

Quick instruction for use of new submission form

1. Overview of types of submissions

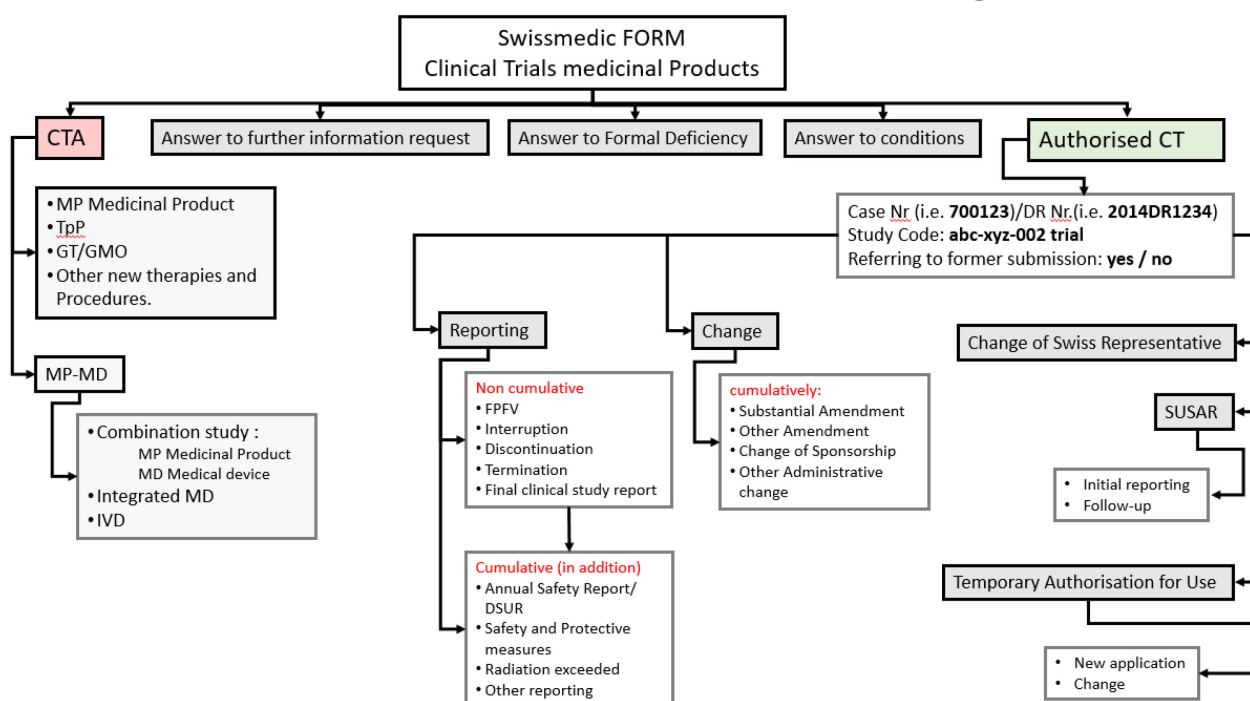
There is only one form for all possible submissions to clinical trials with Medicinal Products or ATMPs (Advanced Therapy Medicinal Products). See picture below.

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, procedures for non-standardisable medicinal products and transplant products.



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

Overview: which form is to be selected for a certain submission target:



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 and place it in the eDoc folder 01FM of the eDoc structure. Save a scan of the printed and signed signature page of the submission form in folder 02FO (you can download the eDoc structure as well as the instructions for filling the eDoc folder structure from the Swissmedic homepage).

Folder Codes:

00F Form Folder: no files on this folder level

01FM Folder: Folder for main submission form may only contain 1 document, the new submission form. This form must be saved as PDF (no scan!).

No "Other forms" are allowed here. Please place "Other forms" in folder 00.02 FO.

02FO Folder: Folder for "Other Forms", scan of the printed and signed signature page of the submission form, other forms e.g. BAG form for radiopharmaceutical studies