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Good Clinical Practice Q&A: Focus on DSMBs

When a DSMB is used, are its records considered part of the sponsor's records? Can the FDA inspect them? Do IRBs have the authority to require the submission and review of DSMB meeting minutes and other related records?

While the FDA has the authority to inspect any organization participating in a clinical trial conducted under an IND, the agency does not currently inspect Data & safety monitoring boards (DSMBs) because it does not have regulations requiring their routine use. An IRB's reach does not extend to inspecting sponsors or, by extension, DSMBs that may be advising them. Further, DSMBs are not monitored by clinical research associates and are not audited. They are autonomous, independent entities that, generally, are not subject to external review. Typically, DSMB records are considered confidential and their decisions are disclosed only to sponsors and possibly to a committee of study investigators.

Although the FDA has never inspected a DSMB or its records, it could, theoretically, seek access to DSMB records as part of a follow-up to a sponsor inspection. The agency might do so, for example, if it suspected that a DSMB made an important safety-related recommendation that a sponsor did not report to the FDA, or if it suspected that a DSMB was being pressured to under-report safety-related concerns to the sponsor. Agency officials concede, however, that the lack of regulations regarding DSMB inspections and the lack of an agency DSMB inspectional program make the FDA's authority in this area less than definitive. However, the agency would have clear authority to inspect a DSMB if the sponsor formally transferred certain regulatory obligations to the board.

Source

"Good Clinical Practice: A Question & Answer Reference Guide", Barnett International. The Guide is available at http://www.barnettinternational.com in electronic and paper form.