

# Instruction for Use

## NOTE TO FILE / DEVIATION FORM

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Template	
<b>Purpose</b>	Notes to the File (NtF) are written to document discrepancies and/or issues in the conduct of a clinical research study, and to provide additional clarification or explanation. They are also used to record the corrective measures taken to fix the situation and prevent recurrence.
<b>Use</b>	Study coordinator, Principal investigator, other site staff, Monitor, Sponsor
<b>Details</b>	<p>NtFs are generated on a case-by-case basis. They are needed to explain how and why things were done in a certain way. NtF provide important information to monitors during monitoring visits, during communication with the Sponsor, and potential audits and regulatory inspections (e.g. Swissmedic).</p> <p>NtF should not be misused to avoid protocol amendment. Repeated protocol deviation may be an indication that an amendment is needed to permanently change the project.</p>
<b>Best Practice Recommendations</b>	<p>A NtF is initiated and authored by the individual or organisation responsible for its content. The form contains:</p> <ul style="list-style-type: none"> <li>• A factual description of the problem or issue,</li> <li>• A route-cause analysis,</li> <li>• A description of corrective and preventive actions to prevent reoccurrence,</li> <li>• A confirmation that corrective action(s) have resolved the problem, or what procedures were implemented if the issue could not be solved,</li> <li>• Applicable dates and signatures,</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> </ul>