

The principal responsibilities of a Clinical Research Associate/Monitor are outlined below:

Ensure Trial Quality and Compliance: The monitor checks that the clinical trial is being conducted according to the protocol, Good Clinical Practice (GCP) and regulatory requirements

Ensure Safety and Data Quality: The monitor checks that the rights, safety and well-being of participants are protected and that the data collected during the trial are accurate, complete and matches with the source documents such as medical records

Follow a Monitoring Plan: A detailed plan outlines how, when and where monitoring should occur, with a focus on parts of the trial that matter most for safety and data quality. The monitor is responsible for strictly adhering to the monitoring plan throughout the clinical trial

Support Site Staff: The monitor helps to ensure site staff are well trained and follow the trial protocol and any standard procedures

Identify and Report Issues: The monitor identifies any issues / findings and takes necessary actions with proper documentation in place , including follow-up actions taken

Adopt Risk-Based Oversight: Monitors use risk-based approaches, which means they focus more on the parts of the trial that have higher risks. They adjust how they work if new risks come up, making sure to spend their time and effort where it matters most to keep the study safe and reliable

Utilize Technology: The ICH-GCP E6 (R3) guidelines adopted on 06 January 2025 support the use of remote monitoring and digital technologies, enabling Monitors to utilize electronic systems for reviewing trial data, documents and procedures efficiently and securely

Thus, monitors play an important role in maintaining the trustworthiness and quality of clinical research, helping to ensure that new treatments are developed successfully and ethically