HTA CG | MEMBER STATE COORDINATION GROUP ON HEALTH TECHNOLOGY ASSESSMENT

Annex 2 to Guidance on filling in the JCA dossier template – Medical products
Technical specifications for dossier submission

V1.0

10 October 2024

Adopted on 28 November 2024 by the HTA CG pursuant to Article 3(7), point (d), of Regulation (EU) 2021/2282 on Health Technology Assessment

Technical specifications for dossier submission

This document describes technical requirements for the HTD submission dossier to support the submission process and ensure a transparent and reproducible organisation of the submitted material.

Appendix D Underlying documentation

All files submitted should be readable, saveable and printable without the need for a password. PDF-documents created by the HTD should also be navigable, electronically annotable and electronically extractable. In addition, these documents should not contain any watermarks. The documents should also be legible when printed. In particular, sufficient point size of the fonts and sufficient resolution of the illustrations should be ensured.

The specifications below partly include a structure of files with several levels. How this will be implemented (e.g. by meta-data or folders) needs to be clarified.

Where the underlying documentation should be provided per PICO, the structure and the naming should follow the respective PICO.

D.1 Full texts of references

The „full texts of references“ should list all sources cited and listed in the corresponding reference list of the dossier

The individual full texts should be provided in PDF-format.

The files should be named as follows:

D.1 Full texts of reference
#reference-No#_#FirstAuthor#_#YYYY#.pdf
#reference-No#_#FirstAuthor#_#YYYY#.pdf
#reference-No#_#FirstAuthor#_#YYYY#.pdf

#reference No# should be replaced with the number of the full text in the reference list in Chapter 6. First author# should be the surname of the first author of the publication. If there is no first author for the source, 'Anonymous' or, if applicable, the institution responsible for the source may be given. YYYYY#' should be replaced by the year of publication or, if applicable, the year of creation of the publication. If neither the date of publication nor the date of creation is known, '0000' can be used.

In addition, a RIS file of the reference list should be provided. The file should be named as follows:

D.1._referencelist.ris

D.2 Documentation of information retrieval

D.2.1 Documentation of search strategies for each information source

D.2.2 Results of the information retrieval in standard format

The documentation of the information retrieval should be provided as described below. If separate searches were performed for different research questions (e. g. per PICO) or different types of evidence (e. g. for RCTs and other studies), the documentation of these searches should be provided separately.

D.2. Documentation of information retrieval		
Search		
	D.2.1. Documentation of search strategies for each information source	
		#search#_#information source#
		#search#_#information source#
		#search#_#information source#
	D.2.2. Results of the information retrieval in standard format	
		#search#_#information source#_results.ris
		#search#_#information source#_results.ris
		#search#_#information source#_results.ris

#search# should be replaced by an informative title identifying the search that is documented. #information source# should be replaced by name of the information source.

All search results should be provided as RIS files. The file is supposed to be named as follows:

D.2#search#_#information source#_results.ris

D.3 Programming code for programs used for analyses

This appendix should provide program code and relevant output if the analyses and corresponding calculations cannot be described by a specific standard method.

The program codes and relevant materials including input data and outputs should be structured and named as follows:

D.3 Programming code for programs used for analyses	
#ID analysis#	
	#ID#_#informative title#.#xxx#
	#ID#_#Informative_title#.#xxx#
	#ID#_#Informative_title#.#xxx#
#ID analysis#	
	#ID#_#Informative_title#.#xxx#
	#ID#_#Informative_title#.#xxx#
	#ID#_#Informative_title#.#xxx#

#ID# should be replaced with an identifier of the analysis to which the material relates. #Informative_title# should be replaced by a clear, preferably descriptive title of the content. This can be, for example, programme code, input data or outputs. #xxx# should be replaced by the respective file extension.

D.4 Study reports for original clinical studies

This appendix should provide CSRs, including study protocols and statistical analysis plans, referred to Annex I, point (b), of the HTAR.

The complete study reports according to ICH E3 including the associated appendices should be enclosed for all studies of the HTD as listed in Section 5.1.1 of the dossier. This comprises studies included in the JCA as well as those excluded from the JCA by the HTD. Appendix D.4 should also include the CSRs from the submission file to EMA.

The table of contents for the appendices, with the details of all associated appendices, may not be removed or otherwise altered. If the study protocol or the statistical analysis plan for a study is not included in the associated appendix, it should be enclosed separately. If reports according to ICH E3 are not available, study reports with a similar level of detail as study reports according to ICH E3 should be enclosed.

The study reports should be structured and named as follows:

D.4. Study reports for original clinical studies; CSR

#STUDYNAME-1#	
	#STUDYNAME-1#_pdf
	#STUDYNAME-1#_#Appendix#.pdf
	#STUDYNAME-1#_#SAP_Version#.pdf
	#STUDYNAME-1#_#SP#.pdf
	#STUDYNAME-1#_#...#.pdf
#STUDYNAME-2#	
	#STUDYNAME-2#_#CSR#.pdf
	#STUDYNAME-2#_#Appendix#.pdf
	#STUDYNAME-2#_#SAP_Version#.pdf
	#STUDYNAME-2#_#SP#.pdf
	#STUDYNAME-2#_#...#.pdf
#STUDYNAME-3#	
	…
	…

#STUDYNAME-1# should be replaced by the name of the study.

If the study report is submitted in several PDFs, the name of the PDFs should be adjusted according to the content of the file (e.g., #CSR_body_of_report#, #Appendix_appendix_no#, #SP_Version_2.0#).

D.5 Study reports for evidence synthesis studies

This appendix should provide all up-to-date published and unpublished information and data-analyses, including study protocols and statistical analysis plans, referred to in Annex I, point (b), of the HTAR required for evidence synthesis studies.

The complete study reports of evidence syntheses including the associated appendices should be enclosed for the included evidence synthesis studies. If the study protocol or the statistical analysis plan for a study is not included in the associated appendix, it should be enclosed separately.

The study reports should be structured and named as follows:

D.5. Study reports for evidence synthesis studies	
#STUDYNAME-1#	
	#STUDYNAME-1#_#Evidence synthesis report#.pdf
	#STUDYNAME-1#_#Appendix#.pdf
	#STUDYNAME-1#_#SAP_Version#.pdf
	#STUDYNAME-1#_#SP#.pdf
	#STUDYNAME-1#_#...#.pdf
#STUDYNAME-2#	
	#STUDYNAME-2#_#Evidence synthesis report#.pdf
	#STUDYNAME-2#_#Appendix#.pdf
	#STUDYNAME-2#_#SAP_Version#.pdf
	#STUDYNAME-2#_#SP#.pdf
	#STUDYNAME-2#_#...#.pdf
#STUDYNAME-3#	
	…
	…

#STUDYNAME-1# should be replaced by the name of the study.

If the study report is submitted in several PDFs, the name of the PDFs should be adjusted according to the content of the file (e.g., #CSR#, #Appendix#, #SP_Version_2.0#).

D.6 Clinical safety and efficacy data included in the submission file to the EMA

This appendix should provide Modules 2.5, 2.7.3 and 2.7.4 of the CTD (format of submission to the EMA) and CSRs (see Section C.4 Study reports in the CSR). For each study, the CSR should be provided only once.

The CTD Modules should be structured and named as follows:

D.6 Clinical safety and efficacy data included in the submission file to the EMA
CTD Module_2.5
CTD Module_2.7.3
CTD Module_2.7.4

The CTD also includes CSRs, however, these do not need to be provided again if they are already available in Appendix D.4. Appendix D.6 should also include a list of CSRs included in the CTD with a reference to Appendix D.4. If any CSRs from the CTD are not provided in Appendix D.4 this should be justified in this list.

D.7 HTA reports of the medicinal product subject to the JCA

The included HTA reports should be structured and named as follows:

D.7 HTA reports of the medicinal product subject to the JCA
#No#_#HTA-Report#_#YYYY#.pdf
#No#_#HTA-Report#_#YYYY#.pdf

#No# should be replaced by the number under which it is listed in the reference list. #HTA-Report# should be replaced by a descriptive short title of the included HTA Report. '#YYYY#' should be replaced by the year of publication. If the publication date in unknown, '0000' can be entered.

D.8 Information on studies based on registries

This appendix should include studies with the medicinal product from patient registries, if available.

D.8 Information on studies based on registries
#STUDYNAME-1#.pdf
#STUDYNAME-2#.pdf

#STUDYNAME-1# should be replaced by the name of the study.

D.9 Information on JSCs

The „Joint Scientific Consultation Outcome document" should be included as PDF.