Open Peer Review on Qeios

Clinical Trial Patient Database Change Control

National Cancer Institute

Source

National Cancer Institute. <u>Clinical Trial Patient Database Change Control</u>. NCI Thesaurus. Code C125438.

A document, report or log summarizing changes made to a clinical trial patient database. May include the reason for change, relevant approvals, impact/risk analysis, associated requirements, specifications and other documentation describing the validation and implementation of the change.