

ICH M8: eCTD IWG/EWG

第43回 ICH即時報告会

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PMDA 審査マネジメント部

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Topics

- June 2021 Updates
- 今後の予定
- 国内実装状況

June 2021 Updates

- 対面およびバーチャル会合は実施せず、隔週のWeb会議およびメールにて各種ドキュメント類に合意
- 下記の文書またはパッケージが更新された:
 - eCTD v4.0 Change Request/Q&A v1.5 (step 4)
 - Specification for Submission Formats for eCTD document v1.3 (step 4)
 - eCTD v4.0 Implementation Package v1.4 (step 4)

June 2021 Updates

- eCTD v4.0 Change Request/Q&A v1.5
 - v1.4から2件のChange request追加
 - v1.4で反映できていなかった点含めeCTD v4.0 Implementation Package v1.4及びSpecification for Submission Formats for eCTD v1.3へ全て反映される
- Specification for Submission Formats for eCTD document v1.3
 - PDF注釈の制限事項からAnnotated CRFsを除外
 - セキュリティについて電子署名PDFに関する記載の追記
- eCTD v4.0 Implementation Package v1.4
 - 主な構成物、更新点は次スライドへ

June 2021 Updates

▪ 主な構成物 - eCTD v4.0 Implementation Package v1.4

Document	Version	Format
eCTD v4.0 Implementation Guide	1.4	PDF
eCTD v4.0 Controlled Vocabularies	1.4	Spreadsheet
eCTD v3.2.2 Transition Mapping Message Controlled Vocabularies	1.4	Spreadsheet
Genericcode Files	-	Folder and files
Package History	-	PDF

- ESTRIに6/17時点で掲載済み、以下より取得可能
 - ICH electronic Common Technical Document - eCTD v4.0
 - <https://www.ich.org/page/ich-electronic-common-technical-document-ectd-v40>

June 2021 Updates

- 主な更新点は以下のとおり:
 - ICH eCTD v4.0 Implementation Guide
 - Address Media Type in IG
 - Document Reuse/File Reuse (within application and across applications - regional)
 - Business Rules/Validation Rules
 - Keyword Type Constraints (00580 & 00590)
 - Required keywords
 - Study Id Study Title validation
 - Allowable Characters
 - Controlled Vocabularies , Genericcode Files
 - Document Types (00600) - M8 CL3 ich-document.gc_v2.xml (update) and M8 CL3 ich-document-tmm.gc_v3.xml (update)
 - Added CDISC – SDTM, SEND and ADAM
 - Media Type (00600) - M8 media-type.gc_v1.xml (remove)
 - Context of Use correction (00570) – remove excipient under 3.2.p.5
 - Implementation Guide OID – corrected assignment (both TMM and v4.0)

今後の予定

- 下記ドキュメントが新たに提出された場合、都度議論および更新する予定：
 - Change request for v3.2.2 Q&A
 - Change request for v4.0 Q&A

国内実装状況

2021年7月時点におけるスケジュール（案）

	Year 2020				2021				2022				2023				2024				2025				2026							
	Quarter 1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4				
ICHガイダンス更新																																
国内通知発出																																
eCTD v4.0 システム構築・改修																																
eCTD v4.0 パイロット																																
eCTD v3.2.2申請																																
eCTD v4.0 申請																																
eCTD v3.2.2/4.0 経過措置期間																																

今ココ
(2021年7月現在)

参考) 他極の実装状況

Region	Technical Pilot ¹	Implementation Dates ²	Implementation Documents
ANVISA, Brazil	2Q 2023 (Planned)	3Q 2023 (Production Pilot) 2023 (Voluntary)	TBD
EC, Europe		TBD	EC, Europe regional implementation page
FDA, United States	2022 (Planned)	2023 (Voluntary) 2028 (Mandatory)	FDA, United States regional implementation page
Health Canada, Canada	2022 (Planned)	2023 (Voluntary) 2026 (Mandatory)	Health Canada, Canada regional implementation page
MHLW/PMDA, Japan	2021 (Planned)	2022 (Voluntary) 2026 (Mandatory)	MHLW/PMDA, Japan regional implementation page
Swissmedic, Switzerland	2022 (Planned)	2023 (Voluntary) 2027 (Mandatory)	Swissmedic, Switzerland regional implementation page
TGA, Australia	TBD	2023 (Voluntary)	2022 (Planned)

¹ A Technical pilot includes industry parties (participation may be limited in some regions) who will submit sample/test submissions. The objective of this testing is to determine if the implementation satisfies the requirements in the technical specification, and make any changes prior to accepting eCTD v4.0 submissions in the production environment.

² A Production pilot includes industry parties (participation may be limited in some regions) who will submit submissions to the regulator for regulatory review. The objective of this testing is to ensure that the production environment is ready for a full release, and to accept the production volume of submissions.

Voluntary dates indicate when eCTD v4.0 submissions will be accepted into the production environment after all pilots are complete.

Mandatory dates indicate when all submissions will be required to be in the eCTD v4.0 format.

TBD = Dates and/or materials are not yet known or not ready for public release, respectively.

This information will be updated biannually based on the progress of ongoing implementation activities.

[Updated January 2021]

(出典 : <https://www.ich.org/page/ich-electronic-common-technical-document-ectd-v40>)

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- ご静聴ありがとうございました