ASCO Research Community Forum

# BASIC STEPS TO BUILDING A RESEARCH PROGRAM

## – AT A GLANCE –

### BOTTOM LINE

Assessing site resources and ability to conduct trials is a critical step before building a research program.

Developing site standard operating procedures is an important aspect of launching an effective clinical trial site.

## KEY CONSIDERATIONS, TIPS, AND BEST PRACTICES

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.

***Major elements of building a research program.***


### *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[2]: 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.[1] 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**

1. Copur MS. How to build a clinical trial infrastructure in the community oncology setting. ASCO Post. 2018.
2. Baer A, Bechar N, Cohen G. Basic Steps to building a research program. *J Oncol Pract*. 2010;6:45-47.
3. Enhancing oncologist participation in research. *J Oncol Pract.* 2009;5(6):309-311.

**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.
- Croghan IT, Viker SD, Limper AH et al. Developing a clinical trial unit to advance research in an academic institution. *Contemp Clin Trials.* 2015;45:270-276.
- 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.
- American Society of Clinical Oncology Research Community Forum Toolkit: The Business of Clinical Trials - Optimizing Clinical Trial Sites and Implementing Best Practices. Alexandria, VA; American Society of Clinical Oncology; 2018.

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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