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Protocol Violation

National Cancer Institute

Source

National Cancer Institute. *Protocol Violation*. NCI Thesaurus. Code C142185.

A significant departure from processes or procedures that were required by the protocol. Violations often result in data that are not deemed evaluable for a per-protocol analysis, and may require that the subject(s) who violate the protocol be discontinued from the study. Compare to protocol deviation. (CDISC Glossary)