the integrityCheck element is different from the checksum of the actual file. ➤ Note that even in case of a Document that refers to a file having the same checksum, if the timing of submission is different, the UUID will be different. However, it does not apply to a case where the Document is reused.
	a)				There are no business rules that should be followed in addition to General above in particular.
	b)				<ul style="list-style-type: none"> ➤ The Submission Unit, which falls under the following, will be rejected. <ul style="list-style-type: none"> • The place indicated by the reference@value attribute value is not the place to store the electronic study data.
	c)				<ul style="list-style-type: none"> ➤ The Submission Unit, which falls under the following, will be rejected. <ul style="list-style-type: none"> • The place indicated by the reference@value attribute value is the place to store the electronic study data.

7.4.18 keywordDefinition

Keyword Definition provides the definition of the keyword. The **contextOfUse** and **document** elements each 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.

Provisional Translation (as of December 2017) *

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 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"/>
    <value>
      <item code="MANU001" codeSystem="My list 001">
        <displayName value="Big Manufacturer"/>
      </item>
    </value>
  </keywordDefinition>
</referencedBy>
<referencedBy>
  <keywordDefinition>
    <code code="jp_keyword_type_2" codeSystem="2.16.840.1.113883.3.989.5.1.3.3.1.12.1"/>
    <statusCode code="active"/>
    <value>
      <item code="SDTMDATE" codeSystem="SDTMVer001">
        <displayName value="2017-01-01"/>
      </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 Example of value	Description
<i>keywordDefinition</i>		[1..1]		This element stores the definition of the keyword.
<i>code</i>		[1..1]		Follow the description of ICH IG.
	<i>code</i>	[1..1]	Text Example: <i>code="ich_keyword_type_1"</i>	Follow the description of ICH IG. Select the corresponding code from “ICH Keyword Definition Type” of ICH CV or “JP Keyword Definition Type” of JP CV.

Provisional Translation (as of December 2017) *

Element		Attribute	Cardinality	Value(s) Allowed Example of value	Description
		<i>codeSystem</i>	[1..1]	Valid OID Example: <i>codeSystem</i> ="2.16.840.1.113883.3.989.2.2.1.5.2"	Follow the description of ICH IG. Provide the OID of “ICH Keyword Definition Type” of ICH CV or OID of “JP Keyword Definition Type” of JP CV.
	<i>statusCode</i>		[1..1]		Follow the description of ICH IG.
		<i>code</i>	[1..1]	Fixed <i>code</i> ="active"	Follow the description of ICH IG.
	<i>value</i>		[1..1]		Follow the description of ICH IG.
	<i>item</i>		[1..1]		Follow the description of ICH IG.
		<i>code</i>	[1..1]	Text Example: <i>code</i> ="MANU001"	Follow the description of ICH IG. Any code value specified by the applicant
		<i>codeSystem</i>	[1..1]	Text Example: <i>codeSystem</i> ="My list 001"	Follow the description of ICH IG. The identifier of the code list, which is specified by the applicant arbitrarily.
		<i>displayName</i>	[1..1]		Follow the description of ICH IG.
		<i>value</i>	[1..1]	Text Example: <i>value</i> ="Big Manufacturer"	Follow the description of ICH IG. The display name of the keyword, which is specified by the applicant arbitrarily.
		<i>updateMode</i>	[0..1]	Fixed <i>updateMode</i> ="R"	Follow the description of ICH IG. When updating the display name of the Keyword, specify “R”.
Submission rules for elements and attributes		➤ When updating the <i>displayName@value</i> attribute value of the Keyword Definition already submitted, the following is required. <ul style="list-style-type: none">• <i>displayName@updateMode</i>			

Provisional Translation (as of December 2017) *

Element		Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
Business Rules	General				<ul style="list-style-type: none"> In addition to the business rules provided in ICH IG, the following will be applied. The Submission Unit, which falls under any of the following, will be rejected. <ul style="list-style-type: none"> ✧ The <i>value.item@code</i> attribute value has 129 characters or more. ✧ The <i>value.item@codeSystem</i> attribute value has 257 characters or more. ✧ The <i>displayName@value</i> attribute value has 129 characters or more. ✧ When submitting the first version, the <i>displayName@updateMode</i> attribute value is provided. ✧ At the time of revision, the <i>displayName@updateMode</i> attribute value is provided, but the <i>displayName@value</i> attribute value is not updated. ✧ The combination of the <i>value.item@code</i> and <i>value.item@codeSystem</i> attribute values is the same as (that of) the Keyword Definition submitted in the past in the same application, but the <i>displayName@updateMode</i> attribute is not provided.
	a)				There are no business rules that should be followed in addition to General above in particular.
	b)				<ul style="list-style-type: none"> ➤ The Keyword Definition, which defines the Keyword to be used in b), shall be provided in b). ➤ The Submission Unit with the <i>displayName@updateMode</i> attribute contained in b) will be rejected.
	c)				<ul style="list-style-type: none"> ➤ The Keyword Definition to define the Keyword to be used in c) may be submitted in b) in advance. ➤ When the Keyword to be used in b) is also to be used in c), provide the Keyword Definition supporting b) only. ➤ The Submission Unit with the <i>displayName@updateMode</i> attribute contained in c) will be rejected.

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

```


Provisional Translation (as of December 2017) *

</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 <i>Example of value</i>	Description
<i>categoryEvent</i>		[1..1]		This element stores the timing of submitting the relevant Submission Unit and the type for first version submission.
<i>code</i>		[1..1]		This element stores the timing of submitting the relevant Submission Unit.
	<i>code</i>	[1..1]	Single-byte alphanumeric characters <i>Example:</i> <i>code="jp_initial"</i>	The code indicating at what timing of the review the relevant Submission Unit was submitted Select the code value from the “JP Category Event” code list of JP CV.
	<i>codeSystem</i>	[1..1]	Valid OID <i>Example:</i> <i>codeSystem="2.16.84 0.1.113883.3.989.5.1. 3.3.1.2.1"</i>	OID of the “JP Category Event” code list
<i>component</i>		[0..1]		This element stores the positioning of the relevant Submission Unit when submitting the first version.
<i>categoryEvent</i>		[1..1]		This element stores the positioning of the relevant Submission Unit when submitting the first version.
	<i>code</i>	[1..1]		This element stores the positioning of the relevant Submission Unit when submitting the first version.
	<i>code</i>	[1..1]	Single-byte alphanumeric characters <i>Example:</i> <i>code="jp_initial_a"</i>	The code indicating the type of the relevant Submission Unit for first version submission Select the code value from the “JP Initial Submission Type” code list of JP CV.

Provisional Translation (as of December 2017) *

Element				Attribute	Cardinality	Value(s) Allowed Example of value	Description
				codeSystem	[1..1]	Valid OID Example: <i>codeSystem="2.16.84 0.1.113883.3.989.5.1. 3.3.1.3.1"</i>	OID of the "JP Initial Submission Type" code list
Submission rules for elements and attributes				<ul style="list-style-type: none"> ➤ When submitting the first version, the component element is required for any of a), b) and c) indicated in 3.3 of this document. ➤ At the time of revision, the component element must not be provided. 			
Business Rules	General			<ul style="list-style-type: none"> ➤ The componenOf2.categoryEvent.code@code attribute value indicating "first version submission", "for expert discussion "or" for the subcommittee" is provided only once throughout the life cycle in principle. If it is necessary to provide any value for multiple times in 1 eCTD application, consult the regulatory authority in advance. 			
	a)			<ul style="list-style-type: none"> ➤ If the Submission Unit to be submitted is a), the componenOf2.categoryEvent.code@code attribute value must be the code indicating a). 			
	b)			<ul style="list-style-type: none"> ➤ If the Submission Unit to be submitted is b), the componenOf2.categoryEvent.code@code attribute value must be the code indicating b). 			
	c)			<ul style="list-style-type: none"> ➤ If the Submission Unit to be submitted is c), the componenOf2.categoryEvent.code@code attribute 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 ICH IG. The Document may be reused at the applicant's discretion in principle. When reusing the Document, (all of) the conditions provided in ICH IG as well as all of the following conditions shall be satisfied.

- 1) Both the application defining the Document to be reused and the application containing the **documentReference** element, which refers to the Document to be reused, shall have been made as the originals according to the eCTD v4.0 specifications.
- 2) The **submissionUnit.code@code** value of both the submission unit defining the Document to be reused and the submission unit containing the **documentReference** element, which refers to the Document to be reused, shall be "jp_ctd".
- 3) The application data defining the Document to be reused shall be included in the scope of the documents to be stored by the regulatory authority and submitted within the specified storage period.
- 4) Any of the following conditions shall be satisfied:
 1. The application defining the Document to be reused has already been approved.
 2. The submission unit defining the Document to be reused belongs to the same application as (that of) the submission unit containing the **documentReference** element which refers to the Document to be reused.

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 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.

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.

☐ CTD heading

☐ CTD heading

☐ CTD heading

☐ Group Title node

[Document title](#)

[Document title](#)

[Document title](#)

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. However, the following keywords will be displayed under the same group title even though the code is different.

- ICH Document Type Keyword
- JP Study Data Category
- JP Analysis Type
- JP Description
- JP Terminology (Tabulation)
- JP Terminology (Analysis)
- JP Japanese Character Code

10. Life cycle management

10.1 Overview

Life cycle management for eCTD in Japan manages addition, change, etc. of application data 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 data 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 data for each file according to its attribute information when adding, changing or deleting any file that constitutes the application data.

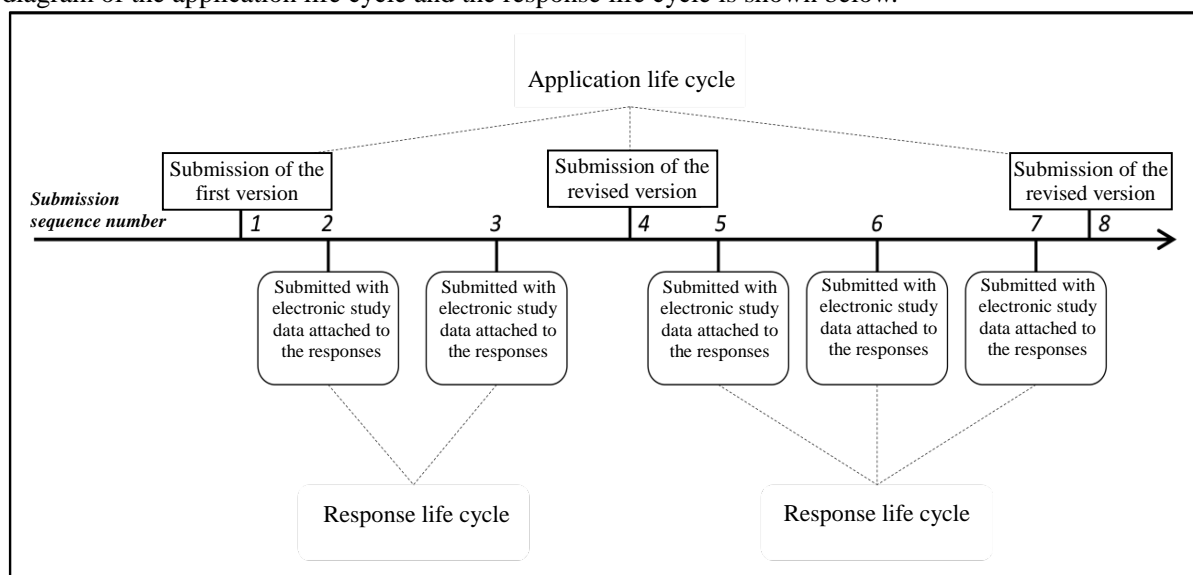
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In life cycle management of eCTD v4.0, the differential submission method is adopted for the eCTD v4.0 XML messages and files in principle. In an eCTD submission (package) after submitting the first version, the applicant shall submit the information 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 10.4 of this document.

10.2 Application life cycle and response life cycle

There are 2 types of life cycle for eCTD v4.0: The application life cycle and the response life cycle. The application life cycle is a life cycle composed of the first version and revised versions of eCTD only, and change of the application data can be traced only through the application life cycle. The response life cycle is a life cycle composed of the relevant eCTD v4.0 when utilizing eCTD v4.0 in order to submit the responses to the inquiries from the regulatory authority with electronic study data attached to them, and a function to conveniently keep track of what kind of change is going to be made to the application life cycle components (the first version and the revised versions) up to the last. You cannot use the response life cycle to submit anything other than electronic study data. (Example: The responses themselves, electronic files other than the electronic study data to be attached to the responses)

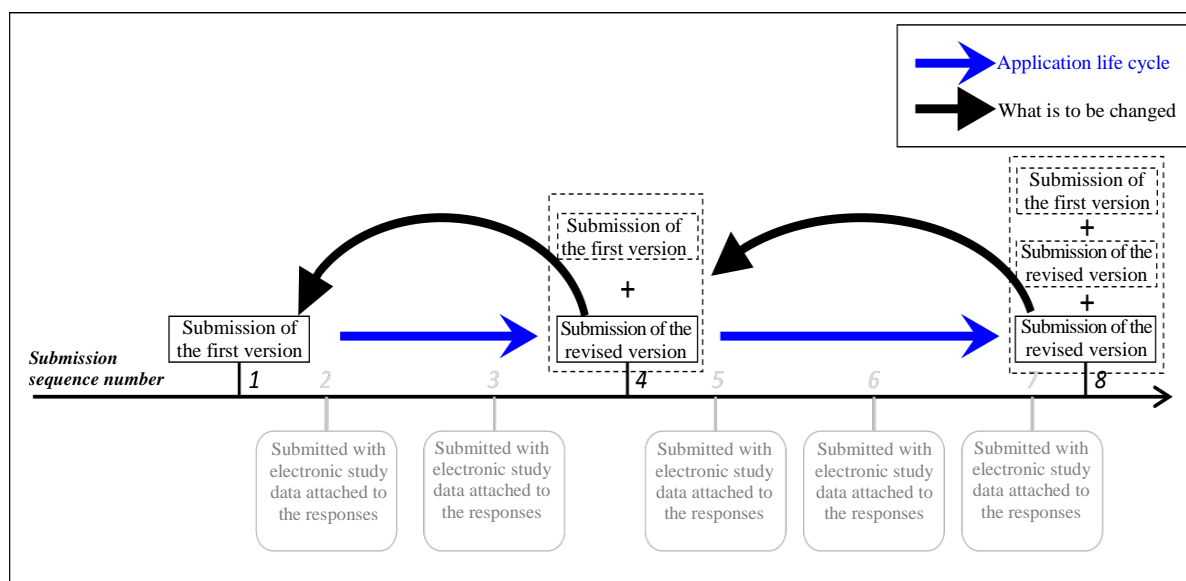
The response life cycle exists between the first version and the revised version or (between) the revised version and the subsequent revised version, and does not continue across revised versions. A concept diagram of the application life cycle and the response life cycle is shown below.



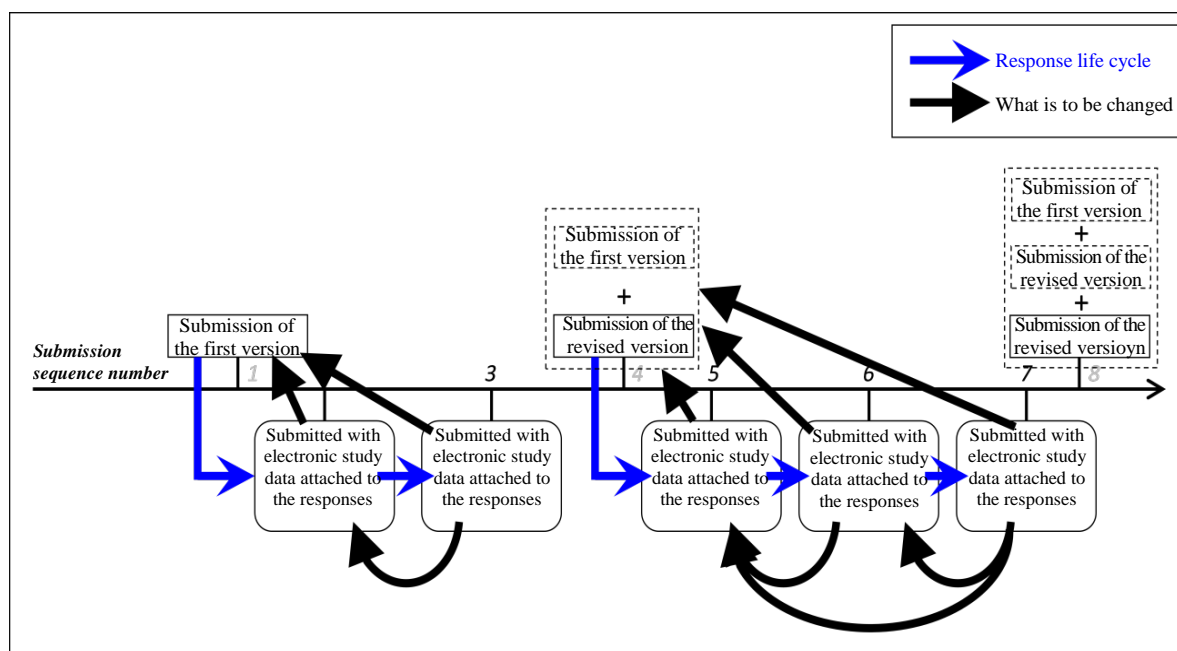
As shown in the diagram above, the submission sequence number is assigned throughout both the application life cycle and the response life cycle.

Transition by the application life cycle and transition by the response life cycle are independently managed, respectively. What is included in the scope of change in the application life cycle are the components of the application life cycle only. On the other hand, in the response life cycle, what each submission makes changes to are the components of the response life cycle which it itself belongs to or the application life cycle components up to the last. However, if the response life cycle makes changes to the application life cycle, the relevant changes are not the formal changes. In order to formally reflect the changes to the data to be attached to the application, the relevant data must be re-submitted as a component of the subsequent application life cycle.

Provisional Translation (as of December 2017) *



After submitting the first version, no matter what change is made by the eCTD to be submitted with electronic study data attached to the responses (hereinafter referred to as “response eCTD”), formal transition of the application data is executed by the application life cycle only. If the revision policies are finalized by the data submitted in the response eCTD, include the relevant data in the revised version when submitting it. In the above example, if the electronic study data submitted through the response eCTDs of submission sequence numbers 2 and 3 are appropriate as the revision policies, include the relevant electronic study data in the revised version of submission sequence number 4 again to submit it. In this case, the relevant electronic study data shall be included in Section 3 of Module 5 and shall not be included in Section 13 of Module 1 of CTD as inquiries (copy) and responses to the inquiries (copy). Also, assign a different UUID from that for response eCTD submission to the Document and Context of Use, which refer to the relevant electronic study data.



The response life cycle keeps track of the transition plans of the electronic study data submitted through the response eCTD. In the above example, the response eCTD of submission sequence number 2 provides

Provisional Translation (as of December 2017) *

change (addition, deletion, replacement, update) to the electronic study data submitted in the first version. The response eCTD of submission sequence number 3 can provide change to the first version and submission sequence number 2. The transition from the first version to submission sequence number 3 is recognized as the response life cycle, and the latest state (the state in which the first version through submission sequence number 3 are reflected) is shown to the regulatory authority. The electronic study data submitted in the response eCTD and agreed upon with the regulatory authority will be included in the subsequent revision (submission sequence number 4) for re-submission. As the response eCTD of submission sequence number 5 or later forms a new response life cycle, it is not possible to execute a change to sequence number 2 or 3.

For creation of response eCTD, refer to 16 of this document.

10.3 Requirements for submission of the first version of eCTD

10.3.1 Folder structure for submission of the first version

Create folder structure referring to 5 of this document. However, do not submit any folder storing no file.

10.3.2 File for first version submission

Create components that should be included for eCTD application referring to 3.1, 3.2, 3.3 and 6 through 7 of this document.

10.3.3 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 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.

10.3.3.1 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 of this document.

1) Example of description of the *submissionUnit* element

```
<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"/>
      <component>
        <categoryEvent>
          <code code="F" codeSystem="G"/>
        </categoryEvent>
      </component>
    </categoryEvent>
  </componentOf2>
</submissionUnit>
```

A: UUID of this Submission Unit

B: The code indicating the type of this Submission Unit (Refer to “JP Submission Unit” of JP CV)

Provisional Translation (as of December 2017) *

- C: OID of the code list defining the code of this Submission Unit (above B:)
- D: The code indicating at what timing in the review this Submission Unit was submitted (Refer to “JP Category Event” of JP CV)
- E: OID of the code list defining the code of this Category Event (above D:)
- F: The code indicating that this Submission Unit is a) indicated in 3.3 of this document (Refer to “JP Initial Submission Type” of JP CV)
- G: 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="O" codeSystem="P"/>
      </keyword>
    </referencedBy>

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

  </contextOfUse>
</component>

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

- H: The value to specify the display order if there are multiple context groups (Also describe it even if there are not more than one.)
- I: UUID of this Context of Use
- J: The code indicating the CTD heading to assign the Document specified by this Context of Use (Refer to “ICH CoU” 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
- M: The *id@root* attribute value of the Document referred to by this Context of Use
- N: Structural attribute required to use the *referencedBy* element. The value must be "REFR".
- O: Code of the keyword assigned to this Context of Use
- P: 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>
```

Provisional Translation (as of December 2017) *

```

        <item root="R" extension="S"/>
    </id>
    <code code="T" codeSystem="U"/>
    <subject2>
        <review>
            <id root="V"/>
            <statusCode code="W"/>
            <subject1>
                <manufacturedProduct>
                    <manufacturedProduct>
                        <name>
                            <part value="X"/>
                        </name>
                        <ingredient classCode="Y">
                            <ingredientSubstance>
                                <name>
                                    <part value="Z"/>
                                </name>
                            </ingredientSubstance>
                        </ingredient>
                    </manufacturedProduct>
                </manufacturedProduct>
            </subject1>
            <holder>
                <applicant>
                    <sponsorOrganization>
                        <name>
                            <part value="AA"/>
                        </name>
                    </sponsorOrganization>
                </applicant>
            </holder>
            <subject2>
                <productCategory>
                    <code code="AB" codeSystem="AC"/>
                </productCategory>
            </subject2>
        </review>
    </subject2>

```

----- (To provide more than one Ingredient Substance, repeat *ingredient*)-----

```

        </manufacturedProduct>
    </manufacturedProduct>
</subject1>
<holder>
    <applicant>
        <sponsorOrganization>
            <name>
                <part value="AA"/>
            </name>
        </sponsorOrganization>
    </applicant>
</holder>
<subject2>
    <productCategory>
        <code code="AB" codeSystem="AC"/>
    </productCategory>
</subject2>
</review>

```

----- (To provide more than one Review, repeat *subject2*)-----

```

</subject2>

```

----- (For Application, refer to 4) below) -----

```

</submission>
</componentOf1>

```

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

Provisional Translation (as of December 2017) *

- R: UUID of the submission which this Submission Unit is associated with
S: eCTD reception number
T: The code indicating the positioning of this Submission (Example: Submission of the original, submission of references, etc.) (Refer to "JP Submission" of JP CV)
U: OID of the code list defining the code of this Submission (above T:)
V: 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".
Z: Active ingredient name
AA: Applicant name
AB: The code indicating the application category (Refer to JP CV "JP Product Category")
AC: OID of the code list defining the code of this Product Category (above AB:)

4) Example of description of the *application* element

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

----- (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>
```

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

5) Example of description of the *document* element

```
<component>
```

Provisional Translation (as of December 2017) *

```
<document>
  <id root="AK"/>
  <text integrityCheckAlgorithm="AL">
    <reference value="AM"/>
    <integrityCheck>AN</integrityCheck>
  </text>

</document>
</component>

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

AK: UUID of this Document

AL: Calculation algorithm for the checksum of the file referred to by this Document. The value must be "sha256".

AM: The path of the file referred to by this Document. The path must be a relative path based on submissionunit.xml.

AN: 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="AO" codeSystem=AP"/>
    <statusCode cd="AQ"/>
    <value>
      <item code="AR" codeSystem="AS">
        <displayName value="AT"/>
      </item>
    </value>
  </keywordDefinition>
</referencedBy>

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

AO: 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)

AP: OID of the code list defining the code indicating the type of the Keyword defined by this Keyword Definition (above AO:)

AQ: Status of this Keyword Definition The value must be "active".

AR: 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.)

AS: 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 (above AR:) 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).

AT: The displayed characters corresponding to the code arbitrarily specified by the applicant, which indicates the contents of the Keyword defined by this Keyword Definition

Provisional Translation (as of December 2017) *

10.3.3.2 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 of this document.

10.3.3.3 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 4.3 of this document.

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

```
<submissionUnit>
  <id root="AU"/>
  <code code="AV" codeSystem="AW"/>

----- (For contextOfUse and submission, refer to 2) and 3) of this section, respectively) -----

  <componentOf2>
    <categoryEvent>
      <code code="AX" codeSystem="AY"/>
      <component>
        <categoryEvent>
          <code code="AZ" codeSystem="BA"/>
        </categoryEvent>
      </component>
    </categoryEvent>
  </componentOf2>
</submissionUnit>
```

AU: UUID of this Submission Unit

AV: The code indicating the type of this Submission Unit (Refer to “JP Submission Unit” of JP CV)

AW: OID of the code list defining the code of this Submission Unit (above AV:)

AX: The code indicating at what timing in this review this Submission Unit was submitted (Refer to “JP Category Event” of JP CV)

AY: OID of the code list defining the code of this Category Event (above AX:)

AZ: The code indicating that this Submission Unit is b) indicated in 3.3 of this document (Refer to “JP Initial Submission Type” of JP CV)

BA: OID of the code list defining the code of this Category Event (above AZ:)

2) Example of description of the *contextOfUse* element

```
<component>
  <priorityNumber value="BB"/>
  <contextOfUse>
    <id root="BC"/>
    <code code="BD" codeSystem="BE"/>
    <statusCode code="BF"/>
    <derivedFrom>
      <documentReference>
        <id root="BG"/>
      </documentReference>
    </derivedFrom>
    <referencedBy>
      <keyword>
        <code code="BH" codeSystem="BI"/>
      </keyword>
    </referencedBy>
  </contextOfUse>
</component>
```

Provisional Translation (as of December 2017) *

<div></keyword> </referencedBy> ----- (To provide more than one keyword, repeat <i>referencedBy</i>)----- </contextOfUse> </component> ----- (To provide more than one Context of Use, repeat <i>component</i>)-----</div>

BB: The value to specify the display order if there are multiple context groups (Also describe it even if there are not more than one.)

BC: UUID of this Context of Use.

BD: The code indicating the CTD heading to assign the Document specified by this Context of Use (Refer to “ICH CoU” of ICH CV or “JP Context of Use” of JP CV)

BE: OID of the code list defining the code of this Context of Use (above BD:)

BF: Status of this Context of Use

BG: The *id@root* attribute value of the Document referred to by this Context of Use

BH: Code of the keyword assigned to this Context of Use

BI: 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

<div><componentOf1> <sequenceNumber value="BJ"/> <submission> <id> <item root="BK" extension="BL"/> </id> <code code="BM" codeSystem="BN"/> ----- (For <i>application</i>, refer to 4) below) ----- </submission> </componentOf1></div>
--

BJ: Submission sequence number of this Submission Unit (“1” for first version application)

BK: UUID of this submission

BL: eCTD reception number

BM: The code indicating the positioning of this Submission (Example: Submission of the original, submission of references, etc.) (Refer to “JP Submission” of JP CV)

BN: OID of the code list defining the code of this Submission (above BM:).

4) Example of description of the *application* element

<div><componentOf> <application> <id> <item root="BO" extension="BP"/> </id> <code code="BQ" codeSystem="BR"/> ----- (For <i>document</i> and <i>keywordDefinition</i>, refer to 5) and 6) of this section, respectively.)-----</div>
--

Provisional Translation (as of December 2017) *

```
</application>
</componentOf>
```

BO: UUID of this Application

BP: Any value (specified) by the applicant

BQ: The code indicating the type of this Application (marketing approval application, etc.) (Refer to JP CV “JP Application”)

BR: OID of the code list defining the code of this Application (above BQ:)

5) Example of description of the *document* element

```
<component>
  <document>
    <id root="BS"/>
    <text integrityCheckAlgorithm="BT">
      <reference value="BU"/>
      <integrityCheck>BV</integrityCheck>
    </text>
  </document>
</component>
```

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

BS: UUID of this Document

BT: Calculation algorithm for the checksum of the file referred to by this Document. The value must be "sha256".

BU: The path of the file referred to by this Document. The path must be a relative path based on submissionunit.xml.

BV: 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="BW" codeSystem="BX"/>
    <statusCode cd="BY"/>
    <value>
      <item code="BZ" codeSystem="CA">
        <displayName value="CB"/>
      </item>
    </value>
  </keywordDefinition>
</referencedBy>
```

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

BW: 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)

BX: OID of the code list defining the code indicating the type of the Keyword defined by this Keyword Definition (above BW:)

BY: Status of this Keyword Definition The value must be "active".

BZ: 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.)

Provisional Translation (as of December 2017) *

CA: 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 (above BZ:) 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).

CB: The displayed characters corresponding to the code arbitrarily specified by the applicant, which indicates the contents of the Keyword defined by this Keyword Definition

10.3.3.4 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 4.3 of this document is not different from the structure of Type a) indicated in 10.3.3.1 of this document except for the following. Keep the following 2 points in your mind to refer to 10.3.3.1 of this document.

- F: The code indicating that this Submission Unit is c) indicated in 4.3 of this document (Refer to "JP Initial Submission Type" of JP CV).
- Q: Submission sequence number of this Submission Unit ("2" for first version application)

10.4 Requirements for eCTD revision

10.4.1 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 with the submission sequence number as the folder name)
- The folder storing the files to be submitted for the relevant revision and its upper folder(s)

10.4.2 Files for revision

The following files will be submitted.

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

10.4.3 eCTD v4.0 XML message structure for revision

For eCTD for revision, use Type a) indicated in 3.3 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 of the *submissionUnit* element

```
<submissionUnit>
  <id root="CC"/>
  <code code="CD" codeSystem="CE"/>
```

----- (For *contextOfUse* and *submission*, refer to 2) and 3) of this section, respectively) -----

```
  <componentOf2>
    <categoryEvent>
      <code code="CF" codeSystem="CG"/>
    </categoryEvent>
  </componentOf2>
</submissionUnit>
```

CC: 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.

CD: The code indicating the type of this Submission Unit (Refer to "JP Submission Unit" of JP CV)

Provisional Translation (as of December 2017) *

CE: OID of the code list defining the code of this Submission Unit (above CD:)

CF: The code indicating at what timing in review this Submission Unit was submitted (Refer to “JP Category Event” of JP CV)

CG: OID of the code list defining the code of this Category Event (above CF:)

2) 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 10.3.3.1 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="CH"/>
  <contextOfUse>
    <id root="CI"/>
    <statusCode code="CJ"/>
  </contextOfUse>
</component>
```

CH: 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.

CI: UUID of the Context of Use to be deleted

CJ: 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="CK"/>
  <contextOfUse>
    <id root="CL"/>
    <code code="CM" codeSystem="CN"/>
    <statusCode code="CO"/>
    <replacementOf typeCode="CP">
      <relatedContextOfUse>
        <id root="CQ">
      </relatedContextOfUse>
    </replacementOf>
  </contextOfUse>
</component>
```

Provisional Translation (as of December 2017) *

```
</replacementOf>
<derivedFrom>
  <documentReference>
    <id root="CR"/>
  </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 10.3.3 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>
```

CK: 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.

CL: UUID of the new Context of Use.

CM: The code indicating the CTD heading to assign the Document specified by the new Context of Use (Refer to "ICH CoU" 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.

CN: OID of the code list defining the code of this Context of Use (above CM:). This value must be the same between the Contexts of Use before and after replacement.

CO: Status of the new Context of Use The value must be "active".

CP: Structural attribute required to use the **replacementOf** element. The value must be "RPLC".

CQ: UUID of the old Context of Use

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

(2) Replace 1 file with multiple files.

```
<component>
  <priorityNumber value="CS"/>
  <contextOfUse>
    <id root="CT"/>
    <code code="CU" codeSystem="CV"/>
    <statusCode code="CW"/>
    <replacementOf typeCode="CX">
      <relatedContextOfUse>
        <id root="CY">
      </relatedContextOfUse>
    </replacementOf>
  </contextOfUse>
  <derivedFrom>
    <documentReference>
      <id root="CZ"/>
    </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

Provisional Translation (as of December 2017) *

the first version, refer to 10.3.3 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="DA"/>
  <contextOfUse>
    <id root="DB"/>
    <code code="DC" codeSystem="DD"/>
    <statusCode code="DE"/>
    <replacementOf typeCode="DF">
      <relatedContextOfUse>
        <id root="DG">
          </relatedContextOfUse>
        </replacementOf>
      <derivedFrom>
        <documentReference>
          <id root="DH"/>
        </documentReference>
      </derivedFrom>
    </replacementOf>
  </contextOfUse>
</component>
```

----- (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 10.3.3 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.)

CS: 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.

CT: UUID of the new Context of Use

CU: The code indicating the CTD heading to assign the Document specified by the new Context of Use (Refer to "ICH CoU" 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.

CV: OID of the code list defining the code of this Context of Use (above CM:). This value must be the same between the Contexts of Use before and after replacement.

CW: Status of the new Context of Use The value must be "active".

CX: Structural attribute required to use the **replacementOf** element. The value must be "RPLC".

Provisional Translation (as of December 2017) *

CY: 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 CY: and DG: are the same.

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

DA: Same as CS:

DB: Same as CT:

DC: Same as CU:

DD: Same as CV:

DE: Same as CW:

DF: Same as CX:

DG: Same as CY:

DH: Same as CZ:

(3) Replace multiple files with 1 file.

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

----- (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 10.3.3 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.)-----

DI: 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

Provisional Translation (as of December 2017) *

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.

DJ: UUID of the new Context of Use.

DK: The code indicating the CTD heading to assign the Document specified by the new Context of Use (Refer to "ICH CoU" 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.

DL: OID of the code list defining the code of this Context of Use (above DK:). This value must be the same between the Contexts of Use before and after replacement.

DM: Status of the new Context of Use The value must be "active".

DN: Structural attribute required to use the *replacementOf* element. The value must be "RPLC".

DO: 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.

DP: Same as DN:

DQ: Same as DO:

DR: Same as DN:

DS: Same as DO:

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

(4) Replace multiple files with multiple files.

```
<component>
  <priorityNumber value="DU"/>
  <contextOfUse>
    <id root="DV"/>
    <code code="DW" codeSystem="DX"/>
    <statusCode code="DY"/>
    <replacementOf typeCode="DZ">
      <relatedContextOfUse>
        <id root="EA">
          </relatedContextOfUse>
        </replacementOf>
      <replacementOf typeCode="EB">
        <relatedContextOfUse>
          <id root="EC">
            </relatedContextOfUse>
          </replacementOf>
        <derivedFrom>
          <documentReference>
            <id root="ED"/>
          </documentReference>
        </derivedFrom>
      </replacementOf>
    </contextOfUse>
  </component>
</component>
```

----- (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 10.3.3 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="EF"/>
  <contextOfUse>
```

Provisional Translation (as of December 2017) *

```
<id root="EG"/>
<code code="EH" codeSystem="EI"/>
<statusCode code="EJ"/>
<replacementOf typeCode="EK">
  <relatedContextOfUse>
    <id root="EL">
    </relatedContextOfUse>
  </replacementOf>
  <replacementOf typeCode="EM">
    <relatedContextOfUse>
      <id root="EN">
      </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 10.3.3 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>
```

DU: 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.

DV: UUID of the new Context of Use

DW: The code indicating the CTD heading to assign the Document specified by the new Context of Use (Refer to "ICH CoU" 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.

DX: OID of the code list defining the code of this Context of Use (above DW:). This value must be the same between the Contexts of Use before and after replacement.

DY: Status of the new Context of Use The value must be "active".

DZ: Structural attribute required to use the *replacementOf* element. The value must be "RPLC".

EA: 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.

EB: Same as DZ:

EC: Same as EA:

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

EE: Same as DU:

EF: Same as DV:

EG: Same as DW:

EH: Same as DX:

EI: Same as DZ:

EJ: Same as EA:

EK: Same as ED:

Provisional Translation (as of December 2017) *

EL: Same as DZ:

EM: Same as EA:

EN: Same as ED:

- 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="EO"/>
  <submission>
    <id>
      <item root="EP" extension="EQ"/>
    </id>
    <code code="ER" codeSystem="ES"/>

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

  </submission>
</componentOf1>
```

EO: 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)

EP: 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.

EQ: eCTD reception number It must be the same value as the eCTD reception number stated in the first version.

ER: 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.

ES: OID of the code list defining the code of this Submission (above ER:). 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="ET"/>
  <submission>
    <id>
      <item root="EU" extension="EV"/>
    </id>
    <code code="EW" codeSystem="EX"/>
    <subject2>
      <review>
        <id root="EY"/>
        <statusCode code="EZ"/>
```

Provisional Translation (as of December 2017) *

```
</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>
```

ET: 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)

EU: 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.

EV: eCTD reception number It must be the same value as the eCTD reception number stated in the first version.

EW: 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.

EX: OID of the code list defining the code of this Submission (above EW:). It must be the same value as the *code@codeSystem* attribute value stated in the first version.

EY: UUID of the Review related to the newly added product item

EZ: 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 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 only by submitting eCTD. Also, to withdraw all the product items contained in eCTD, you do not need to submit eCTD after submitting a withdrawal request.

```
<componentOf1>
  <sequenceNumber value="FA"/>
  <submission>
    <id>
      <item root="FB" extension="FC"/>
    </id>
    <code code="FD" codeSystem="FE"/>
    <subject2>
      <review>
        <id root="FF"/>
        <statusCode code="FG"/>
      </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.)-----

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

```
</submission>
</componentOf1>
```

Provisional Translation (as of December 2017) *

- FA:** 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)
- FB:** 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.
- FC:** eCTD reception number It must be the same value as the eCTD reception number stated in the first version.
- FD:** 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.
- FE:** OID of the code list defining the code of this Submission (above FD:). It must be the same value as the *code@codeSystem* attribute value stated in the first version.
- FF:** UUID of the Review related to the withdrawn product item
- FG:** 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="FH"/>
  <submission>
    <id>
      <item root="FI" extension="FJ"/>
    </id>
    <code code="FK" codeSystem="FL"/>
    <subject2>
      <review>
        <id root="FM"/>
        <statusCode code="FN"/>
        <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>
```

- FH:** 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)
- FI:** 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.

Provisional Translation (as of December 2017) *

- FJ:** eCTD reception number It must be the same value as the eCTD reception number stated in the first version.
- FK:** 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.
- FL:** OID of the code list defining the code of this Submission (above FK:). It must be the same value as the **code@codeSystem** attribute value stated in the first version.
- FM:** UUID of the Review related to the product item containing changes.
- FN:** 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>
      <item root="FO" extension="FP"/>
    </id>
    <code code="FQ" codeSystem="FR"/>
    <reference>
      <applicationReference>
        <id root="FS"/>
        <reasonCode>
          <item code="FT" codeSystem="FU"/>
        </reasonCode>
      </applicationReference>
    </reference>
  </application>
</componentOf>
```

----- (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>
```

FO: UUID of this Application

FP: Any value (specified) by the applicant

FQ: 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.

FR: OID of the code list defining the code indicating the type of this Application (above FQ:). It must be the same value as the **code@codeSystem** attribute value stated in the first version.

FS: eCTD reception number of the related application of this Application

FT: The code indicating the type of the relationship of the related application indicated in FS: above (Refer to JP CV "JP Application Reference Reason")

FU: OID of the code list defining the code of the type of relationship (above FT:)

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 10.3.3 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 to 10.4.4.2.

Provisional Translation (as of December 2017) *

- 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 10.3.3 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 to 10.4.4.3.

10.4.4 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.

10.4.4.1 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 ICH IG.

10.4.4.2 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 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 included in the already approved application.
- Update the Document title of another application.
- Update the title of the Document submitted in any other format than eCTD v4.0.
- Updating the title changes the positioning of the document instead of correction of the typo.

10.4.4.3 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 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 display character string of a certain Submission Unit only, define a new Keyword Definition. Note that modification of the notation of the Keyword display character string does not affect another application.

10.4.5 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

Provisional Translation (as of December 2017) *

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.

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. Important notes for referring to the electronic study data are provided below.

- 1) The following information must be the same between the Context of Use, which refers to the electronic study data, and the Context of Use, which refers to the report related to the relevant electronic study data.
 - ***code@code*** and ***code@codeSystem*** attribute values of the Context of Use
 - Information indicated by the following CoU Keywords
 - study id_study title
 - indication
 - site-id
 - group title
- 2) If there is an appropriate Document Type Keyword, it may be assigned as a CoU Keyword. Also, there will be no problem even if the assigned Document Type Keywords are different between the Context of Use, which refers to the electronic study data, and the Context of Use, which refers to the corresponding report.

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

Scope	Code list	Code / value	Keyword Definition
All the electronic study data	JP Study Data Category	Appropriate code	Not needed
SDTM data set	JP Keyword Definition Type	jp_keyword_type_2	Needed
ADaM data set	JP Keyword Definition Type	jp_keyword_type_3	Needed
Electronic study data in the clinical pharmacology area	JP Analysis Type	Appropriate code	Not needed
	JP Keyword Definition Type	jp_keyword_type_1	Needed
Electronic study data containing the Japanese language	JP Japanese Character Code	Appropriate code	Not needed

- 4) 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***
 - ***priorityNumebr@updateMode***
 - ***document.title@value***
 - ***document.title@updateMode***

12. CoU Keyword to be assigned to the clinical study report

When submitting the clinical study report to be included in Module 5 of CTD, which is composed of more than one file, an appropriate one of the Codes with the item number of the clinical study report provided in the column of “E3-Reference” among the “ICH Document Type” of ICH CV must be assigned as a CoU

Provisional Translation (as of December 2017) *

Keyword to the Context of Use, which refers to each file. Also, when submitting the clinical study report in 1 file, assign "ich_document_type_2" to the Context of Use, which refers to the relevant file.

13. Validation rules

In addition to the validation rules provided in ICH IG, validation rules for eCTD application in Japan are separately established.

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

Provisional Translation (as of December 2017) *

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 if necessary.

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 data 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	
1.13.1-2 Review report	m1-13-01-02.pdf	
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 (copy)	m1-13-02-XX.pdf	

Provisional Translation (as of December 2017) *

Document type	File name	Remarks
1.13.3 Inquiries (copy) and responses to the inquiries (copy)	m1-13-03-XX.pdf	
1.13.4.1.1-1 List of submission data on new additives	m1-13-04-01-01-01.pdf	
1.13.4.1.1-2 Individual review product item outline table	m1-13-04-01-01-02.pdf	
1.13.4.1.1-3 Marketing application (copy)	m1-13-04-01-01-03.pdf	
1.13.4.1.1-4 Overview of new additives	m1-13-04-01-01-04.pdf	
1.13.4.1.1 XX Data on new additives: Attached submission data XX	m1-13-04-01-01-XX.pdf	
1.13.4.1.2 List of target values / setting values, etc. in the manufacturing process column on the marketing application	m1-13-04-01-02.pdf	
1.13.4-2 Data submitted to the Ministry of Health, Labour and Welfare	m1-13-4-2.pdf	
1.13.5 Important notes on the format of eCTD, etc.	m1-13-5.pdf	

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

Of the already approved pharmaceutical products-related data to be included in Module 1 of CTD, the overview of the data and the attached submission data list may be submitted by any of the following methods. However, you are not allowed to change the submission method in the middle of the life cycle in principle.

- 1) Include the relevant files in the m1/jp folder, get them referred to from the Document, and associate them with the corresponding CTD headings using the Context of Use.
- 2) Reuse the Document of the approved application to associate it with the corresponding CTD 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.

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 eCTD by 1) or 2).

15.5 Handling of the electronic study data included in the inquiries (copy) and the responses to the inquiries (copy)

If any electronic study data are included in the response to the inquiry in the review process, include the response excluding the electronic study data in the section of the inquiries (copy) and the responses to the inquiries (copy). Include the electronic study data, which should be submitted as part of the application life cycle, in Module 5.

16. Appendix 2: Important points for utilizing eCTD v4.0 for the response to the inquiry

16.1 Overview

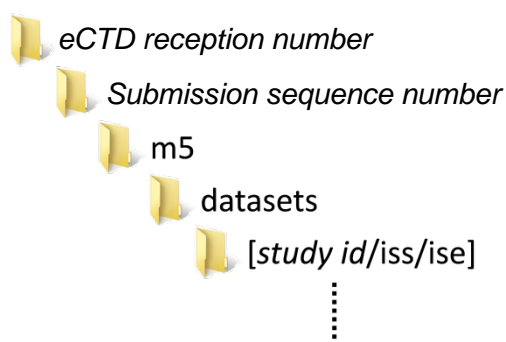
When attaching electronic study data to the response to the inquiry, the relevant electronic study data must be submitted to the regulatory authority by utilizing eCTD v4.0. For the time being, you are not allowed to use eCTD v4.0 to submit any electronic file related to the response to the inquiry other than the electronic study data (Example: The response itself, an electronic file other than the electronic study data to be attached to the response). Also, as the purpose of the response eCTD is to submit the entity of the electronic study data in principle, when submitting a response eCTD not associated with entity submission, consult the regulatory authority in advance.

In this section, the eCTD indicated in 1 through 15 of this document is conveniently called the “application eCTD”. The specifications not mentioned in this chapter are not different from (those of) the application eCTD.

16.2 Folder structure and folder naming rules

For the folder structure of the response eCTD, follow the instructions below.

- 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 of the relevant application, and the second level folder name shall be the submission sequence number. Assign the submission sequence number consistently without distinction between the application eCTD and the response eCTD. For example, when submitting a response eCTD after submitting the submission sequence numbers "1" and "2" (both are application eCTDs) by submitting the first version of eCTD application, the submission sequence number for the relevant response eCTD shall be "3". In addition, when submitting a revised version of the eCTD (application eCTD) after that, the submission sequence number for the relevant revised version shall be "4".
- Place only the "m5" folder at the third level.
- For (the structure) below the “m5” folder, follow the folder structure indicated in the technical conformance guide. An example of folder structure is shown below.



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

16.3 Requirements for the response eCTD v4.0 XM message

As the eCTD gets its life cycle uniquely managed and is intended to submit only the electronic study data to be attached to the response, some items of the structure and rules are different from those of the application eCTD. The section below provides important notes for utilizing the response eCTD.

Provisional Translation (as of December 2017) *

16.3.1 Required elements (controlActProcess)

The controlActProcess element and attribute required to start the payload of the response eCTD v4.0 XML message as well as its child element and attribute are not different from those of the application eCTD. Refer to 7.4.1 of this document.

16.3.2 submissionUnit

The Submission Unit in the response eCTD refers to a collection of the electronic study data to be provided for the regulatory authority through a single act of submission of responses. The technical specifications for the Submission Unit of the response eCTD are not substantially different from those of the application eCTD, but as the information to be submitted is limited to the electronic study data to be attached to the response, keep in mind that there are differences in the business rules, etc.

16.3.2.1 XML elements and attributes

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

Element	Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
<i>submissionUnit</i>		[1..1]		This element stores the electronic study data to be provided for the regulatory authority by attaching it to the response.
<i>id</i>		[1..1]		Follow the description of ICH IG.
	<i>root</i>	[1..1]	Valid UUID <i>Example:</i> <i>root="cb454b90-9405-454a-add0-ac473bc389fc"</i>	Follow the description of ICH IG.
<i>code</i>		[1..1]		Follow the description of ICH IG.
	<i>code</i>	[1..1]	Fixed <i>Example:</i> <i>code="jp_response"</i>	The code indicating the type of this Submission Unit Select the code value from the “JP Submission Unit” code list of JP CV. Fixed in the response eCTD
	<i>codeSystem</i>	[1..1]	Valid OID <i>Example:</i> <i>codeSystem="2.16.84 0.1.113883.3.989.5.1. 3.3.1.1.1"</i>	OID of the “JP Submission Unit” code list of JP CV
<i>title</i>		[0..1]		Follow the description of ICH IG.

Provisional Translation (as of December 2017) *

Element		Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
		value	[1..1]	Text <i>Example: value="Response on 16 Feb"</i>	Follow the description of ICH IG.
	component		[0..*]		This element stores the contextOfUse element. For details of the contextOfUse element, refer to 16.3.4 of this document.
	componentOf1		[1..1]		This element stores the sequenceNumber element and the submission element. For details of the sequenceNumber element, refer to 16.3.8 of this document. For details of the submission element, refer to 16.3.9 of this document.
Submission rules for elements and attributes		<ul style="list-style-type: none"> ➤ The applicant shall determine whether to provide the submissionUnit.title element arbitrarily. ➤ If the submissionUnit.title element is provided, the following is required. <ul style="list-style-type: none"> • title@value 			
Business Rules	Response eCTD	<ul style="list-style-type: none"> ➤ In addition to the business rules provided in ICH IG, the following will be applied. <ul style="list-style-type: none"> • The Submission Unit, which falls under any of the following, will be rejected. <ul style="list-style-type: none"> ✧ Multiple submissionUnit elements are provided. ✧ The submissionUnit element is not provided. ✧ The title@value attribute value has 129 characters or more. ✧ The component element is not provided. • At the time of revision, if there is no contextOfUse element to be provided, then the component element will not be provided. • The submissionUnit.statusCode element is not used. To withdraw the eCTD once submitted, consult the regulatory authority. • The regulatory authority does not use the submissionUnit.title@value attribute in principle. 			

16.3.3 priorityNumber for contextOfUse

As the electronic study data are displayed in ascending order of the folder name or file name at the regulatory authority, the Priority Number of the response eCTD does not make much sense to the regulatory authority. The applicant can use any value for his/her own convenience as long as it does not overlap in the same context group. The Priority Number is provided by the **priorityNumber** element. The technical specifications for the Priority Number of the response eCTD are not substantially different from those of the application eCTD, but as the information to be submitted is limited to the electronic study data to be attached to the response, keep in mind that there are differences in the business rules, etc.

Provisional Translation (as of December 2017) *

16.3.3.1 XML elements and attributes

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

Element	Attribute	Cardinality	Value(s) Allowed Example of value	Description
<i>priorityNumber</i>		[1..1]		This element Priority Number stores the information indicating the display order of the Contexts of Use in the context group.
	<i>value</i>	[1..1]	Single-byte numbers Example: <i>value="1000"</i>	The applicant specifies any integer.
Submission rules for elements and attributes		<ul style="list-style-type: none"> ➤ If the <i>contextOfUse</i> element is provided, the following is required. <ul style="list-style-type: none"> • <i>priorityNumber@value</i> ➤ It is not possible to update the <i>priorityNumber@value</i> attribute value of the already submitted Context of Use in the response eCTD. <ul style="list-style-type: none"> • <i>priorityNumber@updateMode</i> 		
Business Rules	Response eCTD	<ul style="list-style-type: none"> ➤ In addition to the business rules provided in ICH IG, the following will be applied. <ul style="list-style-type: none"> • The Submission Unit, which falls under any of the following, will be rejected. <ul style="list-style-type: none"> ✧ In the same application, multiple Contexts of Use, which belong to 1 context group, have the same (value of the) Priority Number. ✧ The <i>priorityNumber@updateMode</i> attribute value has been provided. • The Priority Number assigned to the Context of Use, which refers to the electronic study data, does not affect the display order of the electronic study data at the regulatory authority. 		

16.3.4 contextOfUse

The Context of Use of the response eCTD defines the positioning of the electronic study data to be attached to the response. The technical specifications for the Context of Use of the response eCTD are not substantially different from those of the application eCTD, but as the information to be submitted is limited to the electronic study data to be attached to the response, keep in mind that there are differences in the business rules, etc.

16.3.4.1 XML elements and attributes

The *contextOfUse* element of the response eCTD and the elements under it as well as their attributes are as follows.

Element	Attribute	Cardinality	Value(s) Allowed Example of value	Description
<i>contextOfUse</i>		[0..*]		This element stores the information to associate the electronic study data submitted to the regulatory authority with the CTD heading.

Provisional Translation (as of December 2017) *

Element	Attribute	Cardinality	Value(s) Allowed Example of value	Description
id		[1..1]		Follow the description of ICH IG.
	root	[1..1]	Valid UUID Example: root="73a24e2d-0ace-4f41-b483-957e96284a73"	Follow the description of ICH IG.
code		[0..1]		Follow the description of ICH IG.
	code	[1..1]	Text Example: code="ich_5.3.1.1"	Follow the description of ICH IG. Select the corresponding code from "ICH Context of Use" of ICH CV to provide it.
	codeSystem	[1..1]	Valid OID Example: codeSystem="2.16.840.1.113883.3.989.2.2.1.1.1"	Follow the description of ICH IG. The OID of "ICH Context of Use" of ICH CV is provided.
statusCode		[1..1]		Follow the description of ICH IG.
	code	[1..1]	Single-byte alphabets Example: 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 relatedContextOfUse element. For details of the relatedContextOfUse element, refer to 16.3.5 of this document.
	typeCode	[1..1]	Fixed typeCode="RPLC"	This attribute is a structural attribute required to use the replacementOf element.
derivedFrom		[0..1]		This element stores the documentReference element. For details of the documentReference element, refer to 16.3.6 of this document.
referencedBy		[0..*]		This element stores the keyword element. For details of the keyword element, refer to 16.3.7 of this document.

Provisional Translation (as of December 2017) *

Element		Attribute	Cardinality	Value(s) Allowed Example of value	Description
		<i>typeCode</i>	[1..1]	Fixed <i>typeCode</i> ="REFR"	This attribute is a structural attribute required to use the referencedBy element.
Submission rules for elements and attributes		<p>➤ If the <i>contextOfUse.statusCode@code</i> attribute value is "active", the following are required.</p> <ul style="list-style-type: none"> • <i>code@code</i> • <i>code@codeSystem</i> • <i>derivedFrom</i> 			
Business Rules	Response eCTD	<p>➤ In addition to the business rules provided in ICH IG, the following will be applied.</p> <ul style="list-style-type: none"> • The Submission Unit, which falls under any of the following, will be rejected. <ul style="list-style-type: none"> ✧ The <i>statusCode@code</i> attribute value is neither "active" nor "suspended". ✧ The <i>replacementOf</i> element is provided under the Context of Use, whose <i>statusCode@code</i> attribute value is "suspended". ✧ The CTD heading indicated by the <i>code@code</i> attribute value does not belong to Section 3 of Module 5. 			

16.3.5 relatedContextOfUse

The Related Context of Use of the eCTD is used when replacing the already submitted Context of Use with a new Context of Use. The technical specifications for the Related Context of Use of the response eCTD are not substantially different from those of the application eCTD, but as the information to be submitted is limited to the electronic study data to be attached to the response, keep in mind that there are differences in the business rules, etc.

16.3.5.1 XML elements and attributes

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

The <i>relatedContextOfUse</i> 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	
<i>relatedContextOfUse</i>		[1..1]		This element stores the information on the Context of Use to be replaced.	
<i>id</i>		[1..1]		Follow the description of ICH IG.	
	<i>root</i>	[1..1]	Valid UUID <i>Example:</i> <i>root</i> ="97664b8f-df6e-47fb-8976-b4c702619c4b"	Follow the description of ICH IG.	
Submission rules for elements and attributes		There are no submission rules that should be followed in addition to the contents of the above-mentioned “Cardinality”, “Value(s) Allowed” and “Description”.			

Provisional Translation (as of December 2017) *

Element		Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
Business Rules	Response eCTD	<p>➤ In addition to the business rules provided in ICH IG, the following will be applied.</p> <ul style="list-style-type: none"> The Submission Unit, which falls under any of the following, will be rejected. <ul style="list-style-type: none"> ✧ The <i>relatedContextOfUse</i> element is provided under the <i>contextOfUse</i> element whose <i>statusCode@code</i> attribute value is "suspended". ✧ The Context of Use indicated by the <i>id@root</i> attribute value belongs to a different context group. ✧ The Context of Use indicated by the <i>id@root</i> attribute value is provided in the relevant Submission Unit. ✧ The Context of Use indicated by the <i>id@root</i> attribute value is not provided through the past submission of the application with the same eCTD reception number. ✧ The Context of Use indicated by the <i>id@root</i> attribute value is deleted through the past submission of the application with the same eCTD reception number. ✧ The name of the file specified as the Document to be referred to by the Context of Use indicated by the <i>id@root</i> attribute value is different from the name of the file specified by the Document to be referred to by the replacing Context of Use. 			

16.3.6 documentReference

The Document Reference of the response eCTD specifies as Document. The technical specifications for the Document Reference of the response eCTD are not substantially different from those of the application eCTD, but as the information to be submitted is limited to the electronic study data to be attached to the response, keep in mind that there are differences in the business rules, etc.

16.3.6.1 XML elements and attributes

The *documentReference* element of the response eCTD 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
<i>documentReference</i>		[1..1]		This element stores the identifier of the Document to be associated with the Context of Use.
<i>id</i>		[1..1]		Follow the description of ICH IG.
	<i>root</i>	[1..1]	Valid UUID <i>Example:</i> <i>root="b56cb652-860a-474f-a089-1c87c9c2ade6"</i>	Follow the description of ICH IG.
Submission rules for elements and attributes	➤ If the <i>contextOfUse.statusCode@code</i> attribute value is "active", the following are required. <ul style="list-style-type: none">• <i>documentReference</i>			

Provisional Translation (as of December 2017) *

Element		Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
Business Rules	Response eCTD				<p>➤ In addition to the business rules provided in ICH IG, the following will be applied.</p> <ul style="list-style-type: none"> The Submission Unit, which falls under any of the following, will be rejected. <ul style="list-style-type: none"> ✧ The Document indicated by the <i>id@root</i> attribute value does not exist in the relevant Submission Unit. ✧ The <i>contextOfUse</i> element not containing the <i>documentReference</i> element has been provided. ✧ The <i>documentReference</i> element is provided under the <i>contextOfUse</i> element whose <i>statusCode@code</i> attribute value is "suspended".

16.3.7 Context of Use keyword

The CoU Keyword of the response eCTD provides additional information to the electronic study data to be submitted. The technical specifications for the CoU Keyword of the response eCTD are not substantially different from those of the application eCTD, but as the information to be submitted is limited to the electronic study data to be attached to the response, keep in mind that there are differences in the business rules, etc.

16.3.7.1 XML elements and attributes

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

as well as their attributes are as follows.					
Element	Attribute	Cardinality	Value(s) Allowed Example of value	Description	
keyword		[1..1]		This element stores the information to specify additional information of the Context of Use.	
	code	[1..1]		Follow the description of ICH IG.	
		code	[1..1]	Text Example: code="ich_route_1", code="MANU001"	Follow the description of ICH IG.
		codeSystem	[1..1]	Text Example: codeSystem="My list 001"	Follow the description of ICH IG.
Submission rules for elements and attributes		There are no submission rules that should be followed in addition to the contents of the above-mentioned “Cardinality”, “Value(s) Allowed” and “Description”.			

Provisional Translation (as of December 2017) *

Element		Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
Business Rules	Response eCTD				<p>➤ In addition to the business rules provided in ICH IG, the following will be applied.</p> <ul style="list-style-type: none"> When assigning multiple keywords to 1 Context of Use, assign multiple referencedBy elements to provide the keyword element for each referencedBy element. The Submission Unit, which falls under any of the following, will be rejected. <ul style="list-style-type: none"> ✧ The CoU Keyword is not assigned. ✧ The JP Study Data Category Keyword is not provided. ✧ Only one of the JP Analysis Type Keyword and the JP Keyword Definition Type Keyword's <code>jp_keyword_type_1</code> is provided. ✧ The keyword required by "ICH Context of Use" of ICH CV is not assigned. ✧ Multiple CoU Keywords of the same type are assigned to 1 Context of Use. ✧ In case that there are multiple values in the relevant application for 1 type of CoU Keyword and a document is provided for each of them, their distinction is not clearly indicated using the relevant type of CoU Keyword. (Example: In an application containing more than one indication, multiple sections of 5.3.5 are provided, but no Indication Keyword is provided; therefore, the indications cannot be distinguished on the CTD heading.)

16.3.8 sequenceNumber

The Sequence Number of the response eCTD 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 Sequence Number is assigned consistently without distinction between the response eCTD and the application eCTD. The technical specifications for the Sequence Number of the response eCTD are not substantially different from those of the application eCTD, but as the information to be submitted is limited to the electronic study data to be attached to the response, keep in mind that there are differences in the business rules, etc.

16.3.8.1 XML elements and attributes

The **sequenceNumber** element of the response eCTD 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
sequenceNumber		[1..1]		This element stores the information indicating the submission order and time series of the Submission Units in the same application.
	value	[1..1]	Single-byte numbers <i>Example: value="3"</i>	Follow the description of ICH IG.

Provisional Translation (as of December 2017) *

Element	Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
Submission rules for elements and attributes				There are no submission rules that should be followed in addition to the contents of the above-mentioned “Cardinality”, “Value(s) Allowed” and “Description”.
Business Rules	Response eCTD			<ul style="list-style-type: none"> ➤ Of the sequence numbers already submitted in the same application at the point of time when submitting the relevant Submission Unit, provide the numeric value obtained by adding 1 to the maximum value as the sequence number. In this case, upon identifying the already submitted Submission Unit having the maximum Sequence Number, distinction of the <i>submissionUnit.code@code</i> value does not matter. ➤ The Submission Unit, which falls under any of the following, will be rejected. <ul style="list-style-type: none"> • Value other than an integer of single-byte Arabic numerals “2” through “999999” is provided as the Sequence Number. • The Sequence Number is not incremented by “1”. • An already submitted Sequence Number value is provided.

16.3.9 submission

As only the electronic study data to be attached to the response is submitted for the response eCTD, addition or change to the information related to the Submission is not submitted through the response eCTD. Therefore, Submission of the response eCTD provides the minimum information only. The technical specifications for the Submission of the response eCTD are not substantially different from those of the application eCTD, but as the information to be submitted is limited to the electronic study data to be attached to the response, keep in mind that there are differences in the business rules, etc.

16.3.9.1 XML elements and attributes

The *submission* element of the response eCTD 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
<i>submission</i>		[1..1]		This element stores the product item information provided in association with the relevant Submission Unit.
<i>id</i>		[1..1]		This element stores the identifier of the relevant eCTD application.
<i>item</i>		[1..1]		This element stores the identifier of the relevant eCTD application.
	<i>root</i>	[1..1]	Valid UUID <i>Example:</i> <i>root=" a7290861-7f38-47a2-9c7c-76d378ea5afe"</i>	UUID of this submission A number is issued by the applicant according to the algorithm based on the standard specifications provided in ICH IG.

Provisional Translation (as of December 2017) *

Element			Attribute	Cardinality	Value(s) Allowed Example of value	Description
			<i>extension</i>	[1..1]	Text Example: <i>extension="20160505001"</i>	eCTD reception number
	<i>code</i>			[1..1]		This element stores the positioning of the relevant eCTD application (submission of the original, submission of references, etc.).
			<i>code</i>	[0..1]	Text Example: <i>code="jp_original"</i>	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.
			<i>codeSystem</i>	[0..1]	Valid OID Example: <i>codeSystem="2.16.840.1.113883.3.989.5.1.3.3.1.5.1"</i>	OID of the “JP Submission” code list
		<i>componentOf</i>		[1..1]		This element stores the <i>application</i> element. For details of the <i>application</i> element, refer to 16.3.10 of this document.
Submission rules for elements and attributes			<ul style="list-style-type: none">➤ It is not necessary to include the <i>subject2</i> element in the response eCTD. Also, if the <i>subject2</i> element is included in the response eCTD, the information under it is not considered to have been provided for the regulatory authority.➤ The information under the <i>code</i> element of the response eCTD is not considered to have been provided for the regulatory authority.			
Business Rules	Response eCTD	<ul style="list-style-type: none">➤ Submit the same value for the following attribute throughout the application regardless of change of the information under <i>submission</i> in principle. If it is necessary to change these values, consult the regulatory authority in advance.<ul style="list-style-type: none">• <i>id.item@root</i>• <i>id.item@extension</i>➤ The Submission Unit, which falls under any of the following, will be rejected.<ul style="list-style-type: none">• The <i>id.item@root</i> attribute value is not provided.• The <i>id.item@extension</i> attribute value is not provided.• The <i>id.item@extension</i> attribute value is different from the eCTD reception number of the relevant application.				

16.3.10 application

The **application** element of the response eCTD provides the electronic study data submitted through the relevant Submission Unit and the Keyword Definition. The technical specifications for the Application of the response eCTD are not substantially different from those of the application eCTD, but as the

Provisional Translation (as of December 2017) *

information to be submitted is limited to the electronic study data to be attached to the response, keep in mind that there are differences in the business rules, etc.

16.3.10.1 XML elements and attributes

The **application** 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
application		[1..1]		This element stores the information on the Application provided in association with the relevant SubmissionUnit.
id		[1..1]		This element stores the identifier of the relevant eCTD application.
item		[1..1]		This element stores the identifier of the relevant eCTD application.
	root	[1..1]	Valid UUID <i>Example:</i> <i>root="cca6ff73-6ffb-409d-b60b-39283dc89e2f"</i>	UUID of this Application A number is issued by the applicant according to the algorithm described in ICH IG.
	extension	[0..1]	Text <i>Example:</i> <i>extension="sender-specified value"</i>	Any value assigned for the purpose of the applicant managing the application
code		[1..1]		This element stores the type of the relevant eCTD application.
	code	[0..1]	Single-byte alphanumeric characters <i>Example:</i> <i>code="jp_maa_nd"</i>	The code indicating the type of the relevant eCTD application Select the code value from the “JP Application” code list of JP CV.
	codeSystem	[0..1]	Valid OID <i>Example:</i> <i>codeSystem="2.16.840.1.113883.3.989.5.1.3.3.1.8.1"</i>	OID of the “JP Application” code list
component		[0..*]		This element stores the document element. For details of the document element, refer to 16.3.11 of this document.

Provisional Translation (as of December 2017) *

Element		Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
	<i>referencedBy</i>		[0..*]		This element stores the keywordDefinition element. For details of the keywordDefinition element, refer to 16.3.12 of this document.
Submission rules for elements and attributes		<ul style="list-style-type: none"> ➤ It is not necessary to include the reference element in the response eCTD. Also, if the reference element is included in the response eCTD, the information under it is not considered to have been provided for the regulatory authority. ➤ If there is a new Document to be submitted through the relevant Submission Unit, provide a component element for each Document. For details of the Document, refer to 16.3.11 of this document. ➤ If a new Keyword Definition to be used for the relevant application is submitted, provide a referencedBy element for each Keyword Definition. For details of the Keyword Definition, refer to 16.3.12 of this document. 			
Business Rules	Response eCTD	<ul style="list-style-type: none"> ➤ Submit the same value for the following attribute throughout the application regardless of change of the information under application in principle. <ul style="list-style-type: none"> • id.item@root Also, if it is necessary to change this value, then consult the regulatory authority in advance. ➤ If the code element is included in the response eCTD, the information under it is not considered to have been provided for the regulatory authority. When including the code element in the response eCTD, submit the same value throughout the application. ➤ The id.item@extension attribute is intended to be used by the applicant. You may include this attribute in the response eCTD v4.0 XML message to be submitted to the regulatory authority, but the relevant attribute value is not considered to have been provided for the regulatory authority. 			

16.3.11 document

For the Document of the response eCTD, the specified files are limited to the electronic study data. The technical specifications for the Document of the response eCTD are not substantially different from those of the application eCTD, but as the information to be submitted is limited to the electronic study data to be attached to the response, keep in mind that there are differences in the business rules, etc.

16.3.11.1 XML elements and attributes

The **document** element of the response eCTD 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		[1..1]		This element stores the information on the file to be submitted to the regulatory authority.
	<i>id</i>		[1..1]		Follow the description of ICH IG.

Provisional Translation (as of December 2017) *

Element	Attribute	Cardinality	Value(s) Allowed Example of value	Description
	<i>root</i>	[1..1]	Valid UUID Example: root="6b0b4fe8-9603-4d45-8be3-ec063e82659a"	Follow the description of ICH IG.
	<i>title</i>			Follow the description of ICH IG.
		[0..1]		
		[0..1]	Text Example: value="ae"	Follow the description of ICH IG.
	<i>updateMode</i>	[0..1]	Fixed updateMode="R"	When updating the title of the Document, specify "R".
	<i>text</i>			Follow the description of ICH IG.
		[1..1]		
	<i>integrityCheckAlgorithm</i>	[1..1]	Fixed integrityCheckAlgorithm="SHA256"	Follow the description of ICH IG.
	<i>reference</i>			Follow the description of ICH IG.
		[1..1]	Text Example: value="../m5/datasets/study001/tabulations/sdtm/ae.xpt"	Specify the location of the file in the relative path format from submissionunit.xml which includes this attribute.
	<i>integrityCheck</i>	[1..1]	Single-byte alphanumeric characters Example: <integrityCheck>fa06926df12aec4356890d4847d43f79101c93548a6b65e4b57bcb651294beef<integrityCheck/>	Follow the description of ICH IG.
	<i>description</i>			Follow the description of ICH IG.
		[0..1]		
	<i>value</i>	[1..1]	Text Example: 26145c7a-3dc7-404d-91c1-6e0e5c71f8f6	Follow the description of ICH IG.

Provisional Translation (as of December 2017) *

Element		Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
Submission rules for elements and attributes					<ul style="list-style-type: none"> ➤ The text element is required. ➤ It is not necessary to include the title element in the response eCTD. Also, if the title element is included in the response eCTD, the information under it is not considered to have been provided for the regulatory authority. ➤ The following attributes are described in ICH IG, but even though a Submission Unit is submitted with these included, they are not considered to have been provided for the regulatory authority. <ul style="list-style-type: none"> • text@language • text@mediaType • text@updateMode
Business Rules	General				<ul style="list-style-type: none"> ➤ In addition to the business rules provided in ICH IG, the following will be applied. <ul style="list-style-type: none"> • As the file name is utilized for the display name of the electronic study data in the environment of the regulatory authority, the title element is not needed. The applicant may submit the title element for his/her convenience. For the business rules for that case, refer to the title element in the application eCTD. • The Submission Unit, which falls under any of the following, will be rejected. <ul style="list-style-type: none"> ✧ A document element not referred to from the Context of Use of the same Submission Unit is provided. ✧ The file corresponding to the location indicated by the reference@value attribute value does not exist. ✧ The place indicated by the reference@value attribute value is not the place to store the electronic study data. ✧ The checksum indicated by the contents of the integrityCheck element is different from the checksum of the actual file. ➤ Note that even in case of a Document that refers to a file having the same checksum, if the timing of submission is different, the UUID will be different. However, it does not apply to a case where the Document is reused.

16.3.12 keywordDefinition

The Keyword Definition of the response eCTD provides the definition of the keywords to be used in the relevant response life cycle. Although the Keyword Definition provided in the past through the application eCTD of the same application can be utilized in the response eCTD, the Keyword Definition provided through the response eCTD cannot be utilized in the application eCTD. The technical specifications for the Keyword Definition of the response eCTD are not substantially different from those of the application eCTD, but as the information to be submitted is limited to the electronic study data to be attached to the response, keep in mind that there are differences in the business rules, etc.

16.3.12.1 XML elements and attributes

The **keywordDefinition** element of the response eCTD 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
keywordDefinition			[1..1]		This element stores the definition of the keyword.
	code		[1..1]		Follow the description of ICH IG.

Provisional Translation (as of December 2017) *

Element	Attribute	Cardinality	Value(s) Allowed Example of value	Description
	code	[1..1]	Text Example: code="jp_keyword_ty pe_1"	Follow the description of ICH IG. Select the corresponding code from "JP Keyword Definition Type" of JP CV.
	codeSystem	[1..1]	Valid OID Example: codeSystem="2.16.84 0.1.113883.3.989.5.1. 3.3.1.12.1 "	Follow the description of ICH IG. The OID of "JP Keyword Definition Type" of JP CV is provided.
	statusCode	[1..1]		Follow the description of ICH IG.
	code	[1..1]	Fixed code="active"	Follow the description of ICH IG.
	value	[1..1]		Follow the description of ICH IG.
	item	[1..1]		Follow the description of ICH IG.
	code	[1..1]	Text Example: code="Description1"	Follow the description of ICH IG. Any code value specified by the applicant
	codeSystem	[1..1]	Text Example: codeSystem="My list 002"	Follow the description of ICH IG. The identifier of the code list, which is specified by the applicant arbitrarily.
	displayName	[1..1]		Follow the description of ICH IG.
	value	[1..1]	Text Example: value=" PK analysis data set (ADaM format)"	Follow the description of ICH IG. The display name of the keyword, which is specified by the applicant arbitrarily.
	updateMode	[0..1]	Fixed updateMode="R"	Follow the description of ICH IG. When updating the display name of the Keyword, specify "R".
Submission rules for elements and attributes		<p>➤ When updating the displayName@value attribute value of the Keyword Definition already submitted in the same response life cycle, the following is required.</p> <ul style="list-style-type: none"> • displayName@updateMode 		

Provisional Translation (as of December 2017) *

Element		Attribute	Cardinality	Value(s) Allowed <i>Example of value</i>	Description
Business Rules	General				<ul style="list-style-type: none"> • In addition to the business rules provided in ICH IG, the following will be applied. • The Submission Unit, which falls under any of the following, will be rejected. <ul style="list-style-type: none"> ✧ The <i>value.item@code</i> attribute value has 129 characters or more. ✧ The <i>value.item@codeSystem</i> attribute value has 257 characters or more. ✧ The <i>displayName@value</i> attribute value has 129 characters or more. ✧ The <i>displayName@updateMode</i> attribute value is provided, but the <i>displayName@value</i> attribute value is not updated. ✧ The combination of the <i>value.item@code</i> and <i>value.item@codeSystem</i> attribute values is the same as (that of) the Keyword Definition submitted in the past in the same application, but the <i>displayName@updateMode</i> attribute is not provided.

16.4 Reuse in the response eCTD

Documents or files must not be reused in the response eCTD. Also, the Documents or file submitted through the response eCTD must not be reused in the application eCTD.

Format 1 (Cover letter for eCTD)

eCTD reception number		
Submission sequence number		
Application category		
Application date		
Name	Generic Name	
	Brand name	
Modules, etc. to be included in this submission (Check the corresponding module, etc.)		<input type="checkbox"/> Module 1 <input type="checkbox"/> The response to the inquiry is included. <input type="checkbox"/> Module 2 <input type="checkbox"/> Module 3 <input type="checkbox"/> Module 4 <input type="checkbox"/> Module 5 <input type="checkbox"/> 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 submissionunit.xml		
Operation confirmation environment		CPU: _____ Memory (RAM) capacity: _____ OS: _____ Browser: _____ (Version: _____) PDF Version: _____
Contact	(Name of the regulatory representative)	Tel: _____ Fax: _____ Email: _____
	(Name of the technical representative)	Tel: _____ Fax: _____ Email: _____
Remarks		

We submit electronic study data for approval of manufacturing / import of pharmaceutical products according to the above.

(Date)

(Applicant)

Address

Name

(Seal)

To the Minister of Health, Labour and Welfare