Guidance on the Submission Process for Clinical Trials with Medicinal Products

FO submission form

Please note that since September 2021 only the **FO submission form** can be used for the submission concerning Clinical Trials with medicinal products.
All other Forms are not accepted and the submission is rejected.
The **FO submission form** is an active PDF and this single form applies for all submissions (New Clinical Trials Applications, Changes and Reporting to approved clinical trials, SUSAR reporting and Temporary Authorization Projects.
The Form (no scan and no digital signature) is to be filed in the 00F folder together with the Form signature page.

Folder structure (eDok_KLV)

All documents to be submitted must be inserted into the eDok_KLV folder structure shown below as an example. The folder structure (eDok_KLV zip file) and the "Instructions for filling the eDok_KLV folder structure" can be downloaded on our homepage.

Folder name	Subfolder name	Folder content
00F		Application form as PDF (no scan, no electronic signature) Scanned signature page of application form
01CL		Cover Letter
02EC		EC Correspondence
03RA		Foreign Regulatory Authorities
04P	41_TP	Trial protocol
	42_MP	Master Protocol
	43_TPA	Appendices to Trial Protocol or Master Protocol
05S	51_IB	Investigator's Brochure
	52_SmPC	SmPC or Information for healthcare professionals
06G	61_GMP_DS	GMP Documents DS
	62_GMP_DP	GMP Documents DP
	63_GMP_P_L	GMP Documents Packaging, Labeling
	64_GMP_rel	GMP Documents Release
07Q	71_sIMPD	TOC_s-IMPD_components
	72_one_doc	TOC_Full IMPD
	73_m3	TOC_IMPDs with m3-Structure
08LA		Labels
09PM		Pharmacy Manual
10ASR		ASR/DSUR
11USM		Urgent Safety Measures
12RAD		Radiopharmaceuticals
13SUSAR		SUSARs (CIOMS Form)
14FSR		Final Clinical Study Report
15ISR		Interim Reports
16DIL		Dear Investigator Letter
17PIP		Pediatric Investigational Plan
18SA		Scientific Advice
19TOX		Toxicology Reports, PK/PD modelling Reports
20TA		Temporary Authorization
21MEP		Medical Devices

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Information on the submission of electronic documents	
File names	The maximum path length is 180 characters. In addition to the specified path, this results in **a maximum length of 60 characters** (incl. file extension) for the file names. Paths should generally be kept as short as possible to avoid technical problems. If possible, the content of the document should be recognisable via the file name.
File formats	As a rule, **only PDF** is permitted as a file format. Preference is given to documents with a digital origin, but scanned documents are also accepted. However, scanned documents must comply with the OCR standard, i.e. the text **must be searchable as text.**
File size	The maximum file size per PDF **must not exceed 200MB**. Larger files must be split.
Preparing the submission	The individual documents must be integrated into the eDok_KLV folder structure according to the "Instructions for filling the eDok_KLV folder structure". Only study documents may be placed in the folders. **Documents with the content "this folder is empty", or "this folder is NA" must not be placed in the folders.** No empty folders must be submitted. **Empty folders must be deleted from the structure.** 1. Submission with CD via mail: The eDok_KLV structure must be transferred to a CD. The Form **FO Confirmation electronic submission** is to be filled in, printed and signed by wet ink signature. This form is to be submitted in paper form and sent together with the CD containing all electronic documentation. 2. Submission via Swissmedic Portal: The eDOK_KLV structure can be uploaded on the Swissmedic Portal. For more details, please refer to www.swissmedic.ch > Services & lists > Submissions > Applications for clinical trials for medicinal products and www.swissmedic.ch > Services & lists > eGov services > Swissmedic Portal > Registration for the Swissmedic Portal
Information on the submission of paper documents	
Preparing the submission	**The submission in paper form is not mandatory** **For submission of a new clinical trials application CTA)** one copy of each document (A4), punched and filed in a 2-hole ring binder (binder spine 7 cm) with 20-part number index. The registers must be filled according to the "Instructions for filling the eDok_KLV folder structure".

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	Documents for register 21 (=Medical Devices) must be provided in a separate folder. Please do not use index pockets or loose-leaf binders for the individual documents. **For submissions concerning authorized clinical trials** see instruction on our web page: Home > Human medicines > Clinical trials Clinical trials on medicinal products > Submission of changes during the clinical trial and reporting
Addressee of the submission	
CD (electronic documents) and paper documents to: Swissmedic Operational Support Services Hallerstrasse 7 3012 Bern Schweiz	

Change history

Version	Valid and binding as of:	Description, comments (by author)	Author's initials
2.0	19.06.2023	Electronic submission via Swissmedic Portal Update	plp
1.1	19.12.2022	VM ID update and content correctionos	plp
1.0	23.11.2022	SAP submission process and eDok_KLV structure	gav

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