The challenges involved in conducting clinical trials can vary across the academic and community oncology setting and by trial sponsor. Effective financial oversight and a qualified research team are an essential part of site success in any practice setting. Regulatory and administrative requirements and resource limitations are common pain points in conducting and managing trials.

Building a Research Program

Before beginning to build a research program, consider site infrastructure including:

- The financial and philosophic dedication of one’s institution: confirm that there is an understanding across the institution of the challenges and commitment that accompany building a research program. Building a budget is a helpful tool to understand the financial impact of conducting trials at the practice.¹
- Available resources: assess available resources including sufficient and qualified physicians and staff, financial support, patient population, technology, and institutional commitment to regulatory requirements.¹
- Ability to conduct research*: assess capabilities to conduct clinical trials including access to an Institutional Review Board (IRB) that is registered with an assurance number with the Office of Human Research Protections (OHRP), and Federal Wide Assurance (FWA). Many community-based research sites use central IRBs, partner with an academic institution and IRB, or access IRBs through a cancer network or industry trial.
- Affiliation with available research bases: research base participation (e.g., National Clinical Trials Network [NCTN], NCI Community Oncology Research Program [NCORP], Academic Medical Centers, Independent Research Organizations) can increase access to trials and available resources.³
- Physician and staff engagement: Engaged physicians and research staff can help drive participation in clinical trials and will support clinical trial processes.² They are a critical investment in building a successful research program.

Standard Operating Procedures (SOPs)

Consider the following strategies in developing site standard operating procedures:

- Develop or purchase a policy and procedure manual reflecting adherence to all Code of Federal Regulations (CFR), which is helpful in ensuring site regulatory compliance.² This can be purchased from a commercial research organization or adopted from another institution or reformatted from an affiliate institution.
- In order to ensure high quality and efficient study start-up and conduct, establish a protocol management process, which includes study initiation, IRB submissions and communications, site visits, communications with study sponsors, drug monitoring, management of regulatory documents, and study close outs.¹
- Establish site SOPs around trial participant management including screening, recruiting, entering and monitoring of patients on protocols, and follow up procedures is necessary to ensure patient safety in study participation.¹
- Consider including procedures for collection, maintenance, and submission of clinical trial data when developing data management SOPs.¹
- Utilize available guidances, trainings, and resources to develop useful site SOPs and training staff.²
- For site quality management, monitor and document adherence to all procedures, policies, self-audits/internal audits, sponsor audits, and external audits.¹
REFERENCES

OTHER RESOURCES
- ASCO Clinical Trial Resources. This online library provides resources addressing many topics related to facilitating the conduct and management of clinical trials, including basic requirements for starting a research site and clinical trial operations.
- Cohn SM, Buchman TG, Croce MA et al. Brief report: EAST workshop on how to build a clinical research program.
- Fredian CG. Setting up a clinical research program in the community hospital setting.

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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