

Audits and Inspections of Clinical Trials of Drugs and Biologics Quizzes 2022

When the FDA conducts an inspection, the inspectors will: - Answer Review regulatory records.

The overall goal of monitoring, audits, and inspection activities is to: - Answer Ensure the protection of human research subjects and data integrity.

According to ICH E6 GCP, an "Audit" is defined as: - Answer A systematic and independent examination of trial-related activities and documents.

OHRP is an oversight body primarily concerned with: - Answer Protection of human research subjects.

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