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voluntary basis. Their involvement in clinical trials research is motivated by scientific, intellectual, and altruistic reasons. Their participation also enables them to bring state-of-the-art cancer management to their patients. Hence, it is imperative that we continue to provide adequate funding for conducting community-based clinical research. The NSABP will continue to seek funding through a variety of mechanisms and from a variety of sources to facilitate continued participation as well as expanded participation of community-based investigators in clinical research. This issue will become increasingly more important in a climate of health care reform and competition for health care dollars. Yet, in this climate, clinical research becomes even more important. It is only with scientifically verified results that physicians will be able to treat patients cost-effectively (i.e., they must know what works, how much it works, and at what cost). We know of no more efficient and effective mechanism for obtaining this information than through well-designed and sufficiently funded clinical trials. The concept of basing clinical practice on the science of medicine has evolved through this century. It must continue into the next.

ACCC's Collaborative Research Group

by Albert B. Einstein, Jr., M.D.

In 1990, the community's contribution to clinical research took another step forward. At the request of a number of ACCC members, the association launched its own Collaborative Research Group (CRG). This group has steadily increased in size and complexity, providing many member organizations involvement in quality clinical research trials from a number of pharmaceutical and biotechnology organizations.

The 60 member hospitals of ACCC's CRG are a powerful resource for clinical trials. Including one NCI Comprehensive Cancer Center, one academic cancer center, 20 of the larger CGOP institutions, and 18 CCOPs, the CRG provides access to more than 60,000 new cancer patients each year. CRG members have accrued 3,774 patients to NCI trials and 1,554 to other trials in 1993 alone through their existing affiliations with the national groups, including the Southwest Oncology Group, the Eastern Cooperative Oncology Group, the National Surgical Adjuvant Breast and Bowel Project, the Radiation Therapy Oncology Group, the Pediatric Oncology Group, the Cancer and Acute Leukemia Group B, and the North Central Cancer Treatment Group.

The group has a wide range of resources. Fifteen have operational BMT units with more than 350 patients treated each year. The group has 1,835 dedicated oncology unit beds, 2,359 oncology nurses, 425 medical oncologists, 192 radiation oncologists, and 167 data managers.

CRG ORGANIZATION

The CRG's multidisciplinary Steering Committee reviews new applicants for membership and conducts a thorough review of potential new protocols submitted by pharmaceutical and biotechnology corporate sponsors.

The idea is to assure that each protocol asks a legitimate and important scientific question and that the data collection requirements are within reason. The group is not interested in doing studies that are Phase IV marketing trials. It wants to be involved in and contribute to solid research activities.

The Steering Committee works with the sponsor, ascertains a price for participation in the trial, and notes problems with the trial (from eligibility requirements to data forms) that might prohibit the sponsor from achieving its goal. In at least one case, the group's recommendations were taken back to the FDA and eligibility requirements were loosened. Simplified contracting and billing procedures eliminate many of the hassles for both sponsors and sites.

Subsequent to the Steering Committee's approval, group members receive a copy of the protocol with a short Request for Proposal, which allows them to indicate whether or not they wish to participate, what conflicts their involvement might have with other protocol obligations, and to discuss their research experience. Sponsors then work with staff and the Steering Committee in making final site selections.

HIGH QUALITY

The CRG membership has won praise from corporate sponsors for its quality of data management. One corporate medical monitor has stated that there were no "data turkeys" among the ACCC group. "By that I mean that none of the sites gave us unacceptable data." Moreover, this same physician indicated that ACCC's sites had been the highest accruers to his study, exceeding prime sites which had been members of the study for twice as long.

As the group's reputation has grown, so have the number of corporations wishing to involve the CRG in studies.

ACCC Executive Director Lee E. Mortenson, D.P.A., has noted the emergence of two different approaches to working with the CRG. On the one hand, some organizations are coming with IND studies that they have had open for some time. These companies are often looking for high-quality sites to supplement ongoing efforts. On the other hand, a number of companies are approaching us about long-term relationships, involving group members in the development of studies, and in publications, in addition to implementation of the trials. This provides the high degree of interest and involvement many of our members have sought.

The CRG hopefully will provide participating ACCC members additional options for involvement in meaningful clinical research and for rapid access to new drugs for their patients.

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