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.

When citing this Toolkit, or any of its components, please include the following content in the citation: American Society of Clinical Oncology Research Community Forum. Library of Resources: Conducting and Managing Cancer Clinical Trials. Alexandria, VA; American Society of Clinical Oncology; Aug 2020.

For more information contact researchcommunityforum@asco.org.
VII. Quality Assurance

The resources listed below cover establishment and assessment of research site quality. Resources provide information on how to create internal quality assessment programs, FDA auditing, and patient safety, among other topics. These resources also feature the ASCO Research Program Quality Assessment Tool.

This section includes the following topics:

A. Data Integrity
   B. Internal Quality Assurance Program and Protocol Compliance
   C. Quality Improvement
   D. Preparing for an Audit

A. Data Integrity
   (i.e., accuracy, completeness, legibility, timeliness, etc.)

- U.S. Food and Drug Administration Providing Postmarketing Periodic Safety Reports in the ICH E2C(R2) Format (Periodic Benefit-Risk Evaluation Report) Guidance for Industry. This guidance describes the conditions under which applicants can use the ICH E2C(R2) Periodic Benefit-Risk Evaluation Report (PBER). (Nov 2016)
- International Code of Harmonisation (ICH) Clinical Safety Data Management: Definitions And Standards For Expedited Reporting E2A. This document provides standard definitions and terminology for clinical safety reporting.
- National Cancer Institute Data Safety and Monitoring Plan. This resource provides links to important information on National Institutes of Health polices and guidances around data and safety monitoring.
- European Clinical Research Infrastructures Network Transnational Working Groups (ECRIN) GCP-compliant data management in multinational clinical trials. This resource presents recommendations for data quality assurance to develop a foundation for harmonized interpretation of Good Clinical Practice requirements.
- Bargaje C. Good documentation practice in clinical research. Perpect Clin Res. 2011 Apr-Jun;2(2):59-63. This article highlights the key principles of good documentation practice and offers suggestions for improvement.

B. Internal Quality Assurance Program and Protocol Compliance
   (Internal quality assurance protocols, procedures, and compliance; minimum quality standards; periodic operational checks and audits of protocol data collection, handling, and processing; periodic internal quality control checks and audits of entire program)

- ASCO Research Program Quality Assessment Tool and Manual, which includes a checklist and templates, is available for free online.
- 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.


C. Quality Improvement

Resources in this section provide information and strategies for identifying and implementing strategies to improve the quality of your site processes.

- Using Change Concepts for Improvement. This resource from Institute for Healthcare Improvement offers strategies to help with developing site-specific quality improvement tactics.

D. Preparing for an Audit

(Sponsor audits: monitoring, inspections, requirements, policies, and procedures, documentation; FDA audits: requirements, policies and procedures, documentation, corrective action plans)

- How to Prepare for an FDA Inspection. This resource from the Johns Hopkins University Office of Human Subjects Research Institutional Review Board provides a brief overview of basic considerations for FDA inspections.
- FDA Audit Readiness Part 1: Reflections from the FDA and a Principal Investigator. (Webinar) ASCO Research Community Forum. 2020. This webinar featured James Reeves, MD from Florida Cancer Specialists and Yang-min Ning, MD from FDA shared insights into site selection and the investigator role in the audit process.
- FDA Audit Readiness Part 2: Site Readiness using the ASCO RCF FDA Audit Readiness Toolkit. (Webinar) ASCO Research Community Forum. 2020. This webinar featured Andrea Buchmeier from Sarah Cannon, Katie Goodman from Florida Cancer Specialists, and Dr. Ning sharing strategies for effective pre-audit preparation and post-audit follow-up.
- How to Prepare for an Audit. *J Oncol Pract*. 2009 Jan;5(1):35-37. This article, which builds on the ASCO Exemplary Attributes series, reviews the audit process including the purpose of audits and how to complete the process.
- National Cancer Institute (NCI) Guidelines for Auditing Clinical Trials for the NCI National Clinical Trials Network (NCTN) Program Including NCI Community Oncology Research Program (NCORP) and NCORP Research Bases