

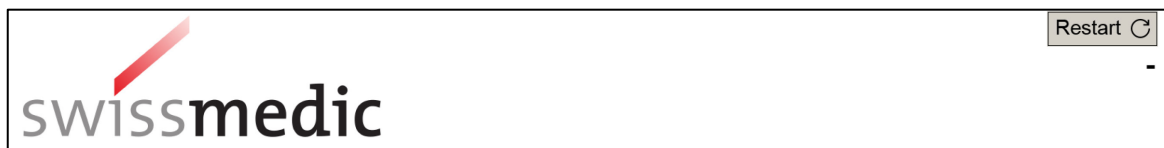
Quick instruction for use of the FO submission form

1 Overview of types of submissions

There is only one form for all possible submissions to clinical trials with Medicinal Products or ATMPs (Advanced Therapy Medicinal Products). See picture below.

ATMPs are transplant products (TpP), gene therapy medicinal products (GT), genetically modified organisms (GMO), other novel therapeutic products (mRNA or DNA products), oligonucleotides, CRISPR/Cas, wild-type viruses/bacteria, bacteriophages, pathogen inactivation procedures, or procedures for non-standardisable medicinal products.

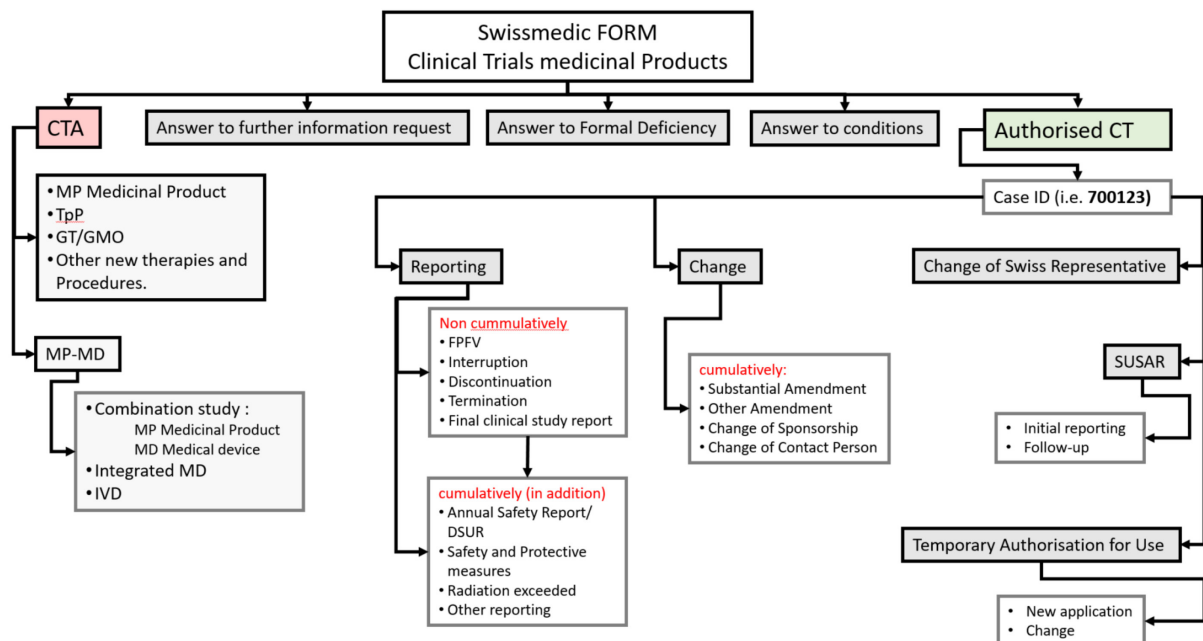
1.1 Restart Button



Use the **Restart button** in case you choose a Form Type and later decide to **change the Form Type**.

1.2 Forms in the Form

Fill in the form as precise and complete as possible. Read the supportive text parts in order to provide all information necessary for assessment of your submission.



2 Instructions for submission

The PDF form can be opened, edited and saved with the free 'Adobe Acrobat Reader' version 10 or higher. The latest version is recommended.

Once completely filled in and dated, save

- the **unsigned** PDF (no scan, no electronic signature)
- plus
- **a scan** of the printed and signed signature page of the submission form

in the eDok_KLV folder 00FM.

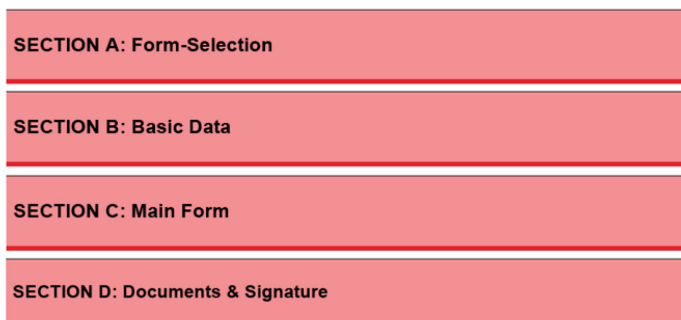
You can download the **eDok_KLV structure as zip-File** as well as the **instructions for filling** the eDok_KLV folder from the Swissmedic homepage.

3 Submission from Version 2

On top of editorial corrections and more precise questions throughout the form, **changes to the format and navigation** were made for userfriendliness.

3.1 Structure and numbering

- a. The whole form is divided in **Section A, B, C and D** visualised with red bars.



- b. A numbering of the headings is introduced.

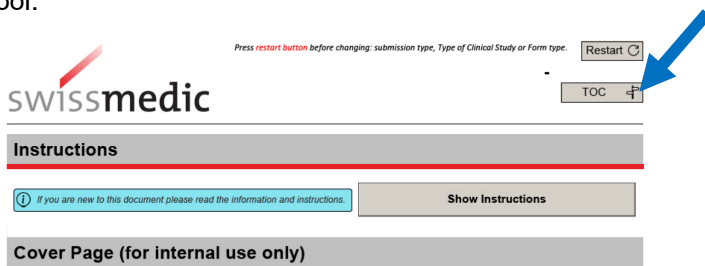
3.2 Navigation tool

The navigation tool allows to jump directly to the sections.

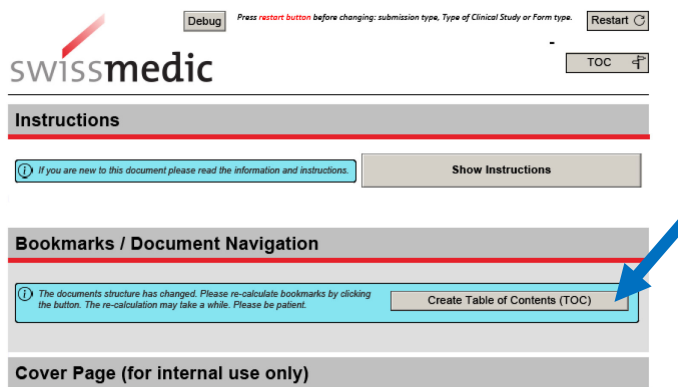
Important remark:

Before submitting the form, please make sure that you have not missed any fields while navigating and that the form is completely filled in.

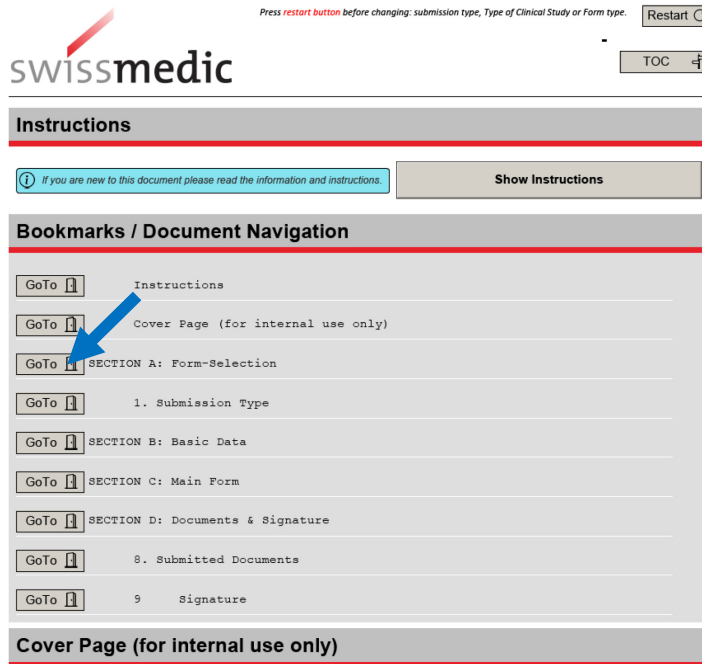
- a. At first opening of the form please click the **TOC-button** (Table of Content) to open the navigation tool.



- b. Click on **Create Table of Content-button**.



- c. To minimise scrolling in forms with a high number of pages, navigate through the document by clicking on the **GoTo-buttons**.



Press **restart button** before changing: submission type, Type of Clinical Study or Form type. Restart

TOC

Instructions

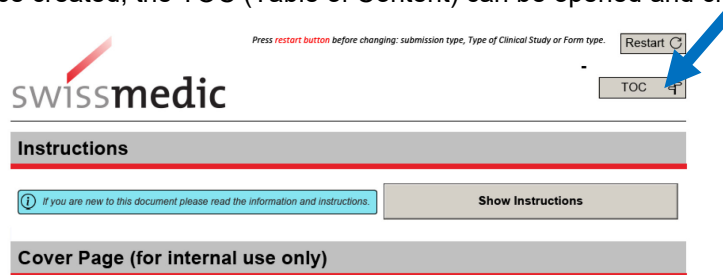
? If you are new to this document please read the information and instructions. Show Instructions

Bookmarks / Document Navigation

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GoTo	SECTION C: Main Form
GoTo	SECTION D: Documents & Signature
GoTo	8. Submitted Documents
GoTo	9. Signature

Cover Page (for internal use only)

- d. Once created, the TOC (Table of Content) can be opened and closed at any time.



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TOC

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Change history

Version	Valid and binding as of:	Description, comments (by author)	Author's initials
2.0	16.06.2023	Numbering and navigation tool added to FO-submission form v2	gav
1.0	23.11.2022	SAP submission process and eDok_KLV structure	gav