

The History & Evolution of SWOG

The following history of SWOG was prepared to document significant events and achievements of the Group over the past fifty years, as well as to chart its evolution into the multidisciplinary adult cancer cooperative research organization represented today.

The 1950s

In 1955, the National Cancer Institute formed a Clinical Studies Panel. During one of its early meetings, it was suggested that the study of leukemia would advance more expeditiously if investigators joined to collaborate on clinical trials through a "cooperative group" mechanism. Precedence for this proposed action had already been established by the collaboration of Veterans Administration hospitals investigating tuberculosis. Two of the initial cooperative groups formed in 1955 were the Acute Leukemia Group A and the Acute Leukemia Group B. These groups later became Cancer and Leukemia Group B (CALGB), with the addition of solid tumor investigations. Also initiated in 1955 was the Eastern Solid Tumor Group, which consisted of a five-member east coast consortium to investigate the relative activities of the available nitrogen mustards. This group later evolved into the present-day Eastern Cooperative Oncology Group (ECOG).

The **Southwest Cancer Chemotherapy Study Group (SWCCSG)** began one year later in 1956 as a pediatric oncology group under the direction of Grant Taylor, M.D., a pediatric oncologist at M.D. Anderson Hospital and Cancer Center in Houston, Texas. Soon after its inception, this group grew to include clinical activities with medical oncology.

In 1958, the National Cancer Institute (NCI), which had multiple chemotherapy agents available requiring clinical evaluation, directed that the Southwest Cancer Chemotherapy Study Group extend its membership to include investigators evaluating adult malignancies. **This action was notable as it established the foundation of what would become the Southwest Oncology Group and eventually SWOG.** The Group then consisted of the following member institutions:

- University of Arkansas
- Baylor University
- University of Texas Medical Branch at Galveston
- M.D. Anderson Hospital and Cancer Center, Houston
- Southwestern at Dallas
- Tulane University

Seven Veterans Administration institutions were also members in the following cities: Dallas, Houston, Little Rock, New Orleans (two institutions), Oklahoma City and Washington, D.C. The pediatric and adult divisions then functioned as two separate entities with separate administrative bodies. Charles Sprague, M.D., the original Principal Investigator at Tulane University chaired the adult division. The Statistical Center, under the direction of Kenneth Griffith, Ph.D., was housed at M.D. Anderson Hospital and Cancer Center in Houston, Texas.

The 1960s

During the first half of the sixties, the adult division of the Southwest Cancer Chemotherapy Study Group slowly began to increase its activities in cooperative clinical cancer trials. The early trials focused on liquid cancers (leukemia and myeloma). The adult division established a Solid Tumor Committee which began developing trials for all solid tumor malignancies based on the availability of new agents, rather than the present scientific prioritization of group committees and advisory groups.

Upon being named Dean at Tulane University, Dr. Sprague resigned as Chairman of the Adult Division and William C. Levin, M.D., became the new Chairman, serving in this position until 1969. Dr. Levin was Head of the Division of Hematology of the University of Texas Medical Branch at Galveston. Dr. Taylor served as overall Chairman of the Southwest Cancer Chemotherapy Study Group until 1969 when he resigned and Emil Frei III, M.D., was elected as his successor.

Also in 1969, a formal document, the Constitution and Bylaws, was adopted by the Group and provided for a single Executive Committee as the governing body of the Group. The Group Chairman was then responsible directly to the Executive Committee. During this time, the Group membership grew to include former participants in the Midwest Cancer Chemotherapy Study Group.

The 1970s

The 1970's brought many changes to the organization of the Group. In 1971, the original Constitution and Bylaws was replaced by a Constitution that provided for two divisions of the Group, Adult and Pediatric, each with its own executive committee.

Dr. Frei left the Group in 1972 to assume the position of Professor of Medicine and Physician-In-Chief of the Dana-Farber Cancer Center. Barth Hoogstraten, M.D., was then elected as Chairman of the Southwest Cancer Chemotherapy Study Group; the Operations Office was subsequently moved to Kansas City.

In early 1973, the large Solid Tumor Committee was disbanded and six separate disease study committees were instituted in the Adult Division of the Group.

The Southwest Cancer Chemotherapy Study Group was formally renamed the **Southwest Oncology Group** in June 1973. At that time, the constitution was again revised to establish stringent performance criteria for the evaluation of its institutions and members. At the end of 1973, two new Standing Committees were established for Radiotherapy and Immunology-Immunotherapy. The composition of the Group continued to change, with the addition of Standing Committees for Surgery and Pathology.

In 1976, the NCI activated the Cancer Control Program (later renamed the **Cooperative Group Outreach Program, or CGOP**) that was developed by the Division of Cancer Prevention and Control (DCPC). It was designed to involve individual physicians and physician groups outside the university medical centers who were interested in participating in studies for cancer management. The Cancer Control Program was developed around the member institutions so that there was a geographic relationship and close communication between the Principal Investigator at the member institution and the Cancer Control affiliates. By the end of 1976 there were 29 participating Cancer Control affiliates in this program. The program objectives were: 1) to make state-of-the-art cancer management available to cancer patients in the community; 2) to involve a wider segment of the community in clinical research than is possible through the existing cooperative group programs; 3) to enhance recruitment of patients from community hospitals into appropriate protocols; and 4) to evaluate the transfer of new patient care technology to the community. These four objectives still serve as the function of the outreach program today.

In 1977, the Southwest Oncology Group adopted the pilot study concept and developed new guidelines to monitor these studies. Pathology review was established in a limited number of disease committees, including: breast, genitourinary, gynecological, leukemia, myeloma, lung, lymphoma, sarcoma and pediatric solid tumors.

In 1978, the New Agents and Pharmacology Committee was reorganized. The Adult Division of the Southwest Oncology Group began to meet twice a year; a year later, the Pediatric Division also began semi-annual meetings. The Constitution and Bylaws were again amended to reflect an attendance requirement of one meeting every two years for all Group members.

The 1980s

In 1980, the Southwest Oncology Group still consisted of separate Adult and Pediatric Divisions. Later that year, the pediatric division sought independent status, and formed the Pediatric Oncology Group (POG), housed in St. Louis. In the summer of 1980, the statistical activities supporting that division moved to Gainesville, Florida.

In January 1981, Dr. Hoogstraten announced his intention to step down as Chairman of the Group. **Charles A. Coltman, Jr., M.D.**, was elected Chairman in March 1981 and the Operations Office was relocated to the Cancer Therapy and Research Center (CTRC) in San Antonio, Texas, where Dr. Coltman had led the CTRC programs of cancer treatment and research since 1977. Shortly after his election, a transition team was appointed to advise Dr. Coltman. Their deliberations resulted in the replacement of the Group Executive Committee by a Board of Governors consisting of funded Principal Investigators and representatives of Discipline Committees. The focus for scientific efforts and administrative responsibility then shifted to the Disease Committees of the Group. On May 28, 1981, recommendations of the transition team were ratified during a meeting of the Southwest Oncology Group Principal Investigators held in Dallas, Texas.

Several new committees were subsequently formed, including Medical Oncology, Quality Assurance, Statistical Center Users, Human Tumor Cloning Subcommittee of New Agents and Pharmacology, Clinical Pharmacology Subcommittee of New Agents and Pharmacology, Pharmacy Subcommittee of New Agents and Pharmacology and the Nurse Oncologist Committee. Later in this period, the Data Managers Committee was formed with the purpose of ensuring excellent quality of data. In 1995, the committee was renamed to reflect the level of professionalism of its membership and is now called the **Clinical Research Associates Committee**. The Bone Marrow Transplantation Committee was also formed in order to effectively evaluate transplantation trials in the Group.

During 1983, the **Community Clinical Oncology Program (CCOP)** began with similar objectives as the CGOP program. CCOP affiliates submit applications directly to the NCI through the Division of Cancer Prevention (DCP), naming the Group as their research base. Primary focus for these new members involved the investigation of cancer control research questions. The Southwest Oncology Group initially served as the research base for 18 CCOP institutions. The Board of Governors amended the Constitution and Bylaws to integrate these participants into a full relationship with the Group, both scientifically and administratively. In the first three months of participation, the CCOP members entered a total of 206 patients to Group cancer clinical trials.

A **Quality Control Program** was developed in conjunction with the new CCOP program and was centered in the Operations Office. The stringent review of CCOP data by the Quality Control system resulted in unparalleled quality of data from the institutions. In Fall 1983, the first Data Manager/Nurse Oncologist Training Course was held in Chicago to educate the new participants in administrative and scientific policies and procedures of the Group.

The major change in the early 1980's was relocation of the **Statistical Center** from Houston, Texas, to Seattle, Washington, under the direction of newly appointed Group Statistician **John J. Crowley, Ph.D.** This change was necessitated by the "disapproval" rating of the Houston Statistical Center following review of the 1983 Competitive Renewal Application. The long and tortuous road to the final selection of the Statistical Center included the national circulation of a Request For Applications (RFA), critique of ten Letters of Intent by Group and non-Group reviewers, evaluation of five applications to identify two contenders, formal site visit of the two applicants and, finally, the selection of the clear leader, the Fred Hutchinson Cancer Research Center. Following grant submissions, NCI audit and initiation of activities, the present Statistical Center began functioning on October 1, 1984.

Scientific activities continued to increase and necessitated the establishment of a Protocol Allocation policy to limit protocol activations to a number manageable for statistical and financial resources of the Group. Presently, the Group has from 90 - 125 active trials at any given time.

In 1985, the Group began preparations for the Competitive Renewal Application, due in February 1987. The exhaustive efforts by Group members resulted in an unprecedented award of five years of funding, with the approval of several new scientific endeavors. The newly funded programs included the Leukemia Biology Program, Central Lymphoma Immunophenotyping Laboratory and Flow Cytometry Program.

During the 1980's, the CCOP program grew steadily. As a result of increased efforts in cancer control activities, a **Cancer Control Research Committee** was developed to address the need for chemoprevention, symptom management, and quality of life programs. Also formed during this time were the Developmental Biologics Committee and the Developmental Therapeutics Committee (previously named New Agent & Pharmacology).

In 1987, the Group established a quarterly newsletter. **The Group Newsletter** serves to inform Group and non-Group members of Southwest Oncology Group activities.

Two major membership changes occurred during 1988 that significantly affected the Southwest Oncology Group. The first initiative was the **Urologic Cancer Outreach Program (UCOP)**, designed to recruit new urologists into the Group, fund data management for current urologists and increase total accrual to genitourinary trials. The second initiative, the **High Priority Program**, was designed by the National Cancer Institute to increase accrual to NCI-designated high priority clinical trials. This program recruited new unfunded members to join the Southwest Oncology Group and accrue patients to selected trials designated as "high priority" by the NCI. Participation in this program diminished over the years and in 1998, the NCI withdrew funding; the Group discontinued it in 1999.

In 1989, Dr. Coltman was elected to another four-year term as Chairman of the Group.

The 1990s

A major emphasis of the Southwest Oncology Group during the 1990's was recruitment of women and minority patients to all cancer treatment and control research trials. In June 1990, the Southwest Oncology Group expanded its CCOP membership to include seven new institutions having access to a 50%-or-greater minority population of new cancer patients. The **Minority-Based CCOPs (MBCCOPs)** provide valuable research data and findings to address and resolve specific concerns regarding the prevention and treatment of cancer in these populations. In a further effort to increase minority representation in cancer research, the Group responded to the Cancer Therapy Evaluation Program initiative to increase minority accrual to clinical trials, the **CTEP Minority Initiative Program**. Of the institutions originally participating in this program, two were universities with significant black populations.

Recognizing the critical need to address the special clinical research concerns of minority groups, as well as to generate research of specific importance to minorities, a new subcommittee of the Cancer Control Research Committee, the **Minority Research Subcommittee**, was formed to address these specific issues within the Group. An initial working group meeting of this subcommittee was held at the semi-annual meeting of Southwest Oncology Group in October 1990.

Another new initiative in 1990 was the development and utilization of a **Race/Ethnicity Questionnaire**. Originally developed for use by institutions participating in the CTEP Minority Initiative program, this Questionnaire was the precursor of the now-mandated collection of race/ethnicity information for all patient registrations to Group protocols. The information collected provides the means to evaluate participation of women and minorities in Group clinical trials.

A new Standing Committee, formally named the **Stomatology Committee**, was added to the Group in 1990. This committee was created to address issues of oral complications from chemotherapy by including dental consultation for ongoing Group protocols, as well as developing protocols related to the study of these issues in clinical trials research. Eventually, this committee and its mission were incorporated into the **Head and Neck Committee**.

At the Spring 1991 Group Meeting, the Group Chairman disclosed the accrual crisis facing the Group. Given that the rapidly increasing accrual was projected to reach over 11,000 patient registrations by the end of 1991, there would be a severe lack of fiscal resources available to support the Statistical Center. It was announced that there would be an immediate cap on accrual, with patient registrations to be held at 6,451. This was the level of annualized accrual to Phase II and Phase III clinical trials reached on March 2, 1991. This action would resolve the immediate crisis, with a long-term solution being the

creation of a non-profit foundation, which would enable the Group to tap private philanthropists for financial support. The Board of Governors accepted and unanimously endorsed this concept and in 1992, a separate 501(c)(3) tax-exempt corporate entity, the **Southwest Oncology Group Foundation**, was formally established. In 1995 an Annual Fund Campaign was initiated to provide the Group's membership the opportunity to support the Foundation.

Also at the spring 1991 Meeting, it was announced that **Mace L. Rothenberg, M.D.**, would serve as the Group's new Executive Officer. He served in that capacity until January 1998 when he accepted a new position with Vanderbilt University.

The Fall 1991 Group Meeting saw the creation of the **Committee on Women's Health** to address specific concerns regarding participation of women in Group clinical trials and activities. The Committee was formally designated as a Group Standing Committee in February 1992. In April 1997, the efforts of the Minority Research Subcommittee of the Cancer Control Research Committee were incorporated into the role of this committee; to reflect its expanded mission, it was renamed the **Committee on Women and Special Populations**. In 2002, the committee name was again changed to the **Committee on Special Populations**, which would itself be superseded in 2007 by the committees within SWOG's new Cancer Control and Prevention program.

Midway through 1991, the Group Chairman met with Masanori Fukushima, M.D., Ph.D., Section Head of the Department of Internal Medicine at the Aichi Cancer Center Hospital in Nagoya, Japan, to explore a collaboration between cancer clinical trial investigators from the United States and Japan with the goal of enhancing the quality of Japanese clinical trials. The first **United States - Japan Clinical Trials Summit**, held in 1992, opened with oncologists from both countries presenting overviews of their respective clinical trials systems and focused on urological and gynecological cancers.

A second Summit was held early in 1993 targeting esophageal and gastric cancers; later that year it was followed by a Clinical Trials Workshop on the methodology and design of clinical trials in the United States. Subsequent Summit Meetings focused on bone and soft tissue sarcomas (1994), lung cancers (1996 and 1998), head and neck cancers (1997), colorectal carcinoma (2000), breast cancer (2001), lymphoma (2002), gastric and colorectal cancer (2005), and multiple myeloma in 2006. Clinical investigators making presentations at the Summit meetings were not exclusively from the Group; instead, premier investigators from throughout the United States and Canada were invited to participate in this important collaboration.

The Group submitted its Competitive Renewal Application to the NCI on February 1, 1992, requesting funding for the next five years. As directed by the NCI, this application included budget requests and progress reports for four membership programs previously supported through separate grant awards: the CGOP, CTEP Minority Initiative, High Priority, and UCOP programs as well as several newly formed Tumor Biology Subcommittees.

In 1992, in response to increased clinical trials within the Group involving agents for which the NCI does not hold Investigational New Drug (IND) documentation, a drug master file was submitted on behalf of the Group to the Food and Drug Administration (FDA). The Group's Operations Office is responsible for the collection of regulatory documentation, the creation and maintenance of an IND database, and the submission of IND applications to the FDA for Group-held INDs.

The Operations Office moved to San Antonio's Texas Research Park on November 16, 1992. A Grand Opening ceremony for the 11,000-square-foot facility and the neighboring Cancer Therapy and Research Center Institute for Drug Development was held on December 4, 1992.

In October 1993, the Southwest Oncology Group launched the first large-scale prevention trial for prostate cancer. The **Prostate Cancer Prevention Trial (PCPT)** was a double-blinded study designed to test whether taking the drug finasteride would prevent prostate cancer. Under the study, 18,000 men were enrolled at over 220 sites located throughout the United States and randomly divided into two groups; half took one finasteride tablet per day for seven years and half took a placebo. The men had annual prostate examinations, including a digital rectal exam (DRE) and a prostate specific antigen test

(PSA). A prostate biopsy at the end of seven years was used to determine if prostate cancer has developed. Three years to the day when registration to the PCPT began, 18,882 men had enrolled in the study, a sufficient number to ensure the randomization goal of 18,000 to the two arms of the study. Enrollment was officially closed on Friday, December 6, 1996, and randomization of all participants was completed by the end of May 1997. The final count of men randomized was 18,882. The PCPT was closed on June 24, 2003, because the study objective had been reached. (See further information under the section "The 2000's.") Also participating in this intergroup study were the Cancer and Leukemia Group B (CALGB), the Eastern Cooperative Oncology Group (ECOG) and NCI-Designated Cancer Centers.

In 1996, the Southwest Oncology Group began a **Strategic Planning** effort to address, head-on, changes in the healthcare environment that would have an impact upon the Group's ability to conduct clinical trials. Group members, as well as key industry leaders outside of the Group, were involved in the development of a questionnaire that was distributed to 4,898 Southwest Oncology Group members. Careful analysis of the response provided specific recommendations for bold initiatives to take the Southwest Oncology Group forward into the year 2000 and ensure continuation of its position of leadership in cancer clinical trials.

In early 1997, after more than a year of extensive preparation, the Group submitted its Competitive Renewal Application to the National Cancer Institute (NCI). Notification was received in November that the Operations Office received an "Excellent" rating and that the Group was funded for another five years at the recommended level of \$31 million.

In April 1997, Dr. Coltman was elected to his fifth term as Group Chairman. At the same time, Dr. Crowley was elected to his fourth term as Group Statistician.

In keeping with the emerging focus on cancer survivorship, a new program was inaugurated at the October 1997 Group Meeting. The "**Cancer Survivors Celebration**" was created to heighten national, local, and Group wide awareness of cancer survivors and the role they play in the research process. The program included a number of long-term (ten years or more) cancer survivors at each Group Meeting. The survivors were introduced to the Group's membership at the Plenary Session. They attended the Disease Committee meeting that focused on their particular type of cancer where they were given insight into the development process of the research that so profoundly affected their lives. In 2001, this program was suspended due to scheduling constraints.

In July 1998, after serving as Interim Executive Officer for a number of months, **Peter M. Ravdin, Ph.D., M.D.**, accepted the position of Executive Officer for the Group, a position he held until late 2002.

The fortieth anniversary of the Southwest Oncology Group was celebrated at the October 1998 Fall Group Meeting held in San Antonio, Texas. The anniversary theme was "**Forty Years of Giving Cancer Patients a Gift More Precious than Gold...Giving Them Time for Life!**" and the Plenary Session program focused on a retrospective look at some of the Group's major scientific accomplishments that contributed to the growth and development of the practice of oncology in ovarian cancer, breast cancer, and acute leukemia. **Richard D. Klausner, M.D.**, Director of the National Cancer Institute, was a featured guest speaker.

It was announced in August 1998 that the name of the Southwest Oncology Group Foundation was officially changed to **The Hope Foundation**; a logo was developed that showed a hand reaching for the stars. The new name and logo were adopted to reflect the hope given all people through the efforts of the Southwest Oncology Group. **Brian D. Chavez** was appointed to the position of Foundation Chief Operating Officer. A National Board of Directors was established and the **Platinum Association** was launched with 48 Charter Members contributing \$1,000.00 each to the Foundation. Following the departure of Mr. Chavez in 2005, **Dorothy (Dott) Freeman, Ph.D.**, was brought onboard as the Director of Development of The Hope Foundation, and the Foundation office was relocated to the Michigan Headquarters. At the Spring 2007 Group meeting, **Jo Horn, M.S.W.**, was identified as the new Foundation Director following the resignation of Dott Freeman.

In Spring 1998, preliminary talks were held to discuss the possibility of launching a new prostate cancer prevention trial. In September 1999, the NCI formally approved first year funding of **\$0000: Selenium and Vitamin E Chemoprevention Trial (SELECT)**, later named the Selenium and Vitamin E Cancer Prevention Trial.

In March 1999, Dr. Coltman organized "The Young Investigators Training Course," an innovative program designed to foster the role of young clinical investigators beginning a career in cancer clinical trials. The training course is sponsored by The Hope Foundation, with initial support coming from Ortho Biotech Oncology. "**The Young Investigators Training Course**" is conducted over an intensive two-week period twice yearly and focuses on statistical principles, data collection and analysis, critical decision making, protocol development and other Group procedures to learn how to develop a clinical trial. Investigators are selected each year through a rigorous and competitive application process. By September 2010, 56 Young Investigators had taken part in the program, and more than 30 of their protocols had been activated across the United States.

At the end of 1999, the NCI announced that the Cooperative Group Outreach Program (CGOP) name designation was changed to the "**Affiliate Program.**" In addition, those affiliates meeting certain requirements established by the NCI would be eligible to qualify as "free-standing" affiliates and, among other things, be able to register patients directly through the internet. The Member Institutions of the Affiliates, however, would still retain some responsibility for free-standing affiliates.

The 2000s

During 2000, two new events were established to heighten awareness of The Hope Foundation and to raise funds in support of its programs; they were adopted for a time as annual events. Porsche joined with the Foundation to establish the **Drive for Hope**, an exciting event that featured a team of Porsches driving across the United States and included a number of celebrity drivers. The **Grand Slam Jam**, held in Austin, Texas, included a tennis tournament, rock concert and charity auction. Major tennis professionals and rock musicians were featured throughout the event.

In 2000, in the Group's ongoing effort to cut down on paper use, **The Group Newsletter** was made available via the internet to all Group members. On-line Group Meeting registration was also introduced.

During the Spring 2001 Group Meeting, Dr. Coltman was elected to his sixth four-year term as Chairman of the Southwest Oncology Group. In addition, he was honored for 20 years of service as Chairman; this was the longest tenure of anyone holding that position in the history of the Group.

On July 25, 2001, the Southwest Oncology Group launched the largest prostate cancer prevention trial to date, the **Selenium and Vitamin E Cancer Prevention Trial (SELECT)**. SELECT was a phase III, double-blind, placebo-controlled four-arm study of selenium, vitamin E, selenium and vitamin E together, and placebo designed to assess the effect of these supplements on the incidence of prostate cancer. The study quickly exceeded its accrual goal, enrolling 35,533 men at 427 sites in the U.S. and Canada in just 33 months. Participants were healthy men age 55 and older (50 and older for African-American men) with no history of prostate cancer. In the fall of 2008, the trial's Data and Safety Monitoring Committee recommended that participants discontinue taking study supplements based on an interim finding of no preventive benefit for any of the arms. In 2009-2010, the almost 31,000 patients remaining on SELECT were transitioned to centralized follow-up. The biospecimens and associated clinical data collected as part of this trial are expected to provide raw materials for translational research for years to come.

SELECT was the first SWOG trial to be conducted using a totally Web-based system designed and developed by the Group's Statistical Center. Enrollment, randomization, study manuals, bulletins, study updates, drug distribution records and data communication were all managed through a secure Internet site.

The Group's next Competitive Renewal Application had been due February 2002; however, in 2001 the National Cancer Institute notified the Group that the due date had been delayed to February 2003. A one-month extension was later granted, with the due date set for March 1, 2003. A Site Visit was conducted at the Statistical Center in June 2003 and the Group's Reverse Site Visit was conducted in Bethesda in July 2003. The Group was awarded an unprecedented six years funding with a recommended support level of \$19,198,623 for the first year. The Operations Office received an "Excellent" rating and a priority score of 171, the highest ever for an Administrative Group.

On May 27, 2003, Dr. Coltman notified members of the Board of Governors that he would not be a candidate for re-election as Chairman of the Group upon the end of his current four-year term on April 8, 2005. This initiated the Group Chair-Elect process in accordance with the revised Group Bylaws. On July 3, 2003, NuMedia/World Post Technologies, Inc., certified that the results of the election for the position of Group Chair-Elect conducted via fax ballots and electronic voting June 27 through July 3, favored **Laurence H. Baker, D.O.** These voting results were then distributed to the Group's membership from the Operations Office via a Group-wide memorandum on July 10, 2003.

At the October 3, 2003, Board of Governors meeting in Seattle, Washington, the new Chair Elect announced that a Southwest Oncology Group Headquarters Office would be established at the University of Michigan in Ann Arbor. During the Group Meeting Plenary Session on May 1, 2004, in Huntington Beach, California, Chair Elect Baker introduced the three new Executive Officers for the Group: **Anne F. Schott, M.D.**, **Harry P. Erba, M.D., Ph.D.**, and **Bruce G. Redman, D.O.**, all faculty members of the University of Michigan.

The Prostate Cancer Prevention Trial was closed on June 24, 2003, as the study objective had been reached. The analysis of the data revealed that men in the finasteride group who were evaluated were 24.8% less likely to develop prostate cancer when compared to the men evaluated who were in the placebo group (18.4% of men on finasteride versus 24.4% of men on placebo developed prostate cancer). Another finding of the study was that men who developed prostate cancer while taking finasteride were more likely to have "high-grade" cancer. The National Cancer Institute funded further research on this issue. Results of PCPT were published in the *New England Journal of Medicine* on July 17, 2003. To further utilize the wealth of data and blood and tissue samples collected over the three years of the study, a program project (PO1) to understand the biologic mechanisms underlying the results of the PCPT was submitted on October 1, 2003. The PO1 included five projects addressing androgen metabolism, insulin-like growth factor axis and insulin resistance, diet and diet-related factors, oxidative damage and DNA repair, and genotypic and phenotypic studies of inflammation. Funding was approved in 2005.

Two significant follow-up findings on PCPT data published over the next several years showed that finasteride treatment does not interfere with sexual function for most men and suggested that the drug aids early diagnosis of the more aggressive form of the disease, primarily by reducing prostate volume and thus making it easier to detect disease. This latter analysis, however, didn't fully put to rest concerns caused by PCPT's initial finding that men on finasteride had a slight increase in the rate of high-grade prostate cancer. In 2009, the U.S. Food and Drug Administration asked finasteride's maker, Merck, to present a request for a new chemoprevention indication for the drug to the FDA's Oncologic Drugs Advisory Committee. Merck took a smaller step, asking for permission to add information on the PCPT results to the drug's label, a move which could have been seen as *de facto* approval of finasteride as a chemopreventive agent for prostate cancer. The FDA's committee voted this down unanimously, expressing continuing concerns about the increase in high-grade cancers seen in men in the study's finasteride arm.

On April 8, 2005, Charles A. Coltman, Jr., M.D., formally passed the chair's gavel to Laurence H. Baker, D.O., who officially succeeded Dr. Coltman as chair of the Southwest Oncology Group. Dr. Coltman's appointment as associate chair for cancer control and prevention was officially confirmed at that time, with the CCOP grant remaining in San Antonio under his leadership. After serving as associate chair for cancer control and prevention for two years, Dr. Coltman was named Southwest Oncology Group chairman emeritus in September 2007. One of Dr. Baker's first official acts as group chair was to reorganize the Scientific Advisory Board and to appoint **Richard I. Fisher, M.D.**, as its chairman. Dr. Fisher was also named deputy chairman of the Group.

Effective April 1, 2005, a U24 grant was awarded for the tumor banking efforts of the Southwest Oncology Group. The funding supported the Group's effort to consolidate and streamline banking activities from 11 solid tumor sites into one central location at the University of Cincinnati under the leadership of Dr. Cecilia Fenoglio-Preiser. In October 2006, the Group's solid tumor bank was relocated to the University of Colorado under the leadership of Dr. Wilbur Franklin. Dr. Franklin also

assumed a leadership role overseeing all banking activities with the assistance of Dr. Carolyn Hoban upon her arrival to the Group in late 2006. In the area of liquid tumors, during 2006, banking activities in Lymphoma and Myeloma were centralized at the University of Arizona, while Leukemia banking activities were consolidated at the University of Mexico.

Primo N. Lara, Jr., M.D., from the University of California, Davis Cancer Center, was appointed chair of the Group's new Professional Standards Committee in the fall of 2006. The primary function of this new committee would be to investigate misconduct within the Southwest Oncology Group on an as-needed basis. Dr. Lara chaired an inaugural committee meeting on October 7, 2006, in Seattle, Washington.

At the October 6, 2006, Board of Governors meeting in Seattle, Washington, Dr. Baker introduced **Carolyn J. Hoban, D.Sc.**, as the Group's fourth Executive Officer in the Headquarters Office in Ann Arbor.

The **50th Anniversary of the Southwest Oncology Group** was celebrated on October 7, 2006, in Seattle, Washington, in conjunction with the October 2006 Group Meeting. Dorothy "Dott" Freeman, Director of The Hope Foundation, organized and acted as Master of Ceremony for the anniversary reception held in the Grand Ballroom of the Sheraton Seattle Hotel. Featured during the evening were limited edition commemorative gifts for guests, live music, visual displays, invited guests, and champagne toasts. SWOG's former chairmen were recognized, beginning with **Grant Taylor, M.D.**, who served from 1956 to 1969, and **Emil "Tom" Frei, III, M.D.**, who chaired the Group from 1969 to 1972. **Barth Hoogstraten, M.D.**, who served from 1972 through 1981, and **Charles A. Coltman, Jr., M.D.**, chairman from 1981 through 2005 were in attendance and spoke of milestones during their tenure.

During the 50th Anniversary Southwest Oncology Group Plenary Session, James H. Doroshow, M.D., Director of the National Cancer Institute (NCI), Division of Cancer Treatment and Diagnosis, and Peter Greenwald, M.D., Dr.P.H., Director of the NCI's Division of Cancer Prevention, presented SWOG Chairman Laurence H. Baker, D.O., with a roster of the Group's scientific accomplishments and a plaque commemorating the Group's 50th anniversary. The scientific portion of the Plenary Session featured presentations by four outstanding and nationally known cancer researchers: Brian J. Druker, M.D., a professor of medicine at the Oregon Health and Science University, the JELD-WEN Chair of Leukemia Research and an investigator at Howard Hughes Medical Institution in Portland, Oregon; James H. Doroshow, M.D., Director of the National Cancer Institute Division of Cancer Treatment and Diagnosis; Peter Greenwald, M.D., Dr.P.H., Director of the National Cancer Institute Division of Cancer Prevention; and Allen S. Lichter, M.D., Executive Vice President and Chief Executive Officer of the American Society of Clinical Oncology (ASCO).

In 2006 and 2007, steep cuts proposed by the NCI for SWOG's budget led the Group to close its Head and Neck Committee and its Sarcoma Committee (the Brain Committee was closed as a part of decision-making prior to the Group's grant renewal in 2003). As NCI funding levels fell and more SWOG trial proposals were denied by the NCI because of funding considerations, SWOG stepped up efforts to attract additional monies from external organizations. To allow worthy investigator-initiated trials to proceed even when the NCI had declined to fund them, the Group organized the **SWOG Clinical Trials Initiative (SWOG-CTI)** as a mechanism to get SWOG trials funded outside of the NCI. Founded for the express purpose of accepting non-federal dollars to support clinical trials, SWOG CTI is a limited liability company whose sole member is The Hope Foundation. SWOG executive officer Anne Schott, M.D., was named SWOG-CTI's first medical director. The first SWOG-CTI funded trial to open would be S0702 in late 2008, an observational study of osteonecrosis of the jaw in patients treated with bisphosphonates, supported through an agreement with the pharmaceutical company Novartis.

Around this time the Group also created a new Translational Medicine Committee with the idea that it would cut across disease committees, encompassing and going beyond the correlative science efforts pursued individually by some disease committees.

In September 2007, **Frank L. Meyskens, Jr., M.D.**, from the University of California Irvine Medical Center, was appointed Associate Chair of Cancer Control and Prevention. Dr. Meyskens, an international expert known for groundbreaking efforts to control and prevent cancer, would head all cancer control and prevention efforts for the Group. Dr. Meyskens presented the structure of the reorganized program at a February 2008 retreat, with stated goals of increasing the program's representation in disease committees, reaching out to clinical pharmacology, and developing training in cancer prevention and control for the next generation of SWOG investigators. The new **Cancer Control and Prevention Program** comprised these five committees:

- Prevention Committee
- Health Disparities and Outcomes Committee
- Molecular Epidemiology Committee
- Cancer Survivorship Committee
- Symptom Control and Quality of Life Committee

In spring of 2007, Dr. Baker proposed reinstating the SWOG Gynecologic Committee. To ensure its success, he stipulated that the new committee should consist of medical oncologists highly active in gynecology departments at premiere institutions who were also actively enrolling patients onto clinical trials. With the support of the National Cancer Institute, the newly reconstituted Gynecologic Cancer Committee met for the first time as the Gynecologic Cancer Working Group at the fall SWOG Group Meeting that year under the chairmanship of **Maurie Markman, M.D.** with **David Alberts, M.D.** as co-chair. This group agreed that its initial focus would be on innovative phase II trials. The relaunch of the committee was aided by a \$250,000 grant from the Marsha Rivkin Foundation for Ovarian Cancer Research. Three years later the committee would close again when Dr. Markman stepped down as committee chair and an appropriate replacement could not be found.

That same year SWOG established the **Charles A. Coltman, Jr., Fellowships** program to promote research by promising investigators early in their careers. SWOG scientific leaders annually nominate candidates for up to three two-year fellowships at \$50,000 per year. Through the Hope Foundation, SWOG received financial support for the fellowships from several pharmaceutical companies, with a long-term goal of building an endowment for the program.

Also in 2007 the Group partnered with AG Mednet of Boston to develop a secure, HIPAA-compliant network for submitting radiology imagery to central repositories and for real-time third-party reads of the images. The Group had been struggling with obtaining concise data on images and getting that information entered efficiently into the research record, difficulties that were thought to be a potential source of bias. This new imaging network linked with SWOG's existing data management system, allowing for the linkage of electronic transmittal forms, and the costs of transferring images via the network proved to be lower than the costs of mailing CDs of data. First use of the imaging network in a live clinical setting took place in fall 2009.

At the spring 2008 Group Meeting the **Clinical Research Associates (CRAs)** celebrated 25 years as a SWOG committee. The committee had been formed in 1983 as the Data Managers Committee at a time when there was little training offered for data managers. It initially consisted of 11 data managers from 5 SWOG institutions and a representative from the Statistical Center. With the expansion of SWOG to include sites in the Community Clinical Oncology Program (CCOP) that same year, the need for a more formal training program was recognized and the committee developed the **Clinical Trials Training Course**. Over 100 data managers attended the first training course in 1983. The Data Managers Committee was approved as a discipline committee in 1986 and was renamed the Clinical Research Associates Committee in 1995. Today, each Disease Committee has CRAs assigned to it who provide vital input into protocol and informed consent development. The Clinical Trials Training Course was held at each semiannual Group Meeting through 2009. In 2010, an online version of the course went live and the in-person version was cut to a once-yearly event, to be held at the spring Group Meeting.

In an attempt to shorten the development timeline of trial protocols, the NCI formed an Operational Efficiency Working Group (OEWG) in late 2008 to recommend methods for making the development

process more efficient and to establish timeline targets the cooperative groups would be held to. SWOG's leadership saw this coming and in 2008 formulated their own approach to cutting the development timeline for high priority protocols – the SWOG Activation Team approach, or SWAT. The first trial developed via this approach, the phase III lung cancer trial S0819, moved from protocol concept approval within SWOG to final protocol approval by the NCI's Central Institutional Review Board in 282 days, roughly half of the average development time. This mark beat the OEWG's timeline target and served as proof-of-concept that SWOG could achieve those OEWG goals, which would become binding at the start of 2011.

At the fall 2008 Group Meeting, Drs. Baker and Crowley were unanimously re-elected as Group Chair and Group Statistician, with their new four-year terms beginning in April of 2009. A new chief of administration for the Group, Nathan Eriksen, was brought on at the Group's Ann Arbor headquarters with administrative responsibility for all Group components.

2008 also saw a reconfiguration of SWOG's Patient Advocates Program. The Group first formally invited patient advocates into its research activities in 1993. The fall Group Meeting that year brought together leaders from a number of advocacy organizations to advise SWOG on strategies for increasing patient input into the clinical trials process. The following year, SWOG had convened a "lay advisors/advocates planning group" as part of a three-year pilot project based within what was then the Committee on Special Populations. With a successful bid for NCI funding for the effort in 1997, the planning group evolved into the Lay Advocates Subcommittee.

The 2008 restructuring placed one or more advocates in each disease committee. To ensure advocates would be integrated quickly into the work of their committees, committee chairs were invited to nominate those advocates who would sit on their committee. Chairs were given two primary criteria to use in making these nominations:

1. The advocate should have leadership experience in a cancer advocacy or survivors' organization.
2. The advocate should have intimate knowledge of what it means to have a cancer diagnosis, either as a survivor of cancer or through caring for a family member or close friend with the disease.

SWOG's Board of Governors established new institutional membership criteria at the spring 2009 Group Meeting, making sites' membership status contingent on their having an average annual accrual over the previous three years of at least 20 initial patient registrations. The Board also agreed to a tiered level of support to members for travel to the semiannual Group meetings, with support tied to each site's accrual over the preceding 12 months.

The spring 2009 meeting also saw two new major appointments – the appointment of **Ian M. Thompson, Jr., M.D.**, as new chair of the Genitourinary Committee, where he had been serving as interim chair, and the appointment of **Razelle Kurzrock, M.D.** as new chair of the Early Therapeutics Subcommittee. This subcommittee was subsequently promoted to full committee status.

At a February 2008 committee review retreat, SWOG had begun developing its treatment grant competitive renewal application for NCI's Cancer Therapy Evaluation Program (CTEP), which would be due the following year. In July of 2009 Group leaders attended a reverse site visit on the NCI campus to present their accomplishments over the previous grant cycle and their plans for the coming years.

The framework of the presentation SWOG leaders gave at this visit was a set of ten research objectives for the Group:

1. To rapidly design, activate, complete, and report on scientifically important and clinically relevant cancer clinical trials.
2. To lead and participate in intergroup studies.
3. To develop and incorporate modern statistical methodology.
4. To integrate relevant laboratory medicine in the design and conduct of our clinical trials, with emphasis upon the outstanding science originating at cancer centers and SPORE programs within our network.

5. To foster and develop young investigators in the Southwest Oncology Group, who will be called upon to lead and sustain our mission in the long term.
6. To conduct our studies with the highest of ethical standards, consistent with assuring public and regulatory agency confidence in our data.
7. To engage all appropriate medical and scientific disciplines including pharmacy and nursing, as well as data managers, regulatory staff, and patient advocates in the design and conduct of our clinical trials.
8. To minimize bias and prejudice in the design and conduct of our clinical trials with respect to gender, age, race, socioeconomic status, and other population characteristics.
9. To dedicate resources so as to continually improve the quality of our data as judged by their users, including regulatory agencies.
10. To work collaboratively with all cooperative groups and the representatives of the NCI toward advancing our joint purpose.

In late 2009, the Group brought **Manuel Valdivieso, M.D.**, on board to head up a quality control initiative. SWOG had launched an initiative two years earlier to improve overall data quality, hiring **Joe Pater, M.D.**, retired director of the National Cancer Institute of Canada Clinical Trials Group, as a consultant charged with reviewing data quality and issuing recommendations. Valdivieso expanded this work and also laid the groundwork for more long-term collaboration with oncologists and cancer centers internationally. The Group's treatment grant renewal late in 2009 included the first U10 grant for a SWOG member outside the US – the University of British Columbia's cancer center in Vancouver. SWOG would expand in a southerly direction the following year, with the official membership in 2010 of Mexico's **Instituto Nacional de Cancerologia (INCan)**, that country's equivalent of the U.S.'s National Cancer Institute.

The centerpiece of SWOG's international initiatives at this time was a trial funded by a \$2.5 million grant from the Bill and Melinda Gates Foundation and conducted across seven nations in Central and South America to compare the effectiveness of three antibiotic regimens against infection with the *Helicobacter pylori* bacterium, which is associated with gastric cancer, one of Latin America's deadliest. The trial would reach its accrual goal of more than 1,400 patients by 2010.

The fall 2009 Group Meeting included a retirement tribute to **Marjorie Godfrey**, who had served as director of SWOG's Operations Office in San Antonio since 1987. **Dana Sparks**, the long-time manager of protocol development for SWOG, was named new director of operations and protocols. That same Chicago meeting also featured the final SELECT training session, which focused on the shift to centralized follow-up for the 30,000+ participants in the SELECT trial.

With a national debate on health care reform going strong at this time, the topic of comparative effectiveness research was much in the news; the climate was right for funding initiatives in this area. SWOG partnered with several institutions, including the Fred Hutchinson Cancer Research Center (FHCRC) in Seattle, home of SWOG's Statistical Center, in a successful bid for \$4 million in NCI funding to develop the **Center for Comparative Effectiveness Research in Cancer Genomics**, or **CANCERGEN**. Led by the FHCRC's Scott Ramsey, M.D., Ph.D., CANCERGEN's mission is to create a comprehensive evaluation, assessment, and design process to identify which emerging cancer genomics technologies are the top candidates for study by SWOG's clinical trials network. S1007, testing the effectiveness of a popular genetic assay in predicting which breast cancer patients would benefit from chemotherapy, was the first trial developed via this new collaboration.

The 2010s

By the end of 2009, NCI's CTEP had formally renewed SWOG's core treatment grant for the period 2010 through 2015, the culmination of a competitive renewal process that had extended over almost two years. The total package of SWOG grants from CTEP, including U10 grants going to its core member institutions to support their work with the Group, was projected to be worth more than \$120 million over the six-year award period.

January 1, 2010 marked the official move of SWOG's Operations Office from the University of Texas, where it had relocated with the Cancer Therapy Research Center several years earlier, to administrative control of The Hope Foundation. Operations Office employees moved to a new facility – still in San Antonio, Texas – and became employees of The Hope Foundation. The CTEP grant funding the Operations Office was also transferred to Hope.

2010 also saw the closure of two SWOG committees and the genesis of a new task force. The Translational Medicine Committee was closed, its functions shifted to the Translational Medicine Subcommittees already in place in each of the disease committees, and the Gynecologic Committee was closed. To help SWOG advance its strategy for biomarker-driven clinical trials, the Group brought together nine eminent researchers in cancer genetics from all over the country to form a new Genomic Medicine Task Force for SWOG.

After several decades as a nationwide – even international – network, SWOG in 2010 dropped the qualifier “Southwest” from its name. Group Chair Laurence Baker, D.O., announced at the Chicago group meeting in October that the Southwest Oncology Group would henceforth be known simply as “**SWOG**.” The Group Chair's office sent a survey in late summer to the entire membership asking them to vote on candidate logos and tag lines for the Group. SWOG members overwhelmingly chose a version of the Group's existing graphical mark -- the white double helix in a blue circle. This circle appeared in the new logo with new typography and the Group's new tag line – “Leading cancer research. Together.”

2010 was a watershed year for the NCI's cooperative group system, with the issuance of a report from the Institute of Medicine (IOM) recommending fundamental changes and consolidation within the system, a working group of the National Cancer Advisory Board charged with rapidly developing a detailed implementation plan for the IOM's report, and the arrival of a new director at the NCI, Dr. Harold Varmus, who saw fundamental reform of the organization's approach to clinical trials as one of his primary objectives. By the end of 2010 it became clear that a number of cooperative groups would be eliminated or merged into other groups, with the multi-modal, multi-disease groups – such as SWOG – serving as the model going forward.

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