

# Tool Summary Sheet

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| **Tool:** | Monitoring Visit Log  |
| **Purpose:** | To record all monitoring visits, beginning with Site Initiation.  |
| **Audience/User:** | Study Coordinators, Principal Investigators (PIs), other site staff, clinical monitor |
| **Details:** | This log should provide a comprehensive list of all monitoring visits. It is required for both observational and interventional clinical research studies. |
| **Best Practice Recommendations:** | * Record monitoring visits as they occur, to ensure completeness and accuracy of the data. If a visit occurs over more than one day, each day should be recorded on a separate line.
* Each clinical site monitor should sign a single line at the start of every monitoring visit day.
* Number each page and maintain this log in the Essential Documents Binder, behind the ‘Clinical Site Monitoring Visits’ tab. (Synonyms for this binder include Investigator Binder, Regulatory Binder, Investigator Site File (ISF), and Study File.)
* Store pages in reverse chronological order, with the newest pages of the log placed at the front of the section.
* At the conclusion of the study, identify the final page of the log by checking the box in the footer and adding a diagonal line across remaining open rows of the final page
* Remove this Tool Summary Sheet before use of the log.
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## Tool Revision History:

| **Version Number** | **Version Date** | **Summary of Revisions Made:** |
| --- | --- | --- |
| **1.0** | **05Feb2010** | **First approved version** |
| **2.0** | **02Mar2010** | **Removed automatic page numbering** |
| **3.0** | **04Jan2012** | **Added Tool Summary Sheet; no revisions to the log**  |
| **4.0** | **14Mar2012** | **Revised Tool Summary Sheet and added check box to footer** |
| **5.0** | **16Aug2021** | **Modified best practices; header information moved and clarified** |

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| **Site Investigator Name:** | **Protocol Number:**  | **Site Name:** |

# Monitoring Visit Log

| **Name** | **Signature** | **Purpose of Visit (SIV, IMV, COV, Etc.)** | **Date of Visit** |
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Version 5.0—2021-08-16 Page

Check if final page of log: ☐