

## Hot Topics in GCP

1. Use of cloud technology (a term that is often misused) in clinical trials
2. Use, or influence of, electronic health records/electronic medical records systems on the collection of clinical trial data
3. The failures and future of clinical trials monitoring
4. Creating systems/processes for CQA to implement/handle, identify, document, etc. CAPA... it has been done in the GMP (documented process); the industry appears to be looking for a more structured approach for GCP...
5. What is the process to ensure that the monitoring provided by the CRO is adequate by the standards of the client?

For example, is it all hands off and you let the CRO manage all the monitoring activities?

Do you (i.e., the client) do 100% reading of monitoring trip reports?

Do you do spot checks?

Do you do co-monitoring visits?

Do you approve the CVs of monitors assigned to your study?

Do you approve when one monitor leaves and another is assigned?

Do you do any training with the new monitors coming on board?

Do you expect 100% monitoring of all subjects all visits or is there some algorithm that you use?

Do you apply a different standard for non-pivotal studies?

6. For devices the client must sign the monitoring plan, but that's not the case for CDER. What is the expectation of the FDA?
7. EMRs used in clinical research at sites
8. Strategic SDV/monitoring (<100%)
9. Results from Part 11 audits
10. Clinical Site Corrective Action Plans: Good, Bad, and Awesome
11. Trends at investigator site audits
12. Developing SOPs for remote SDV for monitoring
13. Assessing Site EMR Compliance with 21 CFR Part 11 during the site selection process.

14. What audit techniques do you use when there is a reduced Monitoring Plan and reduced SDV?
15. What audit techniques combined with EDC assist with performing audits efficiently?
16. How will the new FDA Monitoring Guidance change GCP auditing?
17. Addressing various aspects of remote monitoring, eCRF direct entry, etc.
18. Global Guideline for GCP Audit developed by JSQA, BARQA and SQA
19. EHRs/EMRs as clinical trial source
20. New FDA draft guidance on the mobile medical apps and how they will be used in clinical trials
21. Remote monitoring – a good idea or not?
22. Considerations with global trials – ethics, monitoring, auditing, recruiting, IRB consistency, etc.
23. New techniques for uncovering fraud
24. FDA inspectional trends and findings
25. Effects of mergers and compound acquisitions on being able to reconstruct the data trail
26. Impacts of excessive outsourcing