Release notes for version 6 of the Harmonised Technical Guidance for eCTD Submissions in the EU

November 2024

Section of the document	Change
Header	Version updated from 5 to 6
2.5.1 Document granularity	Corrected the link to the ICH Granularity Document
2.9.2 File formats	Updated the entire sub-chapter with the latest information (other file formats exceptionally accepted), including the link to the Annex "EU Accepted file formats for eCTD"
2.9.4 Sequence numbers	Added clarification for when a sequence should be re-submitted with the same sequence number or with a different one
2.9.5 Related sequence	Added clarification on the relationship between submission unit type and the related sequence
	Added a new table (number 4): "Example of a Variation for CAPs/NAPs"
2.9.6 Leaf lifecycle operation attributes	Small editorial changes
2.9.7 Bookmarks and Hypertext Links	ICH link updated
2.9.9 Extensible Mark-up Language (XML)	ICH link updated
2.9.10 Other file formats	Renamed the chapter to "Working documents"
	For EMA led procedures, note added related to the validation reports ("validation reports must NOT be included in the workingdocuments folder")
	Small editorial changes
2.9.11 Technical Validation of eCTD Submissions	Clarification added related to the structure of the submission folder
2.12.1 Portals/Gateways	Small editorial changes (added "pam-sda" as an alternative name for Signal detection)
3.2.3.1 Cover letter	Small editorial changes
Tables	A new table introduced after Table 3, therefore all the other tables shifted one number