From the Co-Chairs
By Peter J. O’Dwyer, MD (left), and Mitchell D. Schnall, MD, PhD
July 2020

Entering the fifth month of restrictions due to the COVID-19 pandemic, we have cause to be optimistic. On the plus side, we and our institutions have proven remarkably adaptable and aligned in the delivery of care, both to virus-infected patients and to those in need of usual care. The promise and limitations of virtual cancer care are now familiar to all of us, if perhaps not as well objectively documented as we wish. Understanding the impact of COVID infection on outcomes of patients being actively treated for cancer remains an important priority. We will describe this for selected EA trials, but in addition, a new NCI-based trial is available for participation with full credit. Entitled “NCI COVID-19 in Cancer Patients Study (N-CCAPS): A Longitudinal Natural History Study,” this trial aims to recruit and follow some 2,000 cancer patients nationwide, and is available for accrual through either NCTN or NCORP institutions.

As management of the infected patients becomes better defined, so too does the recovery of space and activity in our medical centers. They are now pivoting back to renewing a focus on general health care, and recouping what may have been lost in that period of less screening, and fewer visits for standard health maintenance. One suspects that the deficit in the care of cancer patients is less than for other medical specialties (because of our ubiquitous embrace of virtual visits), but any impact of delayed surgery or chemotherapy needs to be negated by a rapid return to standard practices. Also in this regard, we are buoyed by the gradual increase in clinical research activity across the group, as more and more trials are re-activated, and as accrual rates come back up to pre-COVID level (the most recent data show treatment-based accrual is back to 85%). Clearly, the recognition that clinical trials often provide state-of-the-art care, and offer therapeutic opportunities that would not otherwise be available, is driving this recovery. We salute the hard-working protocol nurses and clinical research associates who express their dedication to patients by being there to assure their smooth transition to a clinical trial, providing hope in a difficult time.

On the other side of the balance sheet, we have to recognize that all of our interactions will be different and more remote until the arrival of an effective vaccine. Our Fall 2020 Group Meeting, scheduled for October 21 to 23, will now be virtual, consistent with those of the other major groups, and with the directions of our own institutions. A formal announcement is forthcoming shortly. Many will already know that the spring committee meetings have been taking place over the last several weeks. We were limited in how many people we could accommodate at each one, and will have increased accessibility for the fall. We are also exploring in these meetings what format works best, and how best to allow discussion in the committees without derailing a tight schedule. We are eager for any feedback you may have, and please contact us directly – we will share the agenda of the Fall Group Meeting in the next few weeks. For larger committees that have sub-committees or working groups, you might consider distilling the input from these through separate meetings in the couple of weeks before. A number of administrative meetings will also take place in these
From the Co-Chairs (cont)

weeks, to ensure a reasonable schedule during the meeting dates. We look forward to a full and exciting program of committee activity.

On Friday, June 26, the ECOG-ACRIN Co-Chairs, together with the Health Equity Committee, hosted the Health Equity Inaugural Meeting. Nearly 350 people attended the virtual event, the first in a series focused on issues related to racism and health disparities in cancer research. The message of this meeting resonates strongly within the group, and serves to both energize and refocus the activities of the Health Equity Committee. ECOG-ACRIN members must identify and pursue ways to make progress, not just by promoting health equity, but also by actively opposing racism. In subsequent meetings, under the leadership of Dr. Melissa Simon and Dr. Edith Mitchell, the committee has chosen three areas of focus to confront racism throughout the breadth of our activities: Awareness Building, Protocol Design, and Recruitment. We will share more information about these areas in the next few months. We are truly grateful to have leadership of the stature of Drs. Simon and Mitchell to guide our embrace of a challenging and uncomfortable subject. We are committed to having a positive influence on the activities of our group, and even beyond. Your engagement and support will be much-needed for success.

On a final note, beginning next month our newsletter will look somewhat different as we migrate to a new format: “News From ECOG-ACRIN” is becoming a blog. We will still send a monthly edition with important news, trial information, and accomplishments – but the blog format will allow our community to engage more fully with this content. We encourage readers to comment on posts and share them on social media or via email. The blog will be a space to network with colleagues, explore new ideas, and allow all voices within ECOG-ACRIN to be heard. We hope the blog will facilitate a sense of connection during this time when we must be physically distant from one another – and that it will enhance our in-person interactions when we are able to meet again.

Remembering Sanjiv Sam Gambhir, MD, PhD
By Mitchell D. Schnall, MD, PhD

On July 18, the field of radiology lost one of its most influential leaders, Dr. Sam Gambhir (pictured right), the Chairman of Radiology at Stanford. To some of you, Sam is a household name in radiology, while for others, this is the first time you are hearing about him. Sam was one of the most prolific and creative molecular imaging researchers in the world. In addition, he was a charismatic advocate for the use of novel diagnostic technology to detect the earliest signs of disease as a means to reduce disease burden, and mitigate the cost of treatment. We were fortunate to have Sam serve on our ECOG-ACRIN board for a brief period.

Despite his remarkable success, what really distinguished Sam was how he cared for people, and his unique way of making everyone he spoke with feel special. The last time I saw him was at the Radiological Society of North America (RSNA) 2019 Meeting in Chicago. Typical of Sam, he took the effort to stand up and walk across a wide corridor, clearly challenged by his illness, just to ask me how I was doing. Radiology lost one its greatest leaders this week, and I lost one of my personal heroes. Sam will be missed by many.

“Despite his remarkable success, what really distinguished Sam was how he cared for people, and his unique way of making everyone he spoke with feel special.”
Now Enrolling: GIANT (EA2186) – A Randomized Phase II Study of Gemcitabine and Nab-Paclitaxel Compared with 5-Fluorouracil, Leucovorin, and Liposomal Irinotecan in Older Patients with Treatment Naïve Metastatic Pancreatic Cancer (GIANT)

Currently, there is no established standard of care for older adults with metastatic pancreatic cancer – yet over 65% of new pancreatic cancers are discovered in people aged 65 and over. The GIANT study, led by Dr. Efrat Dotan (Fox Chase Cancer Center), aims to obtain much needed data to guide oncologists regarding the optimal management of patients over the age of 70 with newly diagnosed metastatic pancreatic cancer. GIANT is the first prospective randomized study in this patient population.

Participants will be randomized to one of two treatment regimens: gemcitabine and nab-paclitaxel given every other week or dose-reduced 5-fluorouracil and liposomal irinotecan given every other week. The study team selected these therapies based on common oncologic practice in the management of older patients with metastatic pancreatic cancer. The primary endpoint of the trial is overall survival.

Ultimately, GIANT will provide important prospective data regarding the ability of older patients to tolerate treatment and the efficacy of these treatments in older adults. Furthermore, the novel design using a screening geriatric assessment for patient selection (available on the CTSU website on the EA2186 protocol page under “Documents” > “Education and Promotion”) will help to clearly define the patient population that should receive such treatment. It is hoped that GIANT will identify the recommended treatment regimen for older adults and a regimen that can be used in the future as a base to study novel treatment options in these patients.

Learn more about GIANT on ECOG-ACRIN.org.

Trial Results: ECOG-ACRIN to Conduct Randomized Phase 3 Trial Based on Recent Results of Phase 2 Study E3311

The overall intent of E3311, which validated a less intense treatment for certain patients with human papillomavirus-positive (HPV+) throat cancer, was to gather essential data for the design of a future, randomized phase three trial. E3311 met its primary objectives, which were 1) to determine the feasibility of a prospective multi-institutional study of transoral robotic surgery (TORS) for HPV+ oropharynx cancer followed by risk-adjusted adjuvant therapy and 2) to assess the oncologic efficacy following transoral resection and adjuvant therapy in patients determined to be at “intermediate risk” after surgical excision. To evaluate the latter, the study team reviewed the two-year progression-free survival rate.

“For intermediate risk patients—those with uninvolved surgical margins, less than five involved nodes, and less than 1mm extranodal extension—reduced-dose postoperative radiation therapy without chemotherapy appears sufficient ... this group had better outcomes than the group on usual high-dose radiation plus chemotherapy,” said lead investigator Dr. Robert Ferris (UPMC Hillman Cancer Center), who presented the results at the American Society of Clinical Oncology virtual annual meeting in May.

These findings confirmed the study’s patient stratification identified low- and intermediate-risk patients well, preserving their throat function and sparing them unnecessary short- and long-term toxicities.

“ECOG-ACRIN now plans to pursue the current data with a randomized phase three trial of TORS-based treatment deintensification compared with conventional chemoradiation,” said ECOG-ACRIN Head and Neck Committee Chair, Dr. Barbara Burtness (Yale University).
ECOG-ACRIN Launches Anti-Racist Agenda with Health Equity Inaugural Meeting

On Friday, June 26, the ECOG-ACRIN Co-Chairs, together with the Health Equity Committee, hosted the Health Equity Inaugural Meeting. Nearly 350 people attended the virtual event, the first in a series focused on issues related to racism and health disparities in cancer research. A recording of the webcast is now available to view on demand.

The meeting began with a brief introduction by Group Co-Chairs Drs. Peter O’Dwyer and Mitchell Schnall, during which they acknowledged the importance of recognizing and rethinking racism, both within ECOG-ACRIN and beyond. Their call to action was clear: ECOG-ACRIN members must identify and pursue ways to make progress, not just by promoting health equity, but also by actively opposing racism. This was followed by a series of thought-provoking presentations.

First, Dr. Edith Mitchell (Thomas Jefferson University), Co-Chair of the Health Equity Committee, reviewed the goals of the Group in pursuing an anti-racist agenda. She summarized the causes of health disparities, noting that while genes undoubtedly play a role in the development of various cancers, the gene environment can be significantly influenced by poverty/lower economic status, culture, and social injustice. All three of these areas must be addressed in order to achieve cancer care equity. Dr. Mitchell also stressed the importance of cultivating a diverse oncology workforce – particularly given that underrepresented/minority doctors often return to serve their neighborhoods and communities.

During his presentation, Dr. Otis Brawley (Johns Hopkins University), Chair of the Social Determinants of Health Working Group, emphasized the critical difference between equity and equality: equity acknowledges that certain populations need more support than others to achieve the same goal. Dr. Brawley also underscored the substantial overlap between socioeconomic determinants of cancer risk and outcomes and racial determinants – and the fact that, in many cases, the two are inextricably linked. In fact, socioeconomic factors are actually a better indicator of outcomes: right now, a person is better off being a Black woman in Massachusetts than a White woman in Oklahoma when it comes to breast cancer mortality. Ultimately, the issue of disparities in health is not just a racial issue, but also an issue of socioeconomics.

Finally, Dr. Carmen Guerra (University of Pennsylvania) reviewed the role that unconscious bias, a tendency present in all human beings, plays in creating disparities. Unconscious biases are the learned stereotypes that are automatic: a thought or behavior that fills in the “story” of something a person encounters – an individual, a circumstance – and informs how they behave. Unconscious biases are pervasive and can be harmful in a number of ways. For example, research shows that patients who are Black receive fewer opportunities to participate in clinical trials – in part because some physicians assume participation would create undue burden and forgo mentioning a trial altogether. Key ways to address unconscious bias include: developing self-awareness, slowing down, prioritizing transparency and inquiry, and striving to assume the “most respectful interpretation” of another’s words or actions.

Dr. Melissa Simon (Northwestern University), Chair of the Health Equity Committee, moderated the meeting and answered attendee questions submitted via chat. Dr. Simon concluded the meeting by noting that ECOG-ACRIN plans to continue the conversation, and encouraged attendees to join the monthly Health Equity Committee calls. The short-term focus will be to define the goals of an anti-racist program at ECOG-ACRIN so that tangible benefits may be targeted over the short- and long-term. The calls take place the first Friday of every month at 11:00 am Eastern Time. If you are interested in attending, email Brenda McCalister-Afflick — and watch your inbox for invitations to future Health Equity Webcasts.
Institution Spotlight: Cancer Research Consortium of West Michigan
By Kathleen J. Yost, MD

The Cancer Research Consortium of West Michigan (CRCWM) was formed in August 2014, when the Grand Rapids Clinical Oncology Program (GRCOP) and the Kalamazoo Community Clinical Oncology Program joined together, with the support of a NCI Community Oncology Research Program (NCORP) Grant. Both programs had previously been legacy participants in the NCI Community Clinical Oncology Program (CCOP), offering national clinical trials through a community-based clinical research program.

Today, CRCWM offers local access to and data management support for over 150 cancer research studies across its 9 member hospitals and health care systems. The Consortium works to provide the highest quality care for cancer prevention and treatment. CRCWM continues to provide access to the latest cancer research both nationally and locally.

CRCWM (then GRCOP) became an ECOG-ACRIN (EA) member in 1996. Its director, Connie Szczepanek has served in a leadership role for the Consortium since 1998. It has had four principal investigators over this time who serve or have served on the EA Principal Investigator Committee. My colleague Dr. Sreenivasa Chandana is a strong proponent of ECOG-ACRIN research and a steady enrollee in its trials. Joan Westendorp, one of our nurse leaders and current CRCWM Consortium Governance Board Chairperson, serves on multiple ECOG-ACRIN committees including: Head and Neck Cancer, Cancer Control and Survivorship, and Cancer Care Delivery Research. She is also an auditor for EA. Barb Lomasney recently became an ECOG-ACRIN auditor, too.

Like all sites right now, CRCWM is working hard to ensure clinical trials continue despite the challenges posed by the pandemic. Enrollment to the TMIST/EA1151 breast cancer screening trial stalled when the country shut down in March, so now we are focused on finding creative ways to restore momentum. Dr. Jon Notarnicola and Dr. Christina Jacobs have been vital to TMIST recruitment efforts, collaborating with primary care practices and developing resources to highlight the importance of the study. We also hold regular meetings to identify issues and accrual barriers – as well as solutions – for TMIST.

As an NCORP site, CRCWM has a special interest in ECOG-ACRIN’s Cancer Care Delivery Research and Cancer Control and Survivorship studies. We participated in the pilot testing for EAQ161CD, Biomarker Testing in Common Solid Cancers: An Assessment of Current Practices in Precision Oncology in the Community Setting. We have also found that studies concerning financial toxicity, like EAQ162CD, resonate deeply with the communities we serve. Our site in Kalamazoo accrued over 60 participants to EA1141, which found that abbreviated MRI outperforms 3-D mammography at finding cancer in dense breasts. Newer EA trials we are prioritizing include EAZ171, studying neuropathy in African American women, and EA2185, comparing two methods of monitoring patients with pancreatic cysts.

CRCWM is particularly proud of its advocate involvement and has its own Patient Advocate Committee, formed in 2008. The group, co-chaired by Sue Schroeder and Marty Smith, brings a unique perspective to CRCWM’s research efforts. The Committee also played a key role in developing patient-friendly content for the CRCWM website. Together with the investigators, research staff, and patients, the advocates help make CRCWM the exceptional research program that it is.
News in Brief

Is something new or noteworthy happening at your institution? Send your updates to support@ecog-acrin.org.

ECOG-ACRIN Research Round-Up

InterAAct/EA2133: Results from this worldwide study, the first randomized trial for inoperable anal cancer, suggest that carboplatin-paclitaxel become the standard treatment for these patients. View the press release or read the article in the Journal of Clinical Oncology.

NCI-MATCH/EAY131 Arm W: Patients with tumors harboring aberrations in the fibroblast growth factor receptor (FGFR) pathway were treated with AZD4547, an oral FGFR1-3 inhibitor, in Arm W of the NCI-MATCH precision medicine trial. Read the article in the Journal of Clinical Oncology.

SOAPP/E220: Data from this study showed that use of higher-than-currently-recommended severity thresholds for symptom alerts for patients receiving outpatient chemotherapy would result in failure to identify and treat many patients requiring clinical intervention for symptoms. Read a summary in The ASCO Post or the full article in the JCO Oncology Practice.

NCI-ComboMATCH Laboratory Application Deadline Extended to September 30

The National Cancer Institute (NCI) is currently seeking Clinical Laboratory Improvements Program certified/ accredited laboratories that test tumor specimens from patients utilizing Next-Generation Sequencing (NGS) assays to participate in the NCI-ComboMATCH trial. Applications must be submitted by Wednesday, September 30.

NCI-ComboMATCH is a successor to the NCI-MATCH/EAY131 precision medicine trial. Learn more and view the Federal Register notices.

New Resource Available to View NCI-MATCH Trial Publications

ECOG-ACRIN recently created a dedicated web page that lists all publications related to the NCI-MATCH/EAY131 Trial. Publications fall into one of two categories: Special Topics About NCI-MATCH or Final Results for Treatment Arms. View the web page now.

Summer 2020 Core Committee Virtual Sessions

This spring marked the first time in ECOG-ACRIN’s history that we could not hold our semi-annual Group Meeting. In an effort to maintain the momentum of our work, we are conducting nine virtual summer core committee sessions, which would have otherwise occurred in-person during the Spring 2020 Group Meeting.

At this time, three of the nine sessions have already taken place, affording committee members the opportunity to discuss new proposals, review active and recently completed trials, and share other important updates.

Fall 2020 Group Meeting Update — As of late July 2020

The ECOG-ACRIN Fall 2020 Group Meeting, scheduled to occur in Fort Lauderdale, FL, from Wednesday, October 21 – Friday, October 23, will not be an in-person event. Due to the evolving and unpredictable nature of the COVID-19 pandemic, we are making preparations to hold the meeting virtually. Please continue to hold these dates on your calendar for the virtual meeting.

A formal announcement is forthcoming shortly – please keep an eye on your email inbox.

TMIST Participant Recruitment Materials Now Available in Chinese and Korean

These translated materials, which are also available in Spanish, include Thank You and Appointment Reminder cards, a clinic poster and phone script, and templates for letters/emails that sites can customize for sending to women scheduled for a mammogram. These and other educational resources for patients and research staff are available for download via the CTSU or the TMIST educational materials page on the ECOG-ACRIN website.