Provisional Translation (as of March 2025) *

Appendix 2

Specification for Submission Formats for eCTD in Japan v1.3.1

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

DOCUMENT CHANGE HISTORY

Version No.	Date	Overview
1.1.0	July 5, 2017	First version
1.2.0	Feb 19, 2020	Revisions due to consistency with ICH SSF v1.2
1.3.0	Feb 6, 2023	・ Changes in the notation of the notification name, etc., due to the revision of the electronic study data-related notification ・ Added “4.4 Security” section
1.3.1	Mar 10, 2025	・ Revisions due to the name change, the “FD application software” to the “Electronic Application Software for Pharmaceuticals, etc.”

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1. Purpose

This document describes handling of Appendix 4 "ICH M8 Expert Working Group Specification for Submission Formats for eCTD v1.3" (hereinafter referred to as "ICH SSF") in Japan upon implementing eCTD. It describes the format of the electronic data containing the information on approval application for pharmaceutical products to be submitted by the applicant to the Regulatory Authority. This document shall be used together with ICH SSF. If there is any difference between the description of this document and the description of ICH SSF, the description of this document shall take precedence.

2. Electronic study data (study dataset files)

For the specifications required for electronic study data, refer to "Technical Conformance Guide on Electronic Study Data Submissions" (PMDA/CPE Notification No. 0401003 and PMDA/CRS Notification No.0401001 as of April 1, 2022 Notification by the Director Center for Product Evaluation, Director of Center for Regulatory Science, Pharmaceuticals and Medical Devices Agency) (hereinafter referred to as "Technical Conformance Guide"), the manuals published on the Web site of the Regulatory Authority and FAQ as well as Section 4 of this document.

3. File format for any other data than the electronic study data

Of the data included in eCTD, if it is necessary to submit any other data than the electronic study data in any other file format than the PDF format or the Microsoft Office format, then consult the Regulatory Authority in advance. However, this does not apply to the eCTD XML instance (index.xml, jp-regional-index.xml, submissionunit.xml, etc.), check sum files (md5.txt, sha256.txt, etc.), DTD, Schema and the style sheet.

4. PDF

The PDF to be submitted to the Regulatory Authority shall be created based on the ICH M2 recommendation "File Format Recommendation - PDF" and ICH SSF in principle. However, if it is difficult to create it based on these, consult the Regulatory Authority in advance. As for Annotated CRF, it may be created as a PDF with annotations. This section describes the specifications that should be followed in addition to these.

4.1. Fonts

4.1.1. Recommended Japanese fonts

The recommended Japanese fonts shall be Unicode-supported MS Gothic, MS Mincho or Medium Gothic and Fine Mincho. English fonts shall be created according to ICH SSF.

ICH SSF contains a description about subset embedding in the Japanese environment, but as font set embedding makes the file size large as stated in the notification, recommended Japanese fonts in Japanese (documents) are specified above to avoid font set embedding as much as possible. Note that this does not prevent any other Japanese font sets than the recommended from being used. If only the recommended Japanese font sets are used in the document, it is not necessary to use any font embedding. When using any other font than the recommended Japanese fonts in Japanese, use sub-set embedding, which embeds only the characters used.

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4.1.2. Font size of the text

The font size of the text, which is to be used for a Japanese document, shall be 10.5pts in principle. However, use a readable size of the font for a diagram, etc., (For example, 8 pts or greater).

4.1.3. Color of the font

Follow the description of ICH SSF in principle. The designation of the hypertext links shall be based on the description of ICH SSF, but it is desirable to use blue fonts. Also, do not apply unnecessary character decoration to the font.

4.2. Bookmarks

Follow the description of ICH SSF in principle. If judged to be useful for review, you may set up a bookmark beyond the 4th layer. It is not necessary to set up any bookmark across other files such as the table of contents for the entire module. However, when composing the same document (See M4 Granularity Annex) with more than one physical file due to file size restrictions, either set up a bookmark for the entire same document or make it possible to recognize that it is composed of more than one file.

4.3. Hypertext linking

Follow the description of ICH SSF in principle. A hypertext links within the same document (same PDF file) or between different documents (different PDF files) shall be properly set up to make the review efficient. Set up a hypertext links from Module 2 to Module 3 through 5 as much as possible.

4.4. Security

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 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.

4.5. Handling of the data created in the past

Of the reports, etc. to be attached to Module 3, Module 4 and Module 5, you may include the data already created as paper media before March 2006 in eCTD if readable even in PDF other than that of the specifications provided in this document (PDF created through scanning, etc.). Create a PDF file from an electronic file for any data created after that (text PDF) in principle.

5. About files specific to Japan

5.1. Patients list

The file format for the case list shall be the PDF format, but if it is judged that it is necessary to carry out a review, we may request you to separately submit it in the Microsoft Excel format. In this case, you do not need to make the appearance, etc. completely agree with the already submitted PDF file, but there shall be no contradiction in the contents between the files in both formats.

5.2. Attached submission data list

A list of attached submission data shall be submitted in the PDF format and the Excel format. Upon creating a list in the Excel format, accommodate the following items in 1 line so that data can be sorted and extracted.

Items for the attached submission data list:

1. Attached submission data number
2. Title
3. Author
4. Period to conduct study
5. Place to conduct study
6. Report type (domestic, overseas)
7. The magazine carrying the articles
8. Whether it is evaluation data or reference data
9. Whether or not electronic study data are submitted

5.3. Marketing application form (copy)

As for a copy of the marketing application, in principle, attach the information output from the Electronic Application Software for Pharmaceuticals, etc., in the PDF format.