# ESSENTIAL DOCUMENTS DEEP DIVE: MONITORING REPORTS

## Essential documents Deep Dive: Monitoring Reports

### Hart's Good Clinical Practice glossary series

Welcome back to the Hart GCP knowledge series. We have been reviewing *essential documents* that are typically generated before the clinical phase of the trial begins. We have looked specifically at the Investigator brochure, clinical protocol/protocol amendments, informed consent tracking, advertisements, and agreements. Now we will look at some key documents required once a clinical trial begins. Our first installment in this phase will be on monitoring reports.


To learn more about the monitoring process go here. The Good Clinical Practice (GCP) guideline, ICH E6 R2, defines a monitoring report as "A written report from the monitor to the sponsor after each site visit and/or other trial-related communication according to the sponsor's SOPs".

The monitoring report should document a study's progress and compliance with GCP guidelines, and should record any problems

at the site, including both minor and major items. Minor findings may be documents with errors or that need to be filed in the study trial file, while major findings could include findings related to safety or informed consent. In either case, the report documents the initial finding and tracks resolution of each finding.


The written monitoring report should be submitted to the sponsor after each trial site visit and should include, at a minimum:

- Date of visit
- Name of monitor
- Name of the site and investigator or other personnel
- A summary of what was reviewed, including statements regarding:
    - significant findings/facts
    - deviations/deficiencies
    - conclusions
    - actions taken or recommended to be taken

A sponsor representative should review and follow-up with any outstanding actions documented in the report, and reports should be signed by the sponsor as final once complete.

GCP indicates that “results of monitoring activities should be documented in sufficient detail to allow verification of compliance with the monitoring plan”, which is a plan for how monitoring will be conducted and who is responsible for given

monitoring tasks.


*Sufficient detail* means that not only should negative findings be reported with enough detail for follow-up and resolution to occur, but also that positive compliance should be detailed. For example, patients for whom the informed consent process was completed satisfactorily should be documented as such, not left blank. Omission of such detail is not an indication of compliance, but is rather a lack of detail that should be included to adequately document compliance.

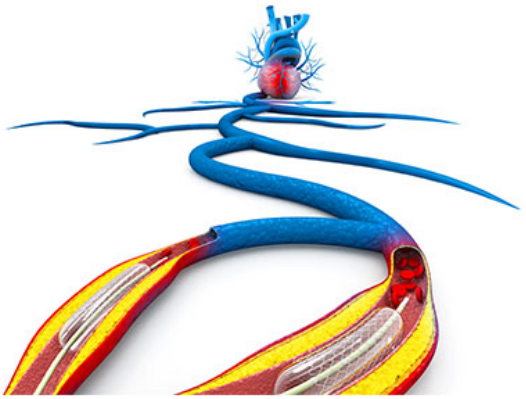
Monitoring reports are a key tool used in conducting a clinical trial. Sponsors and CROs usually have operating procedures for how monitoring should be conducted and how the reports are to be written.  Some additional sources for monitoring and reports can be found here, here, and here.

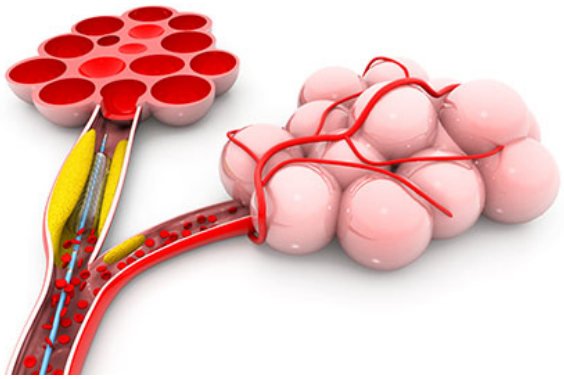
Thank you for reading HCC's glossary series and happy monitoring to you!

# STAFF LOCATIONS


Our CRAs are located across the US, allowing for regional coverage of your project

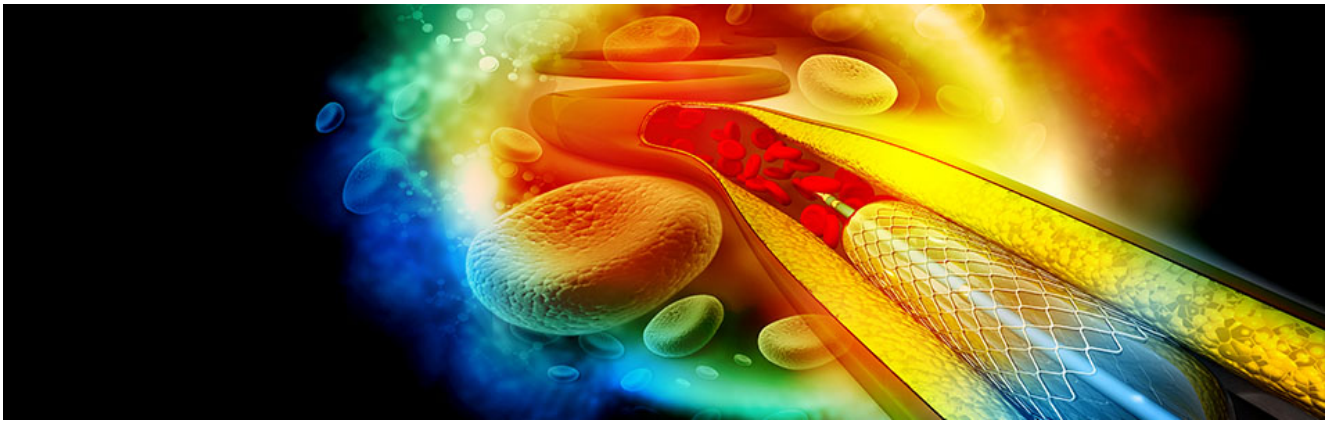
Experience managing all phases of clinical trials





Extensive on-site monitoring experience using a variety of data collection processes


Experts at implementing FDA GCP regulations and ICH guidelines for clinical trials



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