What is quality assurance?

Quality Assurance (QA) in research consists of planned, systematic activities that are conducted to ensure that a research is performed in compliance with the protocol, Good Clinical Practice (GCP) guidelines, and all other applicable regulatory requirement(s).

Why is QA important?

Research that is not conducted according to high standards of quality yields invalid data. It is also unethical because it may put research participants at risk.

Quality data are critical to ensure that the results of studies are interpreted correctly. Sloppy or incorrect data can lead to misleading conclusions. Careful attention to standards of quality also ensures that studies are completed in a timely fashion. Timely completion of high quality studies bridges the gap between research and practice by bringing effective new treatments to clients more quickly.

Who is responsible for QA?

All members of the protocol team are responsible for QA.

The sponsor and Principal Investigator (PI) has ultimate responsibility for implementing and maintaining QA systems. This responsibility includes oversight of all QA systems as well as any research-related functions performed or managed by other parties

Investigators and every member of the protocol team are expected to perform his or her duties diligently and thoroughly, thus ensuring that the trial is conducted according to the highest possible standards of quality.

Summary of monitors' responsibilities

Monitors ensure that the trial is conducted properly by

Verifying that:

- Only eligible participants are being enrolled in the study.
- Written informed consent was obtained before each participant's enrollment.
- The investigator has adequate qualifications, resources, and facilities (including laboratories, equipment, and staff) to conduct the study.
- The investigator is following the approved protocol and any approved amendment(s).

- The investigator and researchstaffs are performing specified trial functions in accordance with the protocol and have not delegated these functions to unauthorized individuals.
- Determining whether all adverse events are appropriately reported within the required time periods.
- Notifying the Research unit/IRB of deviations from the protocol, SOPs, GCP, and applicable regulatory requirements and taking appropriate action to prevent their recurrence.
- Participants are appropriately screened and enrolled.
- Inclusion and exclusion criteria are applied properly.
- Randomization procedures are followed, and the blinding is maintained.
- Performa are filled out accurately, completely, legibly and verifiably based on the participant's source documentation.
- All source documents are attributable, legible, contemporaneous, original, accurate, and complete.
- Medication dosing and documentation are in compliance with the protocol.
- All adverse events and serious adverse events have been documented and appropriately reported to the Sponsor, Lead Investigator(s), IRB and Research Unit.
- Providing all research team members with adequate training before the trial begins.
- Monitoring progress early in the study to assess the quality of screening, recruitment, randomization, and documentation practices (for example, after the first few participants have been randomly assigned to a treatment group). This helps to ensure that any deficiencies are detected early and at the source (i.e., at the site where the research is performed), that inefficiencies and wasteful procedures are eliminated, and that any necessary retraining is performed in a timely fashion. Early monitoring also helps to reduce the likelihood that errors will occur later in the trial, by providing additional information to help troubleshoot for future risk mitigation strategies and risk-based monitoring of the study.
- Increasing the frequency of monitoring when necessary to correct any deficiencies in the conduct of the trial or to provide technical support.