Conducting and Managing Cancer Clinical Trials
A Library of Resources

Chapter I. Basic Requirements for Starting a Research Site

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ASCO® CENTRA
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This library of resources was compiled to centralize resources related to conducting and managing clinical trials. The resources are particularly helpful for physician investigators and research staff. A Task Force of the Research Community Forum, representing a range of community research stakeholder groups with a wealth of experience, compiled this list to help make it easier for research sites to find needed resources. Decisions to include resources were solely based on the Task Force’s own go-to resources, consultation with colleagues, and an environmental scan of available resources on these topics. Resources from commercial, for-profit entities are generally excluded from the library. The items listed are not necessarily endorsed by ASCO; they are listed based on the discretion and expertise of the Task Force.

This list is not exhaustive and will be updated periodically. Your feedback is welcomed! If you have ideas for content to add or edit, please email your suggestions to the ASCO Research Community Forum.

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Disclaimer: This library contains resources and templates that are provided as examples only for research programs to consider as they formulate their own resources. ASCO makes no warranties, expressed or implied, as to results obtained by individuals using the information and is not responsible for any action taken in reliance on the information contained herein.

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For more information contact researchcommunityforum@asco.org.
I. Basic Requirements for Starting a Research Site

A variety of online resources are listed below with information about some of the basic considerations when building a clinical research site, including infrastructure, regulatory requirements, patient engagement, access to trials, and best practices. This list is not exhaustive and will be updated periodically.

This section includes the following topics:

A. Building an Effective Research Program
B. Partnerships
C. Marketing your Research Program
D. Building Program Infrastructure
E. Mission Statements and Policies
F. Creating a Culture of Research
G. Mentorship
H. Good Clinical Research Practices
   i. ICH GCP References
I. Building a Clinical Trial Portfolio
J. Standard Operating Procedures

A. Building an Effective Research Program

Clinical research moves medicine forward and is a necessary part of bringing any new therapy, device, or procedure into routine medical care. However, it can be costly and convoluted. Building an effective research program requires establishment of a clinical trials infrastructure, financial oversight and a sustainable qualified research team. Although the physicians are vital to creating a research culture and enrolling patients on trials, nonphysician staff-including nurses, data managers, clinical research associates, pharmacy staff and staff responsible for reimbursement are imperative to the overall success of the program.

- Copur MS. How to build a clinical trial infrastructure in the community oncology setting. The ASCO Post. 2018 Dec.
- Association of Clinical Research Professionals Webinar Replay: We are Going to Run an Investigator-Initiated Trial? What do we Do? (Free to ACRP members). This webinar covers the roles and responsibilities to consider when launching an investigator-initiated trial.
- A Manual for Participants in Clinical Trials of Investigational Agents Sponsored by DCTC, NCI. This manual from the Division of Cancer Treatment and Diagnosis (DCTD), National Cancer Institute (NCI) includes policies and procedures related to various elements of the development of new investigational agents.
- Cancer Clinical Trials Basics. This online module, produced by the National Cancer Institute, provides introductory-level information regarding cancer clinical trials.
- Conducting Clinical Trials. Information from the National Cancer Institute is available for investigators, including tools for managing trials, registration/reporting and ensuring patient safety.
- Association of Clinical Research Professionals Core Competencies for Clinical Research Coordinators (CRCs)
• Association of Clinical Research Professionals Functional Competency Guidelines for Principal and Sub Investigators

• A Handbook for Clinical Investigators Conducting Therapeutic Clinical Trials Supported by CTEP, DCTD, NCI. This resource from the National Cancer Institute covers policies and implementing procedures for conducting clinical trials sponsored by the Division of Cancer Treatment and Diagnosis (DCTD), National Cancer Institute (NCI).

• Minimizing Research Delays: Identifying Successful Strategies to Keep a Clinical Trial Moving Forward. J Oncol Pract. 2007 Nov;3(6):306-307. In this article, representatives from practices awarded the 2007 ASCO Clinical Trials Participation Awards discuss strategies they have implemented to keep clinical trials on track.

• National Cancer Institute Resources for Researchers. This directory of resources provides National Cancer Institute supported tools and services for cancer researchers.

• Association of Clinical Research Professionals Webinar Replay: Drug Development Process: A Review of ICH E8 (Free to ACRP members). Content includes principles and practices for the conduct of clinical trials and overall development strategy, evaluation of international trial data, and overview of ICH guidelines pertinent to clinical trials.

• The Elements of Success, Conducting Cancer Clinical Trial; A Guide. This document is intended as a resource to provide general information on the conduct of clinical trials for new and prospective clinical trial investigators and sites.

• ASCO Exemplary Attributes Series: An ongoing article series in the Journal of Oncology Practice provides practical information on how to implement the GCP guidelines and exemplary attributes.
  o Enhancing Oncologist Participation in Research. J Oncol Pract. 2009 Nov;5(6):309-311. This article, from the ASCO Exemplary Attributes Series, offers strategies to increase oncology engagement in research.

• Human Subjects Research: This webpage, produced by the National Institutes of Health, provides the user with access to ethical codes and standards such as the Declaration of Helsinki, Belmont Report, and International Conference on Harmonization Guideline for Good Clinical Practice.
• National Institutes of Health (NIH) Standards for Clinical Research within the NIH Intramural Research Program
• International Clinical Trials Workshops through ASCO. These workshops support cancer researchers in low- and middle-income countries in developing research skills.
• Various projects from the Clinical Trials Transformation Initiative related to clinical trials.
• How to start a clinical research site. PharmaTimes. 2018 Jul.

B. Partnerships
A strong partnership is commonly at the heart of a successful clinical research program. The resources below provide insights into the benefits and how to establish effective partnerships.

• Communities as Partners in Cancer Clinical Trials: Changing Research, Practice and Policy. Communities as Partners in Cancer Clinical Trials is supported by grant number 1-R13-HS016471 from the Agency for Healthcare Research and Quality (AHRQ), with co-funding from the National Cancer Institute (NCI). This is a copy of their report highlighting the potential impact of the community site and need for improved partnerships.
• NCI's National Clinical Trials Network (NCTN). NCI's National Clinical Trials Network (NCTN) is a collection of organizations and clinicians that coordinates and supports cancer clinical trials at more than 3,000 sites across the United States and Canada. The NCTN provides the infrastructure for NCI-funded treatment, screening, and diagnosis trials to improve the lives of patients with cancer.
• Conway L. Academic-community cancer program affiliations: How to make sure you both benefit. The Advisory Board Company: Oncology Roundtable 2014. This briefing covers five dimensions of affiliations to help you take the informed approach needed to structure a productive, mutually beneficial partnership.
• Welford B. The 12 step checklist for a successful business partnership. Under 30 CEO, 2013. The priority and timing for the goals to be achieved by the partnership should be equally satisfactory for both partners. Those of us in the cancer community can learn from our business colleagues.
• Copur MS, Gulzow M, Zhou Y, et al. Impact of National Cancer Institute (NCI) Community Cancer Centers Program (NCCCP) and NCI Community Oncology Research Program (NCORP) on clinical trial (CT) activities in a community cancer center. J Clin Oncol. 2018 May;36(15_suppl), e18500-e18500.
C. Marketing your Research Program
Marketing your research program involves sharing it with a wider audience to make it more visible. This can be helpful in the initial steps of research, particularly when actively recruiting for participants to enroll in your clinical trials. Generating awareness of clinical trial enrollment can help increase interest and ultimately assist in helping you to reach your enrollment goals.

- Keck School of Medicine of University of South Carolina. How and Why to Promote your Research.
- BioMed Central. 10 Tips for Promoting your Research Online.
- Enago Academy. Promote your Research with these 7 Simple Techniques!

D. Building Program Infrastructure
Refer to the below resources for information on the elements and steps involved in establishing program infrastructure.

- Baer A, Bechar N, Cohen G, and Devine S. Basic Steps to Building a Research Program. J Oncol Pract. 2010 Jan;6(1):45-47. This article from the ASCO Exemplary Attributes series provides practical advice for investigators on research program financial oversight and how to sustain a qualified team.
- ASCO Building A Research Program At-a-Glance Summary. This ASCO resource provides an overview of the key tips, takeaways and considerations for building a research program.
- U.S. Food and Drug Administration. Computerized Systems used in Clinical Trials. (April 1999)
- Including Clinical Trials into your Practice: This online module, produced by the National Cancer Institute, targets healthcare professionals with advanced knowledge of cancer clinical trials who want to better incorporate trials into their practice.
- Copur MS. How to build a clinical trial infrastructure in the community oncology setting. The ASCO Post. 2018 Dec.

E. Mission Statements and Policies
(e.g., participation in research, selection of clinical trials, clinical trial portfolio and diversity, etc.)

- Enhancing Clinical Trial Awareness and Outreach. J Oncol Pract. 2009 Jul;5(4):205-207. This article from the ASCO exemplary attributes series discusses clinical trial education programs, diversification of trial mix, multidisciplinary involvement, and high accrual.

**F. Creating a Culture of Research**
Creating a culture of research within an organization helps to ensure commitment and buy-in to participation in clinical trials.

- Dimond EP, St Germain D, Nacpil LM, et al. *Creating a “culture of research” in a community hospital: Strategies and tools from the National Cancer Institute Community Cancer Centers Program*. *Clin Trials*. 2015 Feb;12(3):246-256. The National Cancer Institute Community Cancer Centers Program experience provides a relevant model to broadly address creating a culture of research in community hospitals that are increasingly networked via systems and consortiums.

**G. Mentorship**
Mentoring is an important component of building an effective research program, benefitting both mentees and mentors. The links below provide guidance on the impact of mentorship and how to get started.

- Henry-Noel N, Bishop M, Gwede CK, et al. *Mentorship in medicine and other health professions*. *J Cancer Educ*. 2019 Aug;34(4):629-637. In this article, the authors describe the development of optimal mentoring relationships, emphasizing the importance of different approaches to mentorship, roles of the mentors and mentees, mentor and mentee benefits, interprofessional mentorships for teams, gender and mentorship, and culture and mentorship.
- Arnold ER. *As a new nurse myself, how can I become a mentor to new nurse colleagues?* *Clin J Oncol Nurs*. 2018 Feb;22(1):120.

**H. Good Clinical Research Practices**
Good Clinical Practice (GCP) is an international standard for designing, conducting, monitoring, measuring performance, auditing, recording, analyzing, and reporting of clinical trials. The resources below will help you ensure credible and accurate data and results and protection for trial subjects, to ensure compliance with GCP standards developed by various entities (i.e., International Code of Harmonisation [ICH] E6 GCP Guidance, U.S. Food and Drug Administration, Clinical Trials Transformation Initiative [CTTI], and TransCelerate BioPharma Inc.). For specific resources on GCP training, refer to section i. Good Clinical Practice Training.

- Baer AR, Hajovsky J, Zon R. *Achieving exemplary attributes with AccrualNet*. *J Oncol Pract*. 2011 Nov;7(6):e40-1. This article, from the ASCO Exemplary Attributes series, highlights how AccrualNet can be used to achieve the seven attributes of exemplary clinical research sites. For more information on the attributes, refer to the ASCO exemplary attributes series.
• **Ethics and Human Subject Protection: A Comprehensive Intro.** (Free for ACRP members) This course from the Association of Clinical Research Professionals provides in-depth training on the history and importance of ethical conduct in clinical trials involving human subjects.

• **Good clinical practice research guidelines reviewed, emphasis given to responsibilities of investigators: second article in a series.** *J Oncol Pract.* 2008;4(5):233-235. This article from the ASCO Exemplary Attributes series describes Good Clinical Practice guidelines and places them into historical perspective before specific aspects of implementing the guidelines—through the use of trained research professionals and well-written Standard Operating Procedures (SOPs)—are discussed.

• **Rare Disease Clinical Research Network Good Clinical Practice and Federal Code of Regulations.**

• **Intro to Good Clinical Practice.** (Free to ACRP members) This course from the Association of Clinical Research Professionals covers the basics and key considerations of Good Clinical Practice, including review of the guidelines of the International Council for Harmonisation’s Good Clinical Practice and investigator roles and responsibilities.


• **TransCelerate Recommendations.** Site qualification and training. TransCelerate BioPharma, Inc.

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**i. ICH GCP References**

• **E6(R2) Good Clinical Practice:** Integrated Addendum to ICH E6(R1) Guidance for Industry. U.S. Food and Drug Administration (Mar 2018)

• **ICH Clinical Safety Data Management: Definitions and Standards for Expedited Reporting E2A.** International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (Jan 1994)

• **General Considerations for Clinical Trials (E8).** International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (Jan 1998)

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**I. Building a Clinical Trial Portfolio**

View clinical trial databases and listings via the following resources.

• **Clinicaltrials.gov.** ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

• **U.S. Department of Health and Human Services Listing of Clinical Trial Registries**

• **US Oncology.** Learn more, find a clinical trial, or join the US Oncology Network of oncology sites.
J. Standard Operating Procedures
(e.g., preparing, maintaining, and training on Standard Operating Procedures [SOPs])

- **NRG Oncology Manual of Operations and Standard Operating Procedures for the San Francisco Biospecimen Bank.** (Direct file download) This resource details the NRG Oncology Biospecimen Bank’s operations and includes helpful templates and sample documents.
- **Draft SOPs documents on a wide range of topics** from Dana-Farber/Harvard Cancer Center. This document library offers draft documents, guidances and policies around SOPs.
- Goldfarb N. **Something for Everyone: Standard operating procedure products for the investigative site.** *J Clin Res Best Pract.* 2005 Apr;1(4). This article discusses various commercial products for investigative site SOPs.
- Duke Global Health Institute **SOP Study Termination Visit.** This resource provides SOPs, which were originally developed for AIDS clinical trials, but many of which can be modified and extrapolated to meet oncology research trial needs.