

## Instruction for Use

# PARTICIPANT IMP/IMD ACCOUNTABILITY LOG

Template	
<b>Purpose</b>	To document the accounting of study product at the participant level
<b>Use</b>	This log may be used to record dispensing/receiving and return of study product on the participant level. The associated “Site IMP/IMD accountability log” is a separate tool that may be used to record overall study product supplies and accounting. In some cases, the two logs may be combined.
<b>Details</b>	This tracking log should provide a comprehensive list of all study product movements for a given participant. It is required for interventional clinical studies using a study product for research.
<b>Best Practice Recommendations</b>	<ul style="list-style-type: none"> <li>• One log per participant should be completed,</li> <li>• 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,</li> <li>• Complete the log as study product is dispensed/received or returned by participants (tick the corresponding box), to ensure completeness and accuracy of the data,</li> <li>• A new line should be completed each time a study product is dispensed /received or returned,</li> <li>• Select IMP N° or Batch N° or UDI (IMD study), depending on what will be entered in the column,</li> <li>• The “Comments” column should be used to document the visit name when dispensing, or any discrepancies,</li> <li>• Site staff completing the log should initial the dedicated line as the information is entered and the monitor should validate each line when verified,</li> <li>• Create additional lines and pages as needed,</li> <li>• 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),</li> <li>• Number each page and store pages in reverse chronological order, with the newest pages of the log placed at the front of the section.</li> </ul>