



Summit Series on Cancer Clinical Trials VIII *Retooling the System: Accelerating Solutions*

Executive Summary

Introduction

The purpose of the *Summit Series on Cancer Clinical Trials* is to provide an interactive platform to discuss methods for improving the cancer clinical trials system. The Summit is the only meeting to include all players within the cancer community: advocates, health care professionals and numerous companies and institutions. These stakeholders are all invested in improving clinical cancer research and have volunteered their time and energy to achieve this goal through the Summit Series. Since its launch in 1998, Summit attendees have worked diligently on reviewing the current state of cancer research, examining the positive and negative aspects of the cancer clinical trials system and suggesting ways to raise public awareness and increase participation in cancer clinical trials. The Summit is currently comprised of four work groups, each focusing on different yet interconnected aspects of the clinical trials system, including education, recruitment, retention, and management.

Summit VIII: September 30—October 1, 2004

The Summit held its eighth conference in Chantilly, VA. Entitled *Retooling the System: Accelerating Solutions*, Summit VIII concentrated on continuing the work groups' varied objectives. Similar to Summit VII, the conference gave work groups the opportunity to share ideas, brainstorm and receive feedback from Summit attendees.

Over the past six years, the Summit has made great strides. The challenge at its eighth meeting was to sustain the momentum. With this in mind, the Summit conveners identified the following three goals for Summit VIII:

1. Invite speakers who will provoke new approaches and ideas that may then be applied to work group activities/projects.
2. Demonstrate the progress made by each of the work groups over the previous year.
3. Energize ongoing work group efforts by bringing participants together to share their progress.

Welcome and Guest Speakers

Ellen Stovall, President and CEO of the National Coalition for Cancer Survivorship, welcomed Summit VIII participants. After introductions, she briefly recapped the progress of the Summit and articulated the great promise that the future holds for cancer clinical trials. She also highlighted the launch of the Summit Series Web site, www.cancersummit.org, which provides a home for all Summit-related materials.

To spark discussion and rejuvenate the Summit's charge, Malcolm Gladwell, author and staff writer for *The New Yorker*, was invited to speak at the meeting. He delivered a stirring discourse on how to "tip" cancer clinical trials – a theory discussed in his book, *The Tipping Point: How Little Things Can Make a Big Difference*.

Gladwell identified three goals to bear in mind while attempting to tip, or make a change in, the cancer clinical trials system:

1. Make a distinction between why and how
 - People need to be shown how to make a certain choice; they will be especially slow to act (if at all) if simply told why they should participate in cancer clinical trials.
2. Decide how you want to frame the issue
 - Settle on one single issue/angle that represents cancer clinical trials (e.g., self-interest vs. altruism).
3. Identify your "maven"
 - Social power is a heavy contender in social change. In making decisions, many people have individuals to whom they defer for advice, deemed "mavens" by Gladwell. In essence, the issue is not about the message, but rather the messenger.
 - Too much information can overwhelm a person, but the trusted maven delivers the simplest information on cancer clinical trials—what and how.

Gladwell offered suggestions on how to apply these theories to the Summit's goals. He emphasized the importance of having a maven to help navigate the complicated system of cancer clinical trials. Gladwell also stressed that all Summit members can continue to act as advisors to their family, friends, and community by maintaining their social influence and by supporting advocacy and patient groups. Attendees identified Lance Armstrong as a maven, but decided that his association with issues other than cancer clinical trials may dilute his credibility as a messenger.

The attendee response to Gladwell was tremendous. Many said that Gladwell inspired them to approach their work group activities with new and innovative ideas in mind.

To listen to Malcolm Gladwell's Summit presentation, visit:
www.cancersummit.org/summit_viii.htm.

In addition to Gladwell, three Summit participants presented on the following topics:

- Harold L. Moses, MD, Vanderbilt-Ingram Cancer Center and Vanderbilt University School of Medicine, elaborated on “Integrating Laboratory Science into Clinical Trials”.
- Jeffrey K. Belkora, PhD, University of California at San Francisco Cancer Center, addressed the issue of “Promoting Patient Participation in Informed Decision Making/ Informed Consent about Medical Treatment and Clinical Research”.
- Peggy Devine, Cancer Information and Support Network, Inc., shared her thoughts on “The Consent Process: An Advocate’s Perspective”.

The discussions following each speaker were valuable and allowed attendees to further explore the importance of these issues within the scope of the cancer clinical trials system.

WORK GROUP REPORTS

In response to the feedback from the Summit attendees, the Summit agenda was designed specifically to maximize the individual work group meeting time. This format proved beneficial and resulted in noticeable progress. Each of the work groups continues to move closer to achieving its goals.

For detailed information on each work groups’ past activities, accomplishments to date, and regularly updated proceedings, please visit www.cancersummit.org.

Work Group 1, 3 (WG1/3) – Patient Education and Communication

WG1/3 has focused on identifying high-quality clinical trials educational resources for patients. In 2003, the group finalized a resource to evaluate cancer clinical trials information on the Web, now available on the National Cancer Institute’s Web site. For this year’s Summit, WG1/3 organized the *Cancer Clinical Trials Patient Education Exhibit*, where many attending organizations presented their clinical trials materials. Summit participants browsed the displays and took home various brochures and booklets to learn more about what other organizations are doing to educate patients in the cancer community.

At the conclusion of the meeting, WG1/3 participants shared their four main objectives for the coming year:

1. Continue to identify the components of high quality, patient-focused cancer clinical trials Web sites.
2. Identify the components of high quality, patient-focused cancer clinical trials educational materials.

3. Determine optimal dissemination and evaluation strategies for cancer clinical trials education materials.
4. Collaborate with NCI to maximize involvement and to leverage investment in clinical trials patient education.

Work Group 2 (WG2) – Provider Education for Successful Clinical Trial Participants

WG2's primary goal is to provide information and support to health care providers in order to increase the recruitment and retention for clinical trials. WG2 is working to assemble an online clinical trials tool kit for health care providers to facilitate trial recruitment and retention. This virtual resource will provide information and support to organizations, institutions, and individuals recruiting for clinical trials.

During Summit VIII, WG2 elaborated on the structure of the tool kit, which will include:

1. *Introduction*—explanation of the importance of cancer clinical trials.
2. *Strategies*—new messages about clinical trials, including mythbusters and education for fellows and interns.
3. *Success stories*—real world examples of different approaches that have and have not worked in increasing recruitment and retention.
4. *Tools*—aids for health care providers, such as downloadable index cards and PDA software with clinical trials talking points.
5. *Resources*—links to other organizations' Web sites (FDA regulations, National Institutes of Health, etc.), as well as a glossary of key terms.

The work group is beginning to pull together the toolkit and explore the Web site needs for the resource. WG2 hopes to eventually incorporate materials from the other work groups and develop a way to evaluate the toolkit.

Work Group 4, 5 (WG4/5) – Adequate Reimbursement of Research Costs

WG4/5 took on the charge of studying clinical trial costs and determining the elements of a successful clinical trial. In 2004, group members identified and compiled the key "success" elements in a checklist. WG4/5 also reviewed existing available costs associated with running a clinical trial to develop the basis for a budget guide (or "BlueBook"). To complete the book, WG4/5 decided to collaborate with C-Change (formerly the National Dialogue on Cancer) and commission a definitive study that will provide a guide for evaluating the associated expenses.

To date, WG4/5 and C-Change have secured respected outside organizations (Lewin Group and Lovett Collins Associates) to accomplish the following:

1. Review and assess regulations and reimbursement practices;
2. review and assess currently available clinical trial studies;
3. develop a survey instrument and obtain responses from clinical researchers at 15 to 18 different locations nationwide;
4. finalize the details of functional requirements and costs;
5. prepare a final report and revise as needed, following the review of the Summit and C-Change.

WG4/5 will take the results of the final cost study report and develop a financial and managerial guidebook for conducting cancer clinical trials. As the first of its kind, the resource book will have three components: the preamble that will describe the value of clinical trials in order to emphasize the importance of the program to those that fund the project; a budget guide that will explain the overall research program costs as well as the specifics of project costs; and the “Essential Elements of a Successful Program,” that will enable clinical trial institutions to understand the practice environment as well as the type of research they want to do and the different affiliations they have.

Work Group 6 (WG6) – Managing Regulatory Burden for the Patient’s Benefit

WG6 was initially charged with proposing a viable alternative to the current system for initial, ongoing review and monitoring of cancer clinical trials. Through significant research, WG6 determined that the current system is inefficient with its emphasis on local review and developed the following concepts:

1. Human Subject Protection Process should be based on a partnership between a specialized central review board for oncology and local review boards.
2. Local Review Board should have guidelines for drafting new system operating procedures that would cover their newly defined responsibilities in relation to their local context.
3. Certain detailed procedures need to be used for providing initial review of multi-center and cooperative groups.
4. Specified procedures should be utilized for performing continuing reviews of multi-center and cooperative group trials.

WG6 recommended that Summit conveners endorse the National Cancer Institute-Central Institutional Review Board Project -- pending the outcome of their project evaluation as well as the [American Society of Clinical Oncology policy statement on the Oversight of Clinical Research. WG6 feels that they have sufficiently completed their initial goal and requested that the conveners support a newly proposed objective. Upon the conveners’ approval, WG6 will focus on exploring ways to better support patients who are given the option of participating in a clinical trial through the use of decision aids and educational materials.

Closing Discussions

Bob Comis, MD, led the closing discussion by recapping the progress that the Summit has made over the past six years. Dr. Comis then highlighted a few of the recent initiatives intended to bring cancer clinical trials into the public spotlight. Two examples he showcased were:

- A special advertising section on cancer clinical trials that ran in the June 7 issue of *Newsweek* magazine, sponsored by the Coalition of National Cancer Cooperative Groups;
- The Tour of Hope's second annual cross-country bike relay, featuring Lance Armstrong, to help raise awareness of cancer clinical research.

These campaigns are a testament to the progress that has been made in generating cancer clinical trials awareness. The Summit Series continues to be a driving force in the evolution of the cancer clinical trials system, and we look forward to future advancements that will result from the Summit's contributions.

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