

Guidance on the new submission process

New FO-Form

The previous FO forms

"Application Form for clinical trials on medicinal products / transplant products / gene therapy / GMO",

"Reporting Related to a Clinical Trial",

"Submission of Changes to a Clinical Trial and Answer to Conditions",

"Submission of Changes to a Temporary use project and Answer to Conditions

"SUSAR Accompanying Form,

"Application form for temporary authorisation of use of an unauthorised medicinal product / transplant product / gene therapy /GMO)",

"Category B clinical trials with medicinal products that may emit ionising radiation", and

"Administrative changes (incl. sponsorship and Swiss rep.)"

will now be replaced by a single "active PDF" VO form.

Please note that only the new application form may be filed in the 01FM folder as an active PDF (only one document, no additional scan). The signature page of the application form with a valid signature and any other forms must be filed in the 02FO folder.

New folder structure

All documents to be submitted must be inserted into the folder structure shown below The folder structure (zip file) and the "Instructions for filling the eDoc folder structure" can be downloaded on our [homepage](#).

Folder name	Subfolder name	Folder content
00F	01FM	Application form
	02FO	Scan signature page of application form, other forms
01CL		Cover Letter
02EC		EC Correspondence
03RA		Foreign Regulatory Authorities
04P	41TP	Trial protocol
	42MP	Master Protocol
	43TPA	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_IMPDPs 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
20TA		Temporary Authorization
21MEP		Medical Devices

Information on the submission of electronic documents on CD/DVD

File names	<p>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.</p> <p>Paths should generally be kept as short as possible to avoid technical problems. If possible, the content of the document should be recognizable via the file name.</p>
File formats	<p>As a rule, only PDF is permitted as a file format.</p> <p>No zip files may be present within the eDoc.</p> <p>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 text.</p>
File size	<p>The maximum file size per PDF must not exceed 200MB. Larger files must be split.</p>
Preparing the submission	<p>The individual documents must be integrated into the eDoc folder structure according to the "Instructions for filling the eDoc folder structure".</p> <p>Study documents must be placed in the corresponding folders. All empty folders must be deleted from the structure.</p> <p>For the submission, the eDoc structure must be transferred to a CD/DVD (no zip files).</p>

Information on the submission of paper documents

The submission of the single paper document "Confirmation electronic submission" (available on our homepage) is the minimum requirement **(A)**. Alternatively, a full paper submission **(B)** is allowed. Please see details below.

(A) (Recommended) Submission of the document "Confirmation electronic submission"	<p>Please complete and sign (wet-ink) the form "Confirmation electronic submission". This form <u>does not</u> need to be additionally scanned and submitted electronically.</p>
(B) Full paper submission	<p>Please submit one copy of each document (A4), punched and filed in a 2-hole ring binder (binder spine 7 cm) with 20-part number index.</p> <p>The section dividers are to be filled according to the "Instructions for filling the eDoc folder structure".</p> <p>Documents for section dividers 21 (=Medical Devices) must be provided in a separate folder/binder.</p> <p>Please do not use index pockets or loose-leaf binders for the individual documents.</p>

Addressee of the submission

Please send the CD/DVD (electronic submission documents) **AND** the wet-ink signed paper form "Confirmation electronic submission" (or alternatively: the full paper documentation) via **postal mail** to:

**Swissmedic
Hallerstrasse 7
3012 Bern
Schweiz**