ASCO Research Community Forum

QUALITY ASSESSMENT OF CLINICAL TRIAL SITES

– AT A GLANCE –

BOTTOM LINE

Quality management in clinical trials is critical to ensuring patient safety and quality clinical trials.

Exemplary trial sites incorporate value-added attributes that exceed GCP compliance.

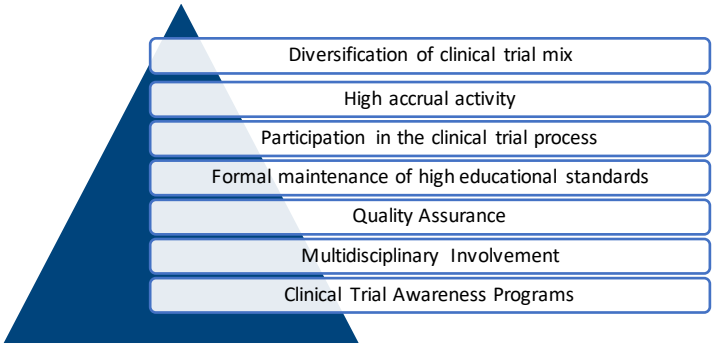
SOPs establish process flow and responsibilities and ensure quality and consistency.

ASCO's Research Program Quality Assessment Tool helps sites establish or enhance internal quality assessment

Participation in clinical research is an important part of developing new and effective cancer therapies. Currently, less than 5% of cancer patients participate in trials.[1] Low clinical trial accrual is influenced by many factors, including lack of access to clinical trials and challenges with developing and implementing high quality clinical trial programs.

KEY CONSIDERATIONS, TIPS, AND BEST PRACTICES

Quality management in clinical research ensures the protection of participants' rights and well-being; the accuracy, completeness, and verification of trial data; and clinical trial adherence to protocol/amendment(s) and federal regulatory requirement(s) and guidelines.[2] Well-designed, high-quality clinical trials also increase research participant access to state-of-the-art medical care.[2] ASCO released a statement in 2008 to provide recommendations on developing and implementing high-quality clinical trial programs.[3] The ASCO Research Program Quality Assessment Tool is available to help sites establish or enhance internal quality assessment programs and exceed the minimum standards of conducting clinical research.[4]



Attributes of an exemplary clinical trial site.[2]

Minimum Standards

For minimum standards of research site quality, consider the following:

- ❑ A quality clinical trial research site, at a minimum, fully complies with the International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) guidelines for designing, conducting, recording, and reporting trials that involve human participants. The responsibility of compliance is shared by the trial sponsor, investigator(s), and institution(s).[3] Depending on the specific nature of the trial, the specific regulations and accepted standards for GCP will vary.[3]
- ❑ Standard operating procedures are a way to facilitate consistent quality in site performance, protection of participant rights, and compliance with GCP.[3] Refer to Zon et al., 2008 for a list of suggested topics for SOPs.

Exemplary Attributes

Consider the following key attributes for a quality clinical trial site that exceed GCP compliance[3]:

- ❑ Diversification of clinical trial site portfolio – A diverse portfolio offers patients a broad range of options and fully utilizes site resources.
- ❑ High accrual activity – Establishing site benchmarks for accrual can help measure progress and facilitate goal setting.
- ❑ Participation in the trial development process – Involvement of all stakeholders in the research process can increase communication among stakeholders and facilitate understanding of the trial process and sharing of resources and support.
- ❑ Formal maintenance of high educational standards – Maintenance of certification, as available, and continuing education for research staff (e.g., specialty board, certification, etc.) demonstrates staff qualifications and ability to perform to an exemplary standard.
- ❑ Quality assurance – An internal quality assurance process and routine self-audits are key parts of site quality assurance. Utilization of tools for continuous improvement, including the plan-do-check-act cycle—a four-step quality model[5]—Six Sigma, Lean, and Total Quality Management can help in developing and maintaining a site quality assurance process.[6] The ASCO Research Program Quality Assessment Tool is helpful for internal quality assessment programs and establishing a proactive approach to quality control.[4]
- ❑ Multidisciplinary involvement in the clinical trials process – Engaging physicians and non-physicians outside of oncology (e.g., surgery, radiology, radiation oncology, pathology, primary care, etc.) could increase a site's capacity for trials.
- ❑ Clinical trial awareness program – Developing awareness programs can increase physician and lay knowledge of clinical trials.

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2. Bennett CL, Adams JR, Knox KS et al. Clinical Trials: Are They a Good Buy?. *J Clin Oncol* 19(23):4330-4339.
3. Zon R, Meropol NJ, Catalano RB, et al. American Society of Clinical Oncology Statement on Minimum Standards and Exemplary Attributes of Clinical Trial Sites. *J Clin Oncol* 26(15): 2562-2567.
4. American Society of Clinical Oncology Research Community Forum. *ASCO Research Program Quality Assessment Tool: Basics for a Quality Community-based Research Site*. Online Version 1.0. Alexandria, VA; American Society of Clinical Oncology; 2015.
5. Kleppinger CF, Ball LK. Building Quality in Clinical Trials with Use of a Quality Systems Approach. *Clin Infect Dis* 51(1): S111-S116.
6. Dahlgaard JJ, Dahlgaard-Park SM. Lean production, six sigma quality, TQM and company culture. *The TQM Magazine* 18(3):263-281.

OTHER RESOURCES

General Quality Considerations

- Dimond EP, Zon RT, Weiner BJ, et al. ReCAP: Clinical Trial Assessment of Infrastructure Matrix Tool to Improve the Quality of Research Conduct in the Community. *J Oncol Pract* 12(1):63-64.
- Quality Assurance and Educational Standards for Clinical Trial Sites. *J Oncol Pract* 4(6):280-282.
- Rare Disease Clinical Research Network. Session 1 – part IA - Good Clinical Practice and Federal Code of Regulations. 2017.
- National Institutes of Health. Research Integrity. 2010.

National Cancer Institute Guidelines and Resources

- NCI Guidelines for Auditing Clinical Trials for the NCI National Clinical Trials Network (NCTN) Program. August 2017.
- *NCI Clinical Trial Assessment of Infrastructure Matrix Tool (CT AIM)*. National Cancer Institute; 2015.
- NCI Data and Safety Monitoring Guidelines Essential Elements of a Data and Safety Monitoring Plan for Clinical Trials Funded by the National Cancer Institute. 2010.

International Conference on Harmonisation (ICH)

- ICH E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry. 2018.
- ICH Clinical Safety Data Management: Definitions and Standards for Expedited Reporting E2A. 1994.
- ICH Harmonised Tripartite Guideline General Considerations for Clinical Trials E8. 1997.

Email researchcommunityforum@asco.org with ideas and suggestions for content revisions, additional and/or new topic summaries.

Visit asco.org/research-community-forum to learn more about the ASCO Research Community Forum initiatives and to access more resources and tools for oncology research sites.

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