

# **Conducting and Managing Cancer Clinical Trials**

**A Library of Resources**

## **Chapter II. Clinical Trial Operations**

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**ASCO**® **CENTRA**

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## OVERVIEW

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](mailto:researchcommunityforum@asco.org).

## II. Clinical Trial Operations

Resources are listed below for some of the administrative considerations for a research program, including site requirements and responsibilities, investigator and staff roles and responsibilities, budgeting and billing, and administrative best practices.

*This section includes the following topics:*

- A. Investigative Site Requirements and Responsibilities
- B. Investigator Roles and Responsibilities
- C. Conflict of Interest in Research
- D. Research Integrity and Scientific Misconduct Policies and Procedures
- E. Research Staff Roles, Responsibilities, and Management
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  - iii. Insurance Coverage of Clinical Trials

### **A. Investigative Site Requirements and Responsibilities**

(e.g., Exemplary Attributes of Clinical Research Sites)

- [E6\(R2\) Good Clinical Practice](#): Integrated Addendum to ICH E6(R1) Guidance for Industry. U.S. Food and Drug Administration 2018.
- Zon R, Meropol N, Catalano R, et al. [Minimum Standards and Exemplary Attributes of Clinical Trial Sites](#). *J Clin Oncol*. 2008 May;26(15):2562-2567. The seminal manuscript in the ASCO Exemplary Attributes series describes the minimum requirements for conducting quality clinical trials and the attributes of an exemplary site.
- Baer AR, Cohen G, Smith DA, et al. [Implementing clinical trials: a review of the attributes of exemplary clinical trial sites](#). *J Oncol Pract*. 2010 Nov;6(6):328-30. Part 1 in a two-part series, this article outlines the following exemplary attributes, diversification of the clinical trial mix, high accrual activity, participation in the clinical trial development process, and maintenance of high educational standards.

- Zon R, Cohen G, Smith DA, et al. [Part 2: implementing clinical trials: a review of the attributes of exemplary clinical trial sites](#). *J Oncol Pract*. 2011 Jan;7(1):61-4. Part 2 in a two-part series, this article outlines the following exemplary attributes, quality assurance, multidisciplinary involvement in the clinical trial process, and clinical trial awareness programs.
- [Quality Assurance and Educational Standards for Clinical Trial Sites](#). *J Oncol Pract*. 2008 Nov;4(6):280-282. This article, which builds on the ASCO Exemplary Attributes series, discusses how quality assurance and formal maintenance of high educational standards contribute to optimal site function.
- Zaren HA, Nair S, Go RS, et al. [Early-Phase Clinical Trials in The Community: Results From the National Cancer Institute Community Cancer Centers Program Early-Phase Working Group Baseline Assessment](#). *J Oncol Pract*. 2013 Mar;9(2):e55-e61. This article discusses how community cancer centers can conduct early-phase trials based on findings from a National Cancer Institute Community Cancer Centers Program Early-Phase Working Group baseline assessment.
- [Identifying and Selecting a Clinical Trial for Your Practice](#). *J Oncol Pract*. 2008 Jan;4(1):27-28. Representatives of three practices recognized by the 2007 Clinical Trials Participation Awards shared their strategies for identifying and selecting trials in this article.
- [American Society of Clinical Oncology policy statement: oversight of clinical research](#). *J Clin Oncol*. 2003 Jun;21(12):2377-2386.
- Refer to [I. Basic Requirements for Starting a Research Site](#) for more information on how to start a research site.

## B. Investigator Roles and Responsibilities

(e.g., investigators roles and responsibilities, oversight, qualifications, credentialing, training, licensure, physician engagement, multidisciplinary team involvement) Refer to the [National Cancer Institute Handbook for Clinical Investigators Conducting Therapeutic Clinical Trials Supported by CTEP, DCTD, NCI](#) for NCI-specific policies and procedures.

- U.S. Food and Drug Administration [Form FDA 1572](#). (Direct file download)
- Baer AR, Devine S, Beardmore CD, et al. [Clinical investigator responsibilities](#). *J Oncol Pract*. 2011 Mar;7(2):124-8. This article from the ASCO Exemplary Attributes series discusses select investigator roles and provides practical advice on how to promote compliance in practice.
- [Delegation of Tasks for Clinical Research](#). (Direct file download) This document from Dana-Farber/Harvard Cancer Center defines the standard research tasks delegated to investigators and each research staff member.
- [Investigator Responsibilities](#). (Free to ACRP members) This Association of Clinical Research Professionals online learning course covers clinical investigator responsibilities and expectations identified by U.S. Food and Drug Administration guidances and International Council for Harmonisation guidelines.
- Baer AR, Zon R, Devine S, Lyss AP. [The clinical research team](#). *J Oncol Pract*. 2011 May;7(3):188-92. This article from the ASCO Exemplary Attributes series offers strategies on developing and maintaining an exemplary research team.

- Saleh M and Naik G. [So you want to be a principal investigator](#). *J Oncol Pract*. 2018 Jun; 14(6):e384-e392. This article addresses investigator responsibilities and the increasing need for structured investigator training.
- National Cancer Institute [Guidelines for Investigators: Adverse Event Reporting Requirements for DCTD \(CTEP and CIP\) and DCP INDs and IDEs](#)

### C. Conflict of Interest in Research

(e.g., regulations, financial conflicts)

- Korenman SG. [Teaching the Responsible Conduct of Research in Humans \(RCRH\)](#). Chapter 4 of this online book, Conflict of Interest, provides information, resources, considerations and case studies to explain the role of conflict of interest in research.
- National Institutes of Health [regulation on financial conflict of interest](#)
- U.S. Department of Health and Human Services [Guidance on Financial Conflict of Interest](#) (2004)
- [Open Payments](#), maintained by the Centers for Medicare and Medicaid Services, is a publicly accessible national disclosure program that provides information on financial relationships between applicable manufacturers and group purchasing organizations and health care providers.

### D. Research Integrity and Scientific Misconduct Policies and Procedures

(i.e., U.S. governmental guidance and policies)

- U.S. Department of Health and Human Services Office of Research Integrity [Introduction to Responsible Conduct of Research](#). This resource provides a comprehensive overview of the basic rules for responsible research.
- [Federal Research Misconduct Policy](#). The policy from the U.S. Department of Health and Human Services Office of Research Integrity establishes the scope of the federal government's interest in the accuracy and reliability of the research record and the processes involved in its development. It consists of a definition of research misconduct and basic guidelines for the response of federal agencies and research institutions to allegations of research misconduct.
- [Research Integrity Policy & Guidance](#). This National Institutes of Health resources provides a definition of research misconduct.

### E. Research Staff Roles, Responsibilities, and Management

(e.g., staff roles and responsibilities, oversight, qualifications, job descriptions, core competencies, training requirements and maintenance, credentialing, orientation, workload assessment, performance)

- [Society of Clinical Research Associates Certification](#) develops clinical research professionals' knowledge understanding and application of international and federal regulations and established ethical principles in the conduct of clinical trials.

#### i. Organization Charts

Refer to the following resource for sample organizational charts to facilitate institutional organization.

- See Appendix A [in the full library](#) for two sample clinical trial program organization charts: one with a larger executive suite, including the CEO, vice presidents, and medical directors, and another with a more streamlined hierarchy, stemming from the CEO and medical director.

## **ii. Staffing Models**

An effective staffing model is key to ensuring a successful workflow and collaborative work culture. The following resources provide strategies to employ effective project managers and clinical research coordinators, learn the attributes of exemplary research, and foster interdisciplinary teamwork.

- Larkin ME, Blumenthal K, Richards D, et al. [Collaborative staffing model](#). *Applied Clinical Trials*. 2011 Jan.
- Nancarrow SA, Booth A, Ariss S, et al. [Ten principles of good interdisciplinary team work](#). *Hum Resour Health*. 2013 May;11(19):1-11.
- Schultz A. [4 essential skills for the ideal clinical trial project manager](#). Forte Research News. 2017 Feb.
- SCORR Marketing & Applied [Clinical Trials Talent Survey Report](#). SCORR Marketing 2017.
- Speicher LA, Fromell G, Avery S, et al. [The critical need for academic health centers to assess the training, support, and career development requirements of clinical research coordinators: Recommendations from the clinical and translational science award research coordinator taskforce](#). *Clin Transl Sci*. 2012 Jun;5(6):470-475.
- Bishop P, Camblos L. [The value of empowered CRAs in rare disease studies](#). *Applied Clinical Trials*. 2017 Aug.
- Kee AN. [Investigator responsibilities for clinical research studies: Proper staffing can ensure an investigator is compliant](#). *J Med Pract Manag*. 2011 Jan/Feb;26:245-247.

## **iii. Clinical Research Staff Positions**

Clinical research staff at a clinical trial site cover a range of roles and responsibilities, and their positions may include Clinical Research Nurse(s), Clinical Research Coordinator(s), Regulatory Coordinator(s), Clinical Research Technician(s), Research Data Manager(s), and Finance and Billing Manager(s). Table 1 describes these clinical trial research staff positions, and Appendix B, [available in the full library](#), provides sample job descriptions for each position.

- [Overview of Clinical Trial Research Staff Positions \(Table 1\)](#). *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.

## **iv. Career Ladders**

Career ladders are an essential component of staff satisfaction, retention, and professional development. The resources below provide frameworks and models for building a successful career ladder for a clinical trials program. Appendix C, [available in the full library](#), also provides a sample career ladder for a clinical research associate.

- Career Excellence Development Program: [Career Development Incentive \(CED\) Program](#). Integris Jim Thorpe Rehabilitation Hospital 2016.
- [The Career Ladder Mapping Project](#). Shirley Ware Education Center 2002.
- [Children’s National Health System Genetic Counselor Career Ladder](#) (Table 1) - Kofman L, Seprish MB, Summar M. Climbing the ladder: Experience with developing a large group genetic counselor career ladder at Children’s National Health System. *J Genet Couns*. 2016 Aug;25(4):644-648.
- Nursing at the National Institutes of Health Clinical Center [Career Ladder](#). National Institutes of Health Clinical Center 2017.
- [Framework for Career Ladder Program](#) (Table 1) - Ko YK, Yu S. Clinical ladder program implementation: A project guide. *J Nurs Adm*. 2014 Nov;44(11):612-616.
- [Career Ladder Point System and Associated Activities](#) (Table 1) Warman G, Williams F, Herrero A, et al. The design and redesign of a clinical ladder program: Thinking big and overcoming challenges. *J Nurses Prof Dev*. 2016 Nov/Dec;32(6):e1-e7.
- [Advancing from within: The value of clinical ladders](#). American Association for Respiratory Care.
- Andrew N. [Clinical imprinting: The impact of early clinical learning on career long professional development in nursing](#). *Nurse Educ Pract*. 2013 May;13(3):161-164.
- Smailes P, Bookless H, Blumenauer C. [Clinical research nurse career advancement using clinical ladder programs](#). *Clin Res*. 2017 Dec;31(6).
- Smith W, Salenius S, Cobb C, et al. [A survey of clinical research coordinators in the cooperative group setting of the American College of Radiology Imaging Network \(ACRIN\)](#). *Acad Radiol*. 2010 Nov;17(11):1449-1454.
- Warman G, Williams F, Herrero A, et al. [The design and redesign of a clinical ladder program: Thinking big and overcoming challenges](#). *J Nurses Prof Dev*. 2016 Nov/Dec;32(6):e1-e7.
- Keenan C. Struggling to keep entry-level staff engaged? [Try a performance-based career ladder](#). The Advisory Board Company: Care Transformation Center Blog. 2017.

#### **v. Staff Retention**

In order to run a successful clinical research program, you must determine the workload that staff members can manage without burning out and understand how to keep them engaged and inspired. These resources will help you understand clinical research talent trends and identify strategies to retain high-performing staff.

- Aarons GA, Sommerfeld DH, Hecht DB, et al. [The impact of evidence-based practice implementation and fidelity monitoring on staff turnover: Evidence for a protective effect](#). *J Consul Clin Psych*. 2009 Apr;77(2):270-280.
- Henderson L. [Salary and satisfaction](#). *Applied Clinical Trials*. 2017 Dec;26(12).
- Henderson L. [Catch \(& keep\) a rising star: Clinical research talent trends](#). *Applied Clinical Trials*. 2018 Mar;27(3).
- Katzenbach JR, Smith DK. [The discipline of teams](#). *Harv Bus Rev*. 1993 Mar-Apr;71(2):111-120.

## **vi. Clinical Trial-Associated Workload**

Regularly assessing each staff member's workload can help research programs monitor trends and shifts, justify current staffing and the need to hire additional staff, assist with budget planning, ensure workload balance, and ultimately improve staff satisfaction. However, workload assessment can compete with other important clinical trial management tasks, such as maintaining data quality, complying with protocol, and meeting program accrual goals. Several resources address this topic are noted below.

- Good MJ, Hurley P, Woo KM, et al. [Assessing clinical trial-associated workload](#) in community-based research programs using the ASCO Clinical Trial Workload Assessment Tool. *J Oncol Pract.* 2016 May;12(5):e536-547.
- Good MJ, Lubejko B, Humphries K, et al. [Measuring Clinical Trial–Associated Workload in a Community Clinical Oncology Program.](#) *J Oncol Pract.* 2013 Jul;9(4):211-215.
- Smuck B, Bettello P, Berghout K, et al. [Ontario Protocol Assessment Level: Clinical Trial Complexity Rating Tool for Workload Planning in Oncology Trials.](#) *J Oncol Pract.* 2011 Mar;7(2):80-84.
- Fowler & Thomas. Acuity Rating Tool. *Research Practitioner.* 2003;4(2):64-71.
- National Cancer Institute Consortia Webinar. [Assessing Clinical Trial Associated Workload.](#) January 2018.
- [National Cancer Institute Trial Complexity Elements & Scoring Model.](#) 2009.
- James P, Bebee P, Beekman L, et al. [Creating an effort tracking tool to improve therapeutic cancer clinical trials workload management and budgeting.](#) *J Natl Compr Canc Netw.* 2011 Nov;9(11).

## **F. Training, Core Competencies, and Performance**

Once the right staff is in place, they must receive the appropriate onboarding and continued training, as well as understand the core competencies of their role and how they're expected to perform, to ensure the success of a quality clinical research program. There are many organizations that offer training on clinical trials and good clinical practice and the resources listed below provide helpful guidance on equipping your team for long-term success. Appendix D, [available in the full library](#), details a research nurse coordinator training and orientation tool to help staff understand good clinical practice and the conduct of research. The list provides examples only, it does not indicate endorsement from ASCO.

- [Training Log Examples](#) (Figures 2 & 3): Baer AR, Zon R, Devine S, et al: Attributes of exemplary research: The clinical research team. *J Oncol Pract.* 2011 May;7(3):188-192.
- [2016 Oncology Clinical Trials Nurse Competencies.](#) Oncology Nursing Society.
- [Harmonized Core Competency Framework.](#) Joint Task Force for Clinical Trial Competency 2017.
- Applied Clinical Trials Editors. [Top 3 skills for clinical trial project managers.](#) Applied Clinical Trials 2014.
- Performance Review Tool – Appendix E, [available in the full library](#), provides a competency and performance review tool, which includes measurements used as a rating for expectations for the research team.



- American Nurses Association (ANA), International Association of Clinical Research Nurses (IACRN): [Clinical research nursing: Scope and standards of practice](#). American Nurses Association 2016.
- [U.S. Food and Drug Administration Clinical Investigator Training Course](#), which is periodically offered in-person, provides information on the scientific background and practical methodology needed for conducting clinical trials.
- The ASCO eLearning course collection, [Fundamentals of Clinical Trials](#), is aimed at familiarizing new investigators with designing and conducting clinical research. Topics addressed include research design and methodology, regulatory and legal issues, data management, ethics, statistics, research teams, exemplary clinical trials sites, promotion of clinical trials, and informed consent.
- Entities Providing GCP and Human Subjects Protection Training:
  - The Collaborative Institutional Training Initiative Program offers paid online courses covering key regulatory and ethical areas, including Good Clinical Practice Training. [Browse the catalogue](#).

### ***i. Good Clinical Practice Training***

Good Clinical Practice (GCP) training covers several topic areas related to ethical and scientific quality standards for designing, conducting, recording and reporting trials, to ensure compliance with GCP standards developed by FDA and other entities (i.e., [ICH E6 Guidance](#), [U.S. Food and Drug Administration](#), [Clinical Trials Transformation Initiative \[CTTI\]](#), and [TransCelerate BioPharma, Inc.](#))

- Collaborative Institutional Training Initiative [Good Clinical Practice \(GCP\) Training For Investigators](#)
- TransCelerate Biopharma Inc. [Minimum Criteria for ICH E6 GCP Investigator Site Personnel Training](#)

## **G. Clinical Trial Operations/Processes**

(e.g., tips for managing multiple sponsors and trials; internal quality assurance program; external inspections, auditing, and monitoring; biospecimen research infrastructure; Protocol Review and Monitoring Committee)

- [Clinical Research Site Infrastructure and Efficiency](#). This article from the ASCO Exemplary Attributes series discusses infrastructure improvements that promote efficiency and provides examples of effective practices implemented at research sites.
- [Clinical Trial Monitoring Competency Framework](#). This document from the Association of Clinical Research Professionals outlines the necessary knowledge, skills, and abilities for clinical trial monitors.
- Baer AR, Smith M, Bendell JC. [Donating tissue for research: patient and provider perspectives](#). *J Oncol Pract*. 2011 Sept;7(5):334-337. This resource from the ASCO exemplary attributes series illustrates common patient and provider concerns about donating tissue for the purpose of research. The article discusses best practices and provides answers to common patient questions.

- National Cancer Institute [Guidelines for Auditing Clinical Trials for the NCI National Clinical Trials Network \(NCTN, CCOP, and NCORP\)](#)
- [Online Educational Videos](#): These online videos, developed by the Office of Human Research Protection (OHRP), cover a range of topics including: “General Informed Consent Requirements,” “Institutional Review Board (IRB) Membership,” “Research Use of Human Biological Specimens and Other Private Information,” and “Reviewing and Reporting Unanticipated Problems and Adverse Events.”
- U.S. Food and Drug Administration Guidance: [Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring](#). This guidance provides information to support development of risk-based monitoring strategies and plans for investigational studies of medical products. (Aug 2013)
- Refer to section [F. Drug Accountability, Storage, Dispensing and Return](#) for information and resources related to managing study drug(s).

### ***i. Clinical Trial Management Systems***

- Appendix F, [available in the full library](#), provides a Clinical Trial Management System (CTMS) checklist, which will aid your team in reviewing your needs for a CTMS. In selecting and purchasing a CTMS, a review of other IT systems and functionality will help to enhance capability once implemented.

### ***ii. Tracking Systems for Management Clinical Trials***

Upon request, you can access three invaluable tools to help track data management, research lab specimens, and new patient screening assignments.

- Data Management Tracker – This sample tool helps staff track and prioritize key data milestones for every subject. It has overdue data flags which are automated within the tool to ensure the team will meet data timeliness requirements. To request a copy, contact [Nancy.Burns2@unchealth.unc.edu](mailto:Nancy.Burns2@unchealth.unc.edu).
- Research Lab Specimen Tracking – This tracking tool can be used by the lab and clinical research team to track research biospecimens. Research sample collection, processing, storage, and shipment are documented in this tool. To request a copy, contact [Nancy.Burns2@unchealth.unc.edu](mailto:Nancy.Burns2@unchealth.unc.edu).
- Screening Assignments – This screening assignments tool and patient screening log tool enable a team to have clarity on new patient screening assignments (performed daily). To request a copy, contact [Nancy.Burns2@unchealth.unc.edu](mailto:Nancy.Burns2@unchealth.unc.edu).

### ***iii. Addressing Administrative and Regulatory Burden***

Cancer clinical trials have become more and more challenging to conduct. Research programs must comply with federal and state legal and regulatory requirements that can be inefficient and costly to implement. In addition, institutions and sponsors often interpret these requirements conservatively and thereby add to the complexity and perceived (but often highly theoretical) risk of conducting clinical trials.

ASCO has several past and ongoing initiatives that seek to reduce the administrative and regulatory burden of clinical trials and facilitating clinical trial participation and accrual.

- Vose JM, Levit LA, Hurley P, et al. [Addressing administrative and regulatory burden in cancer clinical trials](#): Summary of a stakeholder survey and workshop hosted by the American Society of Clinical Oncology and the Association of American Cancer Institutes. *J Clin Oncol*. 2016 Nov;34(31):3796-3802.

## H. Regulations

(i.e., U.S. federal regulations)

- U.S. Food and Drug Administration [Regulations Relating to Good Clinical Practice and Clinical Trials](#). This listing also includes links to publications that contributed to the development of the FDA's regulations.
- [Society of Clinical Research Associates sponsored FDA Clinical Trial Requirements Regulations, Compliance, and GCP Conferences](#). These paid conferences offer continuing education credits.

## I. Electronic Medical Records Policies and Procedures

(e.g., requirements and processes)

- U.S. Food and Drug Administration [Use of Electronic Health Record Data in Clinical Investigations Guidance for Industry](#). Jul 2018.
- [Laws, Regulation, and Policy](#). HealthIT.gov provides an overview of health IT related legislation and regulations.

## J. Privacy

(e.g., HIPAA, privacy, confidentiality, and compliance related to participants, trials, and sponsors)

- Department of Health and Human Services [Health Information Privacy the Privacy Rule](#) and related rules and information.
- [Privacy, Security, and HIPAA](#). HealthIT.gov offers information and resources to help researchers ensure the privacy and security of health and patient information.
- National Institutes of Health [Health Insurance Portability and Accountability Act \(HIPAA\) Privacy Rule](#).
- [Understanding HIPAA privacy in research](#). This resource from the U.S. Department of Health and Human Services explains each element of the HIPAA Privacy Rule.
- Stanford University [Human Research Protection Program Policy Manual](#) (Direct file download).

## K. Budget Management and Billing

Resources in this section address the financial management of a research program, including developing program budgets, sample budgets, patient billing procedures, and insurance coverage.

- University of California San Francisco [Sample Budget for Clinical Trials](#)

- [Budget Preparation](#). This resource from Ohio State University Center for Clinical and Translational Science provides high-level considerations for budget preparation.
- [Cost-Neutral Clinical Research Enterprise](#). *J Oncol Pract*. 2009 Mar;5(2):76-79. This article from the ASCO exemplary attributes series addresses the challenge of creating a research program that at minimum will be self-supporting. Two attributes of a cost-neutral clinical research enterprise are diversification of trial mix and high accrual activity.
- [Industry Clinical Trials Budgeting and Financial Management](#). This presentation from the University of California San Francisco provides an overview of the financial aspects and considerations of conducting clinical trials.
- Farrell B, Kenyon S, Shakur H. [Managing clinical trials](#). *Trials*. 2010;11(78). This article discusses the need for standard trial management guidelines and evaluation methods.
- Lee K. [How to Keep the Project on Budget in the Clinical Trial Study](#). This article, from Cytel Inc., covers the different elements involved in the biometrics budgeting process of clinical trials.
- Association of Clinical Research Professionals Webinar Replay: [Clinical Trial Billing Basics](#) (Free to ACRP members)
- [Making Research Dollars Stretch for Community Practices](#). *J Oncol Pract*. 2008 Mar;4(2):81-82. Several representatives from practices who received the 2007 ASCO Clinical Trials Participation Awards share strategies on how their sites handle clinical trial funding issues.

### ***i. Finance and Site Development/Growth***

Review the links below to learn about return on investment in clinical cancer research and how to develop an investigator site budget.

- Fricker J. [Study estimates economic returns from UK cancer research](#). *Lancet Oncol*. 2014 Jun;15(8):e314. This study shows that there is a 40% return on investment yearly for each pound spent on clinical cancer research in the UK!
- [Developing an investigator site budget for clinical trials](#). *J Oncol Pract*. 2007 Mar;3(2):94-97. Article discussed site budget issues and the importance of covering all costs.

### ***ii. Research Patient Billing Procedures***

(e.g., U.S. policies on patient billing, information for patients)

- Centers for Medicare and Medicaid Services [National Coverage Determination for Routine Costs in Clinical Trials](#).
- ASCO Resources on [Insurance Coverage of Clinical Trials](#) include information on the Affordable Care Act Requirements for private insurance coverage, Medicare coverage, Medicaid coverage, and relevant state laws and cooperative agreements.
- [Form to Demonstrate that a Trial Meets Statutory Requirements](#). ASCO has created an attestation form based on the law that can help demonstrate that the trial and patient's circumstances meet the coverage requirements.
- [ASCO Insurance Coverage At-a-Glance Summary](#). This ASCO Research Community Forum resource provides key tips, considerations and strategies to assist sites with insurance coverage of clinical trials.

- [Health Insurance Coverage and Clinical Trials](#). This resource for patients from Cancer.net provides an overview of and considerations for insurance coverage of clinical trial participation include relevant legislation and related resources.

### **iii. Insurance Coverage of Clinical Trials**

The ASCO resources listed below will help you prepare the proper coverage in your clinical research program and overcome billing compliance burden.

- The [ASCO Clinical Trial Insurance Coverage Analysis Toolkit](#) helps research sites conduct coverage analyses, deal with coverage denials, and navigate the appeals process. The toolkit is available for free online.
- Szczepanek CM, Hurley P, Good MJ, et al. [Feasibility of a centralized clinical trials coverage analysis](#): A joint initiative of the American Society of Clinical Oncology and the National Cancer Institute. *J Oncol Pract*. 2017 Jun; 13(6):395-400.
- Morillo A. [Understanding Medicare coverage analysis for clinical trials](#). Becker's Hospital CFO Report 2012.
- Meade R, Willenberg K, Roach MC. [Medicare coverage for cancer research](#). *J Clin Res Best Pract*. 2010 Mar;6(3):2-5.
- Willenberg KM. [Managing clinical trials-frustration or bliss?](#) *J Oncol Manag*. 2004 Nov/Dec;13(6):24-26.