Instruction for Use

PARTICIPANT AE LOG

Template	
Purpose	Source document to record comprehensive information on all AEs that happen to a participant, if the information is not already present in the source medical records (e.g. studies with healthy volunteers).
Use	Study coordinator, Principal investigator, other site staff, Monitor
Details	This form is cumulative and captures adverse events of a single participant throughout the study.
Best Practice Recommendations	If information is not already present elsewhere, record AEs as they occur, to ensure completeness and accuracy of the data. Also, only certain parts of the log can be considered as sources (to be defined in the Source Data Location List). • In the upper part of the page identifying the study, delete (Local) if the study is monocentric, and () if the study is multicentric, • This document should be nominative as it is a source document, • Severity is determined by using the drop-down menu: here “Mild, Moderate, Severe, Life-threatening, Death” is suggested, the reference severity scale for the study though is normally given in the protocol, • Seriousness (SAE?): Yes, NO, NA, (drop-down menu). In the event of a SAE, a specific form should be completed, • The outcome must be updated. It can be adapted according to the study; to do this, go to the second page (Dropdown), and change the data in the outcome table, • Causality (relationship) to the study intervention/procedure is assessed via the drop-down menu, • Finally record the actions taken by using the drop-down menu, • Add the initials of the assessor, that needs to be a physician according to GCPs.