SCTO PLATFORMS

Instruction for Use

DOCUMENT TRACKING LIST

Template	
Purpose	To document regularly which study documents are in force, meaning approved by the EC +/- RA.
Use	This document must be filed at the root of the TMF/ISF to avoid using or applying documents that are obsolete or not yet authorised by the EC +/- RA
Details	This tracking log should provide a list of important documents approved by EC +/- RA (at least protocol and Participant Information Sheet-Informed Consent Form_PIS-ICF) The set of columns are suggestions and can be customised to meet the needs of the study
Best Practice Recommendations	To be used in electronic format. Record documents in the tracking list as they are approved, to ensure completeness and accuracy of the data. In the upper part of the page identifying the study, delete (Local) if the study is monocentric, and () if the study is multicentric. Number each page and maintain this log in the TMF/ISF. Specify if the approval was silent (Silent Approval = SA), i.e. no document was sent by EC +/- RA (except e-mail) Store pages in reverse chronological order, with the newest pages of the log placed at the front of the section. Tick the box under “Obsolete” column when the document is replaced by a newest version