Inspection:

Topic covered

- introduction of infection
- pre inspection activities
- inspection process

INTRODUCTION:

Regulatory inspections are an important and essential part of clinical research to evaluate the integrity of the data submitted to health authorities (HAs), presence of infrastructure to conduct clinical research, measures implemented to protect patient's interest and safety, adequacy of site/sponsor quality systems, and verification of compliance with the principles of ICH-GCP as well as local regulations.

Inspections generally occur after submission of data for marketing approval of an investigational drug; however, inspections may happen at any time during the conduct of the trial like FDA's Early Intervention Program.

PREINSPECTION ACTIVITIES

The HAs generally contact sponsors to arrange for site inspections and confirmation of dates. Subsequently, there may be direct communication between HAs and sites. Inspectors

Inspectors may request for preinspection documents such as curriculum vitae of (sub) investigators, serious adverse events (SAE), and also documentation of sponsor oversight, such as monitoring reports

It should be noted that site data (as submitted in marketing approval package) would generally have been thoroughly reviewed by assessors, inspectors, and other subject matter experts before inspection. Therefore inspectors may come prepared with specific queries about safety and efficacy data, GCP compliance issues, and/or other points.

INSPECTION PROCESS

Generally, inspections are conducted by 1–2 inspectors and may last for 1 week depending on the study.

All site personnel who had a significant role in the conduct of trial should be present during the inspection – principal investigator (PI), sub-investigators (SI), Study coordinator (SC), radiologist, lab personnel, pharmacist (as applicable).

Sponsor representatives may be present at the site to facilitate the process; however, it should be clearly understood by all personnel that it is site inspection and site personnel should be at the forefront. Undue interference by sponsors may not be taken well by the inspectors.

The inspection focus is on investigator role in the study, delegation of duties (with documentation), qualification of site staff, ethical issues – consent process, and ethic committee review.

The data review generally includes subject history, informed consent, subject eligibility, investigational drug administration, compliance, safety reporting, compliance to study procedures, and other study-specific issues. There is a frequent interaction between inspectors and site personnel to clarify points, issues, and to provide supporting documents.

Refrance:

http://www.accessdata.fda.gov/scripts/cder/cliil/index.cfm