pcrg
PACIFIC | CLINICAL | RESEARCH | GROUP™

CLINICAL STUDY MONITORING

Classically defined, Clinical Study Monitoring means overseeing the progress of a clinical trial, and ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and applicable regulatory requirements.

Fundamentally, monitoring is a process designed to ensure Data Integrity. It is an integral part of trial conduct not an add-on – and quality monitoring visits, and comprehensive monitoring reports are among the most important pieces of both study and patient data.

Honed over years of study development, modern site monitoring certifies the reliability of the data gathered. In Australasia independent monitoring is carried out by the CRO or third party.

PCRG's national team of CRAs in Australia and New Zealand travel to sites for on-location monitoring in most cases. Experience proves this is the most effective form of monitoring and solidifies our already strong connection with clinical sites. Moreover, on-site presence underscores our serious approach to monitoring. We are nothing if not agile and adaptable – we can and do support remote monitoring visits when significant complexities make site visits impractical or impossible.

PCRG's Clinical Research Associates (CRAs) monitor studies across

Australia using tools co-created in tandem with the study sponsor. These tools include:

CFRs (Case Report Forms). These are:

- A product of the study protocol; created based on an approved protocol
    - Co-crafted by the sponsor or the CRO
- Properly ordered questions measured against the database designed from the protocol (to speed data comparison with patient medical records)
- Completed by the site (usually a research coordinator or site staff) on a patient-by-patient basis
- Forms that follow study enrollees pre- and post-procedure through follow-ups as designated by the protocol

CRAs are dispatched to compare the CRF entries with each patient's medical chart and query any discrepancies in the data collected. E.g.,

- Was informed consent signed and cataloged?
- Veracity of patient?
- Was the device used in the proper manner per the trial design?

All the details are checked and verified.

History has proven this method most effective in terms of data integrity and compliance.

To find out more about PCRG, **click here**.

Our CRA Team

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