

## Section 1: Clinical Trials and Sponsorship

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The DF/HCC is involved in several types of research:

**DF/HCC in-house trials (PI-initiated)** originate with and are conducted by the DF/HCC medical staff that treat DF/HCC-registered subjects. Generally, the data for these trials are collected and analyzed at the DF/HCC. The practices of these trials are dictated by the policies and procedures found in this guide and established by the DF/HCC offices and committees.

**NCI-sponsored trials** either are written at the DF/HCC and approved by the NCI or written by the NCI. Generally, the data for these trials are collected and analyzed at either the NCI or the DF/HCC, depending on the trial. The investigational agents are supplied by the NCI for these protocols.

**Cooperative group trials** are sponsored by the NCI but are categorized separately because of their large volume. Cooperative groups bring together academic institutions and community-based cancer treatment centers throughout the United States and Canada to conduct cancer treatment trials and research. Because of the size of cooperative groups, these clinical trials are designed to answer therapeutic questions that require a large group of study participants. The data for these trials are analyzed at a cooperative group statistical center. The Cooperative Groups enroll approximately 20,000 new participants per year into cancer treatment trials. They are completely separate organizations with separate leadership and research goals.

The Cooperative Groups sponsored by NCI are:

- American College of Radiology Imaging Network ([ACRIN](#))
- American College of Surgeons Oncology Group ([ACOSOG](#))
- Cancer and Leukemia Group B ([CALGB](#))
- Children's Oncology Group ([COG](#))
- Eastern Cooperative Oncology Group ([ECOG](#))
- European Organisation for Research and Treatment of Cancer ([EORTC](#))
- Gynecology Oncology Group ([GOG](#))
- National Cancer Institute of Canada Clinical Trials Group ([NCIC CTG](#))
- National Surgical Adjuvant Breast and Bowel Project ([NSABP](#))
- North Central Cancer Treatment Group ([NCCTG](#))
- Radiation Therapy Oncology Group ([RTOG](#))
- Southwest Oncology Group ([SWOG](#))

**Cancer Trials Support Unit (CTSU)** is a pilot project sponsored by NCI's [Cancer Therapy Evaluation Program \(CTEP\)](#) to accomplish the following objectives:

1. To **facilitate** physician and patient access to NCI-sponsored clinical trials by developing an efficient enrollment procedure that will facilitate cross-Group accrual, and permit non-Group members to enroll patients on NCI-sponsored trials
2. To **streamline** data entry and collection for clinical trials through the use of standard case report forms and reporting mechanisms
3. To **reduce** the regulatory and administrative burdens on Clinical Trials Cooperative Groups sponsored by NCI by unifying and standardizing membership rosters and institutional review board approvals

**Consortium-Sponsored Trials** originate and are conducted by an association of two or more individuals, companies, organizations or government (or any combination of these entities) with the objective of participating in a common activity or pooling their resources for achieving a common goal.

**Industry-Initiated Sponsored Trials** are designed and sponsored by a pharmaceutical or biotechnology company. Multiple institutions may collaborate on these trials. All data are sent to the sponsoring company or designated contract research organization (CRO) for analysis. The practices of these trials are outlined by the sponsor and/or CRO but still must meet DF/HCC standards and policies.

**PI-Initiated/industry-Supported Trials** originate with and are conducted by the DF/HCC medical staff that treats DF/HCC-registered subjects. A pharmaceutical company may be sought to support or fund the trial.

**Community-based and Quality-of-Life Trials** are research trials designed to explore public health problems, measure the quality of life of people with cancer, and evaluate human behavior, social science, education and epidemiology. Methods and instruments used may involve questionnaires, surveys, interviews, and observations. These studies may be initiated by a DF/HCC investigator or an outside agency or group.