

Cancer and Leukemia Group B Clinical Research Associates Committee

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Abstract The Cancer and Leukemia Group B is dedicated to developing and implementing training programs that will enhance the skills and abilities of Clinical Research Associates (CRA) involved in all aspects of data collection and research. Training programs not only improve overall knowledge and professionalism but also improve the integrity of study data. The CRA roles and responsibilities include the following: collect, analyze, and monitor data; collaborate with other members of the health care team; insure regulatory mandates are followed; manage the care of research participants; assist in the recruitment and enrollment of human subjects; protect subjects rights by adhering to Institutional Review Board guidelines, the Code of Federal Regulations; prepare and submit timely adverse event experience reports; maintain case report forms and drug accountability records; educate other health care professionals, patients, and families regarding clinical trials; participate in research audits; and function as a team member with the research team. In addition, CRAs may also be responsible for writing reports, grant, and budget development and the development of protocols, forms, and informed consent documents.

Purpose and Introduction

As we celebrate the 50th anniversary of the Cancer and Leukemia Group B (CALGB), we acknowledge the contributions that Clinical Research Associates (CRA) have made to the scientific validity of CALGB studies. Early CALGB protocols often lacked data collection tools. Upon reviewing archived files, it was not uncommon to find only a single page data collection tool for leukemia studies. In the community setting, pioneering physicians were typically responsible for all aspects of the protocol, including registering the patient, completing data collection form(s), and handling all Institutional Review Board requirements. As the number and complexity of protocols evolved, physicians recognized that it was essential to have assistance with data collection, regulatory document management, and many other aspects of protocol implementation and participation. Thus, the critical position of CRA was born. The primary purpose of the CALGB CRA Committee is to provide educational programs and a forum for physicians and research professionals to exchange information (Table 1).

Roles and Responsibilities

The CRA is primarily responsible for collecting, organizing, and submitting data for a clinical trial. Responsibilities may

also include recruitment efforts; patient enrollment; toxicity coding/reporting; collection of cost analysis data; development of data collection forms; regulatory compliance monitoring; assistance in the collection and shipment of blood, bone marrow, tissue, and/or urine for correlative science studies; and audit participation.

CALGB CRAs have varied educational backgrounds and job descriptions. Although many CRAs have nursing degrees, others hold degrees in areas such as biology, statistics, and health care administration. The diversity of our membership contributes to our strength. Knowledgeable CRAs enhance the conduct of clinical trials. CRA expertise promotes protocol adherence and prevents protocol violations. Nationally, there are very few educational programs specific to the CRA, and most CRAs obtain their education from on-the-job training. The employment turnover rate is very high. Therefore, the CALGB CRA committee offers a variety of educational opportunities for CRAs to learn and exchange information contributing to professional growth, improving job satisfaction, and building fundamental skills for successful clinical research outcomes.

The CRA Committee meets formally twice each year and informally via conference calls or in person as needed to accomplish Committee tasks. At each committee meeting, all agendas for the subsequent CRA meetings and workshops are planned. In addition, discussions are held, and recommendations are made regarding policies, procedures, committee liaison activities, and administrative issues. Individual CRA Committee members serve as liaisons to disease and modality committees and perform other functions such as committee secretary, coordinator of the liaisons, protocol review coordinators, surgical workshop coordinators, audit preparation workshop coordinators, reference table planner, poster coordinator, CAL-Gab Newsletter coordinator, and special projects.

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Table 1. CALGB CRA Committee

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| Chair | Kandie Price, M.S., R.N., OCN, CCRP Delaware CCOP/Christiana Care Health Services, Inc. |
| Vice Chair | Barbara Barrett, M.S., CCRP University of Missouri/Ellis Fischel Cancer Center |
| Protocol Editor | Kathleen S. Karas, B.S. CALGB Central Office, University of Chicago |
| Staff Statistician | Donna R. Hollis, M.S. CALGB Statistical Center, Duke University |
| Cadre Member | Anne Burgess, B.S.N., R.N., CCRP Brigham and Women's Hospital |
| Cadre Member | Mary Dierker Missouri Baptist Medical Center |
| Cadre Member | Angela Dodley, LPN The Ohio State University |
| Cadre Member | Debra Herzan, R.N., B.S.N., OCN Dept. of Veterans Affairs, Minneapolis, MN |
| Cadre Member | Rebecca Laughlin, CCRP University of Vermont |
| Cadre Member | Carolyn Mobley Wake Forest University School of Medicine |
| Cadre Member | Judith L. Murray, M.S. University of Illinois at Chicago |
| Cadre Member | Linda Spillett, CCRP SUNY Health Science Center, Syracuse, NY |
| Cadre Member | Susan Tuttle, R.N. Southeast Cancer Control Consortium, Inc. |
| Cadre Member | Linda Veit, B.S. SUNY Upstate Medical University |
| Cadre Member | Howard Weiner, CCRP University of Chicago |
| Cadre Member | Margaret E. White, R.N., OCN, CCRP New Hampshire Oncology-Hematology |
| CALGB Training Manager | Angela Rice-Warren, B.A. Data Management Center, Duke University |
| Data Management Director | Debbie G. Sawyer, B.A. Data Management Center, Duke University |
| Patient Advocate Liaisons | Kathryn Adams Edith Fitts Deborah Collyar |

To insure that CALGB research is of the highest quality, the primary objectives of the CRA Committee are to:

- Offer continuing education to institutional CRAs in the diagnosis, staging, and multimodality treatment of malignancies studied by CALGB.
- Educate both new and experienced CRAs in the efficient and accurate documentation and timely submission of data.
- Instruct CRAs in compliance with federal regulations regarding informed consent, Institutional Review Board submission, serious adverse event reporting, secondary malignancy reporting, National Cancer Institute (NCI) drug accountability, audit preparation and procedures, and organizational and interpersonal skills.

- Provide instruction in the ethical conduct of clinical trials and human subject protection.
- Interact with disease and modality committees during the development and implementation of new protocols.
- Collaborate extensively with staff at the Statistical Center in the development of data management policies and procedures, forms, and other issues that will affect the data collection procedures of the Group.
- Provide input from the CRA perspective regarding CALGB policies and procedures.
- Provide guidance to new committees and working groups regarding data management issues, forms, and educational materials as those committees/working groups design their initial protocols.
- Represent CALGB in NCI-sponsored efforts to make data management policies and procedures more uniform among the cooperative groups.
- Represent CALGB on Cancer Trials Support Unit (CTSU) advisory boards and review protocol patient education materials.

Educational Meetings and Workshops

CRA meeting. The CRA meetings are held at each semiannual CALGB Group Meeting. At these meetings, staff from the CALGB Central Office, including the group administrator, protocol editors, regulatory affairs coordinators, and web manager, present pertinent information to the CRAs. Liaisons from other committees and study chairs use this meeting to introduce new studies to the CRAs and to provide updates regarding accrual or data issues. Staff members from the Statistical Center relay new information about forms, clarify data issues, CALGB policies and procedures, and CALGB Information Systems. The remaining meeting time is used to provide information on topics of general interest to CRAs, such as NCI initiatives, CTSU updates, ethics, institutional review board policies, etc. CRA members are encouraged to provide feedback at these interactive meetings.

Continuing education workshop for CRA. The emphasis of the Continuing Education Workshop for CRAs is on progressive education and refinement of data management skills. This workshop is typically held at each semiannual CALGB Group meeting and occasionally may be combined with the CRA Meeting, the Oncology Nursing Committee meeting, or the Pharmacy Committee meeting. Topics alternate between disease-specific presentations and administrative-related presentations. CALGB physicians provide scientific presentations about diagnosis and staging of various diseases, new investigational agents and/or treatment modalities, patient care implications of CALGB treatment programs, and laboratory techniques.

CRA workshop for surgical protocols. Members of the CRA Committee work closely with the Surgery Committee to coordinate this workshop that is presented semiannually. This session addresses specific issues regarding data management of surgical studies and provides an open forum to identify and solve difficulties that CRAs may encounter with surgical studies.

Audit preparation workshop. The Audit Preparation Workshop is presented annually, usually at the Fall Group Meeting, and includes presentations by both physician and CRA members of the Data Audit Committee. Topics presented

include the history of CALGB audits, relevant elements from policy and procedures, timeline for preparation, the physician/PI perspective, preparation of medical records and Institutional Review Board files, pharmacy audit, and responding to the audit report. Presentations are given by and are targeted to physicians, pharmacists, and CRAs. An extensive handout, including the workshop presentations and additional resources, is provided to each attendee.

Clinical trials management orientation program. The CRA Committee, in collaboration with the CALGB Statistical Center, is responsible for planning and presenting the annual training workshop for new CALGB CRAs. The 2-day workshop encompasses a wide range of topics presented both as lectures and small group discussions with hands-on activities. Training includes an overview of processes related to collecting, organizing, and submitting data for clinical trials. Presentations include the role of cooperative groups in cancer research, disease overviews, patient enrollment, informed consent and Institutional Review Board issues, toxicity coding/reporting, data collection forms, and audit participation. A review of CALGB information systems is also presented. The CRA Committee has collaborated extensively with the Statistical Center in developing a comprehensive Beginner CRA Manual. The manual is given to each workshop participant, and extra copies are made available to sites by the Statistical Center throughout the year. The goal of the workshop is to build fundamental skills for successful clinical research outcomes.

Society of Clinical Research Associates (SoCRA) certification exam. In addition to the formal group sessions listed above, the committee also sponsors the Certified Clinical Research Professional certification examination that The Society of CRA administers at each group meeting (Table 2). Society of CRA established the statistically and psychometrically validated Certification Program for Clinical Research Professionals to create an internationally accepted standard of knowledge, education, and experience for clinical research professionals to be recognized by the health care research community. Those individuals so approved may use the title "Certified Clinical Research Professional."

Major accomplishments. The CRA Committee has excelled in its primary focus of presenting educational programs for CALGB CRAs and contributing to the administrative and scientific goals of the Group, including being responsive to opportunities to assist in implementing new initiatives within CALGB and at the NCI. Over the past several years, there have been a significant number of changes within the cooperative groups. The NCI initiated changes to their informatics systems, which included the Adverse Event Expedited Reporting System and Common Toxicity Criteria, and made efforts to enhance the efficiency of cooperative group research by implementing the CTSU, Central Institutional Review Board, and a new informed consent template. Within CALGB, there have been numerous enhancements to the Group's information systems and changes in policies and procedures.

The CRA Committee has allotted time at each Group meeting for NCI-sponsored presentations regarding the development of the Common Toxicity Criteria and Adverse Event Expedited Reporting System. Additional hands-on sessions have been held at multiple Group meetings. In addition, since 2000, an NCI representative has attended each of the annual CRA

Table 2. CALGB CRA Committee meeting schedule

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| CRA Meeting | June and November | CRAs and Nurses |
| Continuing Education Workshop | June and November | CRAs and Nurses |
| CRA Workshop for Surgical Protocols | November | Surgical CRAs and Nurses |
| Audit Preparation Workshop | November | Physicians, CRAs and Nurses |
| Clinical Trials Management Orientation Program | October | CALGB CRAs with <1 y Experience |
| Society of CRA Certification Exam | June and November | CRAs with 2 y Experience |

Orientation Programs to provide an overview to the new CRAs. Past NCI presentations included information about the NCI Informed Consent Working Group and the Response Evaluation Criteria in Solid Tumors criteria for unidimensional tumor response assessments.

The CRA Committee has been involved with the CTSU since its inception. The committee has appointed a liaison to serve as a member of the CTSU Education and Training Advisory Board. The CTSU staff is invited to each Group meeting and the CRA Orientation Program to provide updated presentations.

In 1998, the CALGB Information System was activated throughout CALGB institutions. With its deployment to the membership, the CRA Committee worked extensively with the Statistical Center in developing a user manual for the software and a training program for CALGB personnel at member institutions. As part of this project, six members of the CRA Committee attended two "train the trainer" workshops at the Statistical Center in preparation for the initial Information System training workshop held at the Group meeting. An Introduction to the CALGB Information System was presented to lead CRAs from each main member institution, each Community Clinical Oncology Program institution, and selected large affiliate institutions. A CRA subcommittee comprised of the original six trainers was created to assist in CALGB Information System training workshops and other System software-related endeavors.

The CRA Committee has continued to collaborate with the CALGB Central Office staff in augmenting the Web site. All Powerpoint presentations from the CRA meeting lectures given at Group meetings and workshops are available on the CALGB web site. Policy and procedure manuals, a sample CRA job description, and an orientation checklist are also available on the web site.

Conclusion

The CRA Committee has been involved in many improvements and enhancements to the CALGB. In addition to playing a role in new initiatives, the Committee has continued to excel in its primary focus of presenting educational programs for CALGB CRAs and contributing to administrative and scientific aspects of the Group. We look forward to the next 50 years of striving to develop tomorrow's cancer treatments today.