Documents to prepare - Research project involving an investigational medicinal product (IMP) submitted to CTIS, going through CTR

By default, please add all the document submitted to CTIS platform in the institutional submission platform.

Procedure available on the AFMHP site.

Folder	Documents	
02	Declarations of conflict of interest	**Mandatory**
04	Informed consent forms in French	**Mandatory**
04	Informed consent forms in Dutch	**Mandatory**
05	Protocol	**Mandatory**
05	Manuals (lab, radio, anatomopathology, etc.)	Recommended
05	Electronic case report form [empty database]	**Mandatory**
06	Investigator brochure or Summary of Product Characteristic (SmPC)	**Mandatory**
07	Patient diary	Recommended
07	Information on patient payment or compensation	Recommended
09	Insurance request	If applicable
09	Insurance certificate	**Mandatory**
11	Clinical trial agreement [draft]	**Mandatory**
11	Budget grid [draft]	**Mandatory**
11	GDPR statement	**Mandatory**