

Tool Summary Sheet

Tool: Monitoring Visit Log

Purpose: To record all monitoring visits, beginning with Site Initiation

Audience/User: Study coordinators, principal investigators, 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.
 - The clinical site monitor should sign each line as a monitoring visit begins.
 - 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.
 - Remove this Tool Summary Sheet before use of the log.

Tool Revision History:

Version		
Number	Date	Summary of Revisions Made:
1.0	24Apr2013	First approved version

