SCTO PLATFORMS

Instruction for Use

SITE IMP/IMD ACCOUNTABILITY LOG

Template	
Purpose	To document the accountability of study product at site level
Use	To record overall study product supplies and accounting. The associated "Participant IMP/IMD accountability log" (7b) is a separate tool that may be used at participant level. In some cases, the two logs may be combined.
Details	This tracking log should provide a comprehensive list of all study product movements at site level. It is required for interventional clinical studies using a study product for research.
Best Practice Recommendations	• One log should be used per batch for IMP studies, • In the upper part of the page identifying the study, Delete IMP or IMD in the title, and (Local) if the study is monocentric, and () if the study is multicentric, • Complete the log as study product is received, dispensed, returned or destroyed, to ensure completeness and accuracy of the data. A new line should be completed for each study product movement. In some case, the column "dispensed" and "returned" can be deleted, • In case of dispensation or return (or destruction), enter the Unique Participant Number (UPN), • A new line should be completed for each study product movement, • Site staff completing the log should initial the dedicated line as the information is entered and the monitor should validate each line when verified, • Create additional lines and pages as needed, • For blinded clinical studies, ensure that this log does not allow identification of the product before filing it in the ISF (a copy for the TMF will be collected at the end of the trial), • Number each page and store pages in reverse chronological order, with the newest pages of the log placed at the front of the section.