

# Instruction for Use

## PARTICIPANT IDENTIFICATION LOG

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| Template                             |   |
|--------------------------------------|---|
| <b>Purpose</b>                       | Link between the study participation number/code (Unique Participant Number_UPN) and the identity of all enrolled participants.   |
| <b>Use</b>                           | <p>This document must be kept by the site only to protect participant privacy.</p> <p>In case the Sponsor and the Investigator is the same person, the combined log 9 may be used instead of 9a and 9b.</p>   |
| <b>Details</b>                       | <p>This log should provide a comprehensive list of all participants who were included in the study.</p> <p>The set of columns are suggestions and can be customised to meet the needs of the study, and the drop-down menu can be adapted in the second sheet.</p>  |
| <b>Best Practice Recommendations</b> | <ul style="list-style-type: none"> <li>• To be used in electronic format and printed out regularly, for example before monitoring visits</li> <li>• In the upper part of the page identifying the study, delete (Local) if the study is monocentric, and () if the study is multicentric</li> <li>• Include all participants as they are successfully enrolled in chronological order, to ensure completeness and accuracy of the data,</li> <li>• This log contains identifying information as this is an investigator document. This document is also known as the identification code list, and must never leave the study site, nor shall it be provided to the Sponsor</li> <li>• Number each page and maintain this log in the ISF, in the “participants section”,</li> <li>• Store pages in reverse chronological order, with the newest pages of the log placed at the front of the section.</li> </ul> |