

REMOTE MONITORING

HOW SITES, SPONSORS, AND CROS CAN HELP EACH OTHER MAKE IT BETTER FOR ALL.

Section 1:

Use Consistent Terminology to Ensure Clarity of Communication

Centralized monitoring is a **remote-evaluation** of accumulating data performed in a timely manner and supported by appropriately-qualified and trained persons (e.g., data managers, biostatisticians). Centralized monitoring processes provide additional monitoring capabilities that can complement and reduce the extent and/or frequency of on-site monitoring and help distinguish between reliable data and potentially unreliable data. [ICH E6 (R2)]. **Centralized monitoring is NOT the same as "Remote Monitoring".**

On-site monitoring (SDV) is performed at the site(s) at which the clinical trial is being conducted. [ICH E6 (R2)]

Risk-based Monitoring

Central Monitoring

On-site Monitoring

Site Monitoring

Off-site Monitoring a.k.a. Remote Monitoring

- Risk-based Monitoring (RBM) is a systematic, prioritized, risk-based approach to monitoring clinical trials. [ICH E6 (R2)].
- RBM includes a combination of centralized monitoring and site monitoring. **RBM is NOT the same as "Remote Monitoring".**

- An evaluation by sponsor personnel, or representatives of similar purpose, carried out on-site monitoring but from a location other than the site.
- Best practice should **not** involve use of redacted records for SDV.

Section 2:

Respect Each Other's Pain Points and Try To Minimize or Eliminate Them

Top Four Asks From Monitors/CRAs

- Please be prepared and ensure the Principal Investigator is available for his/her part of scheduled phone calls.
- Please be on time for calls and stay for the scheduled duration (unless there is a true emergency).
- Please be proactive in raising any minor issues or questions to help prevent protocol non-compliance.
- Please be timely in your entry of data as this will drive many downstream off-site activities and allow for more productive on-site visits.

- Please drastically minimize or eliminate the need for print...redact...send...repeat. Especially the «repeat» part.
- In most cases, this is actually more burdensome to us than on-site monitoring, so please compensate us for our extra time and resources that otherwise are diverted from recruitment, retention, and timely data entry.
- Please minimize unscheduled calls/requests unless they are really urgent... and only say it's urgent when it is really urgent.
- Please compensate us when we use of our own systems/solutions (i.e. eConsent, eSource, etc.) instead of the one you provide.

Top Four Asks From Sites