



Cancer Leadership Council
Cancer Research and Prevention Foundation
Coalition of National Cancer Cooperative Groups
Oncology Nursing Society
American Society of Clinical Oncology

EXECUTIVE SUMMARY
Summit III: Increasing Patient Participation
October 27-29, 1999, Washington DC

INTRODUCTION

The Summit Series on Clinical Trials continued in October 1999 with the third meeting focusing on the role and participation of patients in the clinical trials process. Current estimates indicate that less than five percent of adult cancer patients participate in clinical trials despite the strongly held belief fact that clinical trials offer access to the newest developments in cancer treatment. A number of efforts are taking place both locally and nationally to reshape and improve the clinical trials system in an effort increase participation. In order to assist and promote these efforts we need to gain insight and understanding into the wants and needs of the patient and advocate community. Through their experiences and suggestions the patients can help shape change.

The goal of Summit III was to exchange information and establish a dialogue in order to develop future strategies for greater patient involvement. Among the constituencies represented were more than 70 national and regional patient advocacy organizations. Even more important was the inclusion of representatives of relatively rare cancers and medically underserved populations that heretofore have not been at the table. Finally, as with previous summits, representatives from the Cooperative Groups, government agencies, the pharmaceutical industry and managed care were on hand.

OVERVIEW

The event opened with an overview of the two previous summits and highlighted the initiatives now underway that developed from action items suggested at those conferences. The agenda also featured presentations on a broad array of subjects within the clinical trials system varying from barriers to participation to efforts by advocates and researchers ongoing either at a regional/community level or at the national level. Summit III culminated in a series of breakout sessions in which participants selected one of five topics that interested them. The sessions covered the following topics:

1. Improving Trial Designs and System Infrastructure
2. Increasing Diversity of Participants
3. Publicizing Trials and Reporting Results
4. Developing Local Implementation Plans
5. Surveying the Public Attitudes Toward Clinical Trials

Following the breakout sessions, moderators for each topic reported on the discussions and the key recommendations that resulted from the groups. The attendees of Summit III then discussed and agreed that the critical issues in clinical trials from the patient perspective and potential solutions were as follows:

- The physician is key to clinical trial enrollment and completion. There should be collaboration among referring physicians, community oncologists and clinical investigators at academic medical centers. All physicians need to be educated early in their training about clinical trials methodology, cancer statistics, treatments and available trials. Physicians need to introduce the topic of clinical trials early on in the diagnosis and in a positive and informed manner.
- The clinical trials system should improve interactions among the different physician groups, the patients and the organizations coordinating the trials through the increased use of a shared and comprehensive database, websites, and simplified consent forms and tracking documents.
- Researchers need to study the science of recruitment to provide evidence of how to change the current model of clinical trials recruitment and accrual. Incentives to participate, for example, may be one way to increase participation. For the physician an incentive may be accreditation that will elevate his/her professional status. Perhaps managed care companies could require participation in clinical trials for network selection in oncology. A centralized Institutional Review Board (IRB), simplified forms and greater resources for staffing would make administering trials easier for physicians. For patients, incentives may include access to transportation for treatments, coverage of childcare costs, and perhaps reimbursement of some kind for actual time spent participating.
- Patients trust their physicians. If a physician's view of a clinical trial is one of quality care and state-of-the-art treatment, patients will be more likely to enroll because of the favorable opinion the physician has of clinical trials.
- To increase diversity of patients enrolled in trials we must increase the diversity of the physicians and healthcare professionals involved in clinical trials. There must be a greater focus on the community and proactive efforts in communities with medically underserved populations. Local organizations can help in efforts to educate and inform the communities about the value of clinical trials. An incentive system should be put in place for encourage institutions with large medically underserved populations to enroll more of these patients. Recognize that not everyone has access to the Internet. Information must be made more readily available and in a variety of mediums. Recognize the differences between minority communities and ensure that messages are tailored to the cultural and social ideals of the particular population.
- Patient advocates are willing to be partners that (a) work with physicians in publicizing clinical trials, (b) assist in trial design and study requirement process to make trials more patient friendly, and (c) work with government agencies such as the Office for Protection from Research Risks (OPRR) to make the system more responsive to real public needs. Advocates can often serve as a navigator for patients, helping guide them through the experience of a clinical trial and providing a readily available resource to answer questions and concerns. It is crucial to keep the advocate community informed of what trials are available so they can direct patients appropriately.
- Open discussion of the availability of trials and the way trials are designed and conducted is critical to debunking myths and misunderstandings. A concerted and in-depth educational program directed at publishers and media executives as well as those that report cancer related news needs to be undertaken in order to counteract and correct the tremendous amount of negative press associated with clinical trials.

- Notifying patients who participated and publicizing the results of trials, both positive and negative, needs to be considered the ethical norm. Publication of results should include a clear and understandable notice to the public that includes a discussion of the rationale for the study, a summary of the data and how the study results will impact future cancer treatment.

Lastly, during Summit III one breakout session was devoted to finalizing a survey that will be conducted by Harris Interactive on public attitudes and opinions that exist on clinical trials. An action item from Summit II, the Harris Interactive survey will look at the attitudes and behaviors towards cancer clinical trials of not only cancer patients and their families, but also the non-oncologist physicians such as family practitioners, internists, surgeons, and pediatricians, as well as a sampling of the public at large. The survey will also be conducted among several of the top media outlets in the United States. Attendees at Summit III played an important role in finalizing the topic list from which the survey tool's questions will be developed. The survey is expected to take place beginning in late January 2000. The final data will be analyzed by sometime midspring 2000 and will be reported at the meeting of the American Society of Clinical Oncology in May 2000 in New Orleans.