

New Alliance formed to address clinical trials in oncology

by Monica M. Bertagnolli, MD, FACS

The American College of Surgeons Oncology Group (ACOSOG), the Cancer and Leukemia Group B (CALGB), and the North Central Cancer Treatment Group (NCCTG) recently merged to form the Alliance for Clinical Trials in Oncology. The Alliance is a new National Cancer Institute (NCI)-sponsored cancer cooperative group, joining three other groups including the

cancer research group known as ECOG-ACRIN (the American College of Radiology Imaging Network and the Eastern Cooperative Oncology Group), NRG (formerly National Surgical Bowel and Bladder Project and Radiation Therapy Oncology Group and Gynecologic Oncology Group), and SWOG (formerly the Southwest Oncology Group).

The mission of the Alliance is

to reduce the impact of cancer by uniting a broad community of scientists and clinicians from many disciplines—each committed to discovering, validating, and disseminating effective strategies for the prevention and treatment of cancer. Presently, the Alliance is conducting 187 clinical trials, concentrating on eight types of cancer: breast, gastrointestinal, genitourinary, respiratory, leuke-

Alliance programs

| Office of the Group Chair | | | | | | | |
|---------------------------|---------------------------------|--------|------------------|--------------------|-------------|------------|---------------------------|
| Leukemia | Lymphoma | Breast | Gastrointestinal | Genitourinary | Respiratory | Myeloma | Neuro-Oncology |
| Patient Advocates | Clinical Research Professionals | | Oncology Nursing | Radiation Oncology | | Transplant | Experimental Therapeutics |

| Statistics and Data Management Program | Central Protocol Operations Program | Translational Research Program | Cancer Control Program | American College of Surgeons Clinical Research Program |
|--|-------------------------------------|--|---|--|
| Statistics and Data Center | Protocol Office | Administration Core | Community Clinical Oncology Program Research Base | Commission on Cancer |
| | | Integrated Biorepositories | | |
| | | Molecular Reference Laboratories | | |
| Biostatistics | Study Concept Review Committee | Leukemia Correlative Science | Symptom Intervention | Member Services |
| Bioinformatics | Publications Committee | Solid Tumor Correlative Science | Health Outcomes | Education |
| | | Imaging | Cancer in the Elderly | Cancer Care Standards Development |
| | | Pharmacogenomics & Population Pharmacology | Community Oncology | Research Development |
| | | Pathology | Prevention | |
| | | Karyotype Review | Health Disparities | |
| | | | Comparative Effectiveness | |

mia, lymphoma, myeloma, and neuro-oncology.

The Alliance member groups all have a long history of working successfully in teams to conduct scientific research, and this capability is evident in the Alliance's structure. The Alliance is organized into six programs, each led by a principal investigator for the new NCI funding application, which is to be submitted this year (see figure, page 45). These programs and their respective principal investigators are as follows:

- *The Office Of The Group Chair.* Located at Brigham and Women's Hospital in Boston, MA, this office is responsible for the Alliance's administrative and fiscal affairs and provides support for scientific leadership and institutional membership services. Monica M. Bertagnoli, MD, FACS, the author of this article, is the principal investigator for this program.

- *The Statistics and Data Management Program.* Based at the Mayo Clinic in Rochester MN, this program supports the activities of the group by achieving the highest standards for the conduct of clinical trials in terms of study design, statistical methodology, data management, protection of patients and their data, and regulatory compliance. The principal investigator for this program is Daniel J. Sargent, PhD, professor of oncology and professor of biostatistics at the Mayo Clinic.

- *The Central Protocol Operations Program.* Housed at the University of Chicago, IL, this program oversees the development and maintenance of all study protocols that are generated by Alliance scientific committees. Gini Fleming, MD, professor of

medicine, director of the medical oncology breast program, and medical oncology director, gynecologic oncology at the University of Chicago, is the principal investigator for this program.

- *The Translational Research Program.* With the advent of molecularly driven oncology, this program plays a major role in the development and execution of most Alliance clinical trials. This program facilitates the scientific agenda of the Alliance by supporting the basic and translational researchers who work within Alliance committees in the fields of biomarker development, imaging, pharmacogenomics, and population pharmacology, pathology, and biorepository operations. This program also promotes successful collaboration between Alliance committees and researchers within Specialized Programs of Research Excellence (SPOREs), cancer centers, and other research groups. The principal investigator is Phillip Febbo, MD, associate professor in the department of medicine (hematology/oncology) at the University of California, San Francisco.

- *The Cancer Control Program.* This program serves as a research base for the Alliance Community Clinical Oncology Programs, which are distinct research networks funded by NCI's Division of Cancer Prevention. The Cancer Control Program has six scientific domains: cancer prevention, symptom intervention, health outcomes, comparative effectiveness research, cancer in the elderly, and cancer health care disparities. Alliance researchers conduct specific trials in these areas and add research questions in these fields to large Alliance

phase III treatment trials. This approach maximizes the opportunity to understand overall patient benefit as it relates to specific cancer treatments and their effects on outcomes. Jan C. Buckner, MD, professor of oncology at the Mayo Clinic, is the principal investigator.

- *ACOSOG.* The American College of Surgeons (ACS) has collaborated with former ACOSOG members on projects aimed at defining and improving the quality of cancer care. This ACS cooperative group relationship will continue in the Alliance through its ACS Clinical Research Program (ACS-CRP). The ACS-CRP comprises four committees: cancer care standards, research development, education, and membership. Heidi Nelson, MD, FACS, assistant professor of surgery and chief of colorectal surgery at the Mayo Clinic, is the principal investigator.

The Alliance's Cancer Care Standards Research Committee will use the College's National Cancer Data Base to design and conduct studies that inform cancer care standards. Published results will be presented to the appropriate sections of the Commission on Cancer (CoC) for consideration during standards development and adoption by ACS-CRP programs. Hence, outcomes research in the Alliance will have an immediate connection to an organization able to apply results to improve cancer care.

The ACS-CRP Research Development Committee will use the resources of the CoC and the NCDB to inform the design of Alliance clinical trials and comparative effectiveness trials. The CoC's Education Committee will

keep investigators aware of ongoing studies, provide education on surgical credentialing for studies, provide regular updates in the *ACS Bulletin*, and disseminate findings from Alliance clinical trials to members to decrease time from clinical trials to incorporation into clinical prac-

tice. The Membership Services Committee will further the relationship with the CoC toward maximizing the participation of surgeons in the Alliance.

More than 460 investigators attended the first Alliance scientific committee meetings in September 2011 and more than

1,000 individuals attended the Alliance group-wide meeting November 17–19, 2011.

Dr. Bertagnolli is the group chair of the Alliance for Clinical Trials in Oncology, and chief of the division of surgical oncology at Brigham and Women's Hospital, Boston, MA.

There isn't an app for that: Banning recording in the office

With the proliferation of mobile communications devices, many patients use their time in physicians' offices to text, surf the Internet, update social media, and make phone calls. They also may be tempted to use smartphones and similar devices to record consent discussions or for medication and follow-up instructions with surgeons and office staff.

Recording discussions about health care via video or audio is not a substitute for listening, however, and could put surgeons and their staff at significant risk, according to experts at The Doctors Company, the official medical liability insurance provider for members of the American College of Surgeons. Surgeons should

prohibit video or audio recording in the office. These recordings breach the confidentiality rights of other patients and infringe on the privacy rights of surgeons and their employees. In many states, it is illegal to record without prior consent.

To prevent patients from using their mobile devices to record their in-office experiences, The Doctors Company recommends the following steps:

- Post a sign in the reception area that states, "To ensure confidentiality and privacy, any type of electronic recording is strictly prohibited at any location within these offices. Thank you for your understanding and compliance."
- Issue a written policy pro-

hibiting the use of recording devices during office visits, and include the statement in patient intake handouts.

- Watch for indications that a patient is recording conversations, and politely ask that they discontinue this activity.
- Remind patients that they or their caregiver may take notes during office visits to help them remember important information, and emphasize that the conversation will be documented in the medical chart.

For more tips, articles, and information from The Doctors Company, go to <http://thedoctors.com/knowledgecenter>.

Come and see why more and more surgeons are using
the American College of Surgeons Web portal:

Update your profile Track your CME credits View surgical videos Explore communities

Stay informed
Log your cases

All this and much more at
e-facs.org

AMERICAN COLLEGE OF SURGEONS
Inspiring Quality
Highest Standards. Better Outcomes