FROM THE CO-CHAIRS
PETER J. O'DWYER, MD (LEFT), AND MITCHELL D. SCHNALL, MD, PhD
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Following upon our successful grant awards for our ECOG-ACRIN research, the Cooperative Group Chairs were invited to meet with National Cancer Institute (NCI) Director Dr. Norman (Ned) Sharpless, along with Drs. Doroshow and Mooney, at Dr. Sharpless's office in Bethesda in early January. The discussion centered on the role of the Groups in helping to advance the national cancer research agenda, and the meeting affirmed the significant contributions of the Groups in the past several years. In addition, there was acknowledgement that the alignment of goals between the NCI and the Groups was close, and that our shared sense of purpose made for the development of innovative and impactful trials in the public system. Nonetheless, we recognized that there are areas of mutual function, principally relating to speed of development at various levels, and access to samples for translational studies, which if improved, would make Cooperative Group research more attractive both for researchers and for pharma. In a follow-up document from the Group Chairs, two areas for future dialogue were identified: structural aspects of operations, and attention to the concept of cooperative development. Ideas have already been exchanged to prepare groundwork for these discussions.

Helpfully, in late December Congress passed and enacted an appropriations bill providing the NCI with a budget increase of $297 million for fiscal year (FY) 2020. This was part of an overall National Institutes of Health (NIH) budget increase of $2.6 billion. In a recent blog post, Dr. Sharpless explained that this will allow the NCI to extend current paylines, fund more than 125 additional competing awards in 2020 (compared to 2019), and fully restore commitments to noncompeting grants. Dr. Sharpless noted that they will allocate more than $210 million to support extramural research and training opportunities at universities, medical centers, and other institutions throughout the United States. Thanks to this budget increase, organizations like ours that rely on government funding can continue building momentum and making progress.

In this issue of the Newsletter, we discuss two trials. One (EA2185) recently activated, and the other (EA3161) in progress. EA2185 is a test of approaches to the monitoring of incidentally found pancreatic cysts, a common finding in abdominal CT scans. Two approaches may be taken in monitoring the growth of these abnormalities, both credentialed by professional societies, one more intensive than the other. Neither has objective data to support its being a superior approach, and most important, there are few metrics that would predict that a given cyst might have a "bad biology." The differences between these standard approaches also potentially amount to billions per year, providing additional reasons to analyze outcomes. We hope that there will be broad interest in accrual to this trial. EA3161 has therapeutic potential in HPV-positive head and neck cancer – it tests the addition of nivolumab (vs. control) after definitive chemoradiation in patients with locally advanced disease. Clearly a successful result here would have the potential to enhance cure rates in this disease.

Finally, we want to provide advance notice of the Second Robert L. Comis Translational Science Symposium. This will take place at our Spring Group Meeting on Wednesday, April 29 from 1:00 – 3:00 pm. The focus of the Symposium follows upon the initial Symposium at our last meeting, and will address the many research opportunities afforded by an emphasis on Big Data – for this meeting, on the generation of Real-World Evidence. As you are aware, for both therapeutic and imaging trials, a successful Phase III study is often the end of that particular research thread. A novel regimen or test, if approved by the FDA, is then implemented in the community without a real-time assessment of how well the novel approach contributes to health. Opportunities for analysis of treatment delivery, test application, benefits, toxicity, and specificity for patient sub-populations are clear, and are of interest both to advocacy groups as well as to the FDA, all through collection of real-world data. Friends of Cancer Research and the FDA have collaborated on guidelines for this research, and will be a key part of this symposium. We invite your participation, and especially will appreciate if you can reach out to researchers who may be particularly interested in such trials.
NOW ENROLLING: EA2185 TRIAL TO COMPARE THE CLINICAL IMPACT OF PANCREATIC CYST SURVEILLANCE PROGRAMS

Pancreatic cystic neoplasms occur in up to 20% of the adult population and prevalence is increasing with more cross-sectional imaging. This trial, led by David S. Weinberg, MD, MSc (Fox Chase Cancer Center, pictured right), aims to compare low intensity and high intensity surveillance in patients with at least one newly diagnosed pancreatic cyst. The "high" intensity strategy will parallel the Fukuoka guidelines, which recommend frequent follow-up via MRI (every six months to two years), as well as lifelong surveillance and surgery in some cases. The "low" intensity approach will be similar to the AGA guidelines, which support less frequent follow-up and a higher bar to qualify for surgery. All patients on the trial will be followed for five years.

It is currently unknown which of these two strategies leads to better outcomes. The results of EA2185 may reveal an optimal surveillance strategy, helping to prevent the over or under treatment of patients. The study may also uncover findings that could predict the behavior of these cysts. Learn more.

SOCIAL MEDIA & CLINICAL TRIALS

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CHAIR, NCORP COMMUNITY ADVISORY COMMITTEE
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Social media, first introduced in the late 1990s, is here and it is not going away. Today, we intuitively understand the importance of social media – even those of us who avoid it or dislike it. Consider, for example, that two presidents used social media to help get themselves elected.

At its core, social media, like other media, is a communication tool – and communication is at the center of what oncology professionals do. We communicate with patients, colleagues, and the public. Social media is different from traditional media in some key ways, however. It is faster, permanent, interactive, and searchable. Often, it amplifies messages beyond the initial "broadcast" audience.

There are countless social media platforms, such as Twitter, Facebook, blogs, YouTube, and more, but the lines between them are increasingly blurred; the channels we know today have evolved and will continue to evolve. More important than the specific platforms is what they enable: content, curation, and connectivity. Social media offers rapid incoming and outgoing forms of communication. Use cases include: 1) increasing the signal-to-noise ratio (such as with hashtag use), 2) education networks, 3) crowdsourcing/crowdfunding, 4) collaboration, and 5) promotion.

In the context of ECOG-ACRIN Cancer Research Group (EA), it is important to think about utilizing social media to promote NCI and EA-initiated clinical trials and publications. Doing so will help our organization accrue patients to studies, share information about available clinical trials, and disseminate findings published from completed studies. Social media can support our research activities in other significant ways, including:

- Helping to identify and overcome clinical trial barriers
- Creating structure and order to conversations through hashtags
- Connecting with and educating patients (particularly those in difficult-to-reach communities)
- Keeping up-to-date on government, pharmaceutical, and other cooperative group activities
- Crowdsourcing ideas for new trials or trials in development
SPEECH MEDIA & CLINICAL TRIALS (CONT’D)

At ASCO’s Annual Meeting several years ago, EA Community Cancer Committee Chair Matthias Weiss, MD, PhD (@mweissthedacare on Twitter) and colleagues presented their work investigating strategies to overcome barriers to accrual to NCI-sponsored clinical trials. They concluded one approach was to educate patients and providers about new trials using social media. This could complement offline efforts such as presenting trials at national meetings and adding educational materials to protocols. Subsequent research has also recommended these strategies, leading to the conclusion that an educated and engaged – via both social media and in-person – public is necessary to sustain a national clinical trials infrastructure and continue advancing cancer research.

TRIAL SPOTLIGHT: EA3161 – A PHASE II/III RANDOMIZED STUDY OF MAINTENANCE NIVOLUMAB VERSUS OBSERVATION IN PATIENTS WITH LOCALLY ADVANCED, INTERMEDIATE RISK HUMAN PAPILLOMA VIRUS (HPV) POSITIVE OROPHARYNGEAL SQUAMOUS CELL CARCINOMA (OPSCC)

NABIL F. SABA, MD

Despite the substantially better survival among patients with HPV-driven OPSCC compared to HPV-negative disease, patients with p16 positive OPSCC with intermediate risk defined as T4 or N2-N3 (AJCC8) or smokers of more than 10-pack-years seem to be at the highest risk for death with an estimated 4-year OS of 68%. Patients with T3N3 or T4N2-N3 are at especially high risk with a 4-year survival of 51%. The clinical benefit from immune checkpoint inhibitors (ICI) in recurrent metastatic squamous cell carcinoma of the head and neck (SCCHN) may be reflected in a prolonged stabilization of disease, raising interest in employing ICI as a form of maintenance therapy.

Recent evidence indicated that nivolumab maintained function and improved symptoms in heavily pre-treated patients with SCCHN, making its use in a maintenance setting attractive. EA3161 is a phase II/III trial randomizing patients with intermediate risk HPV-related OPSCC to maintenance nivolumab versus observation following definitive therapy with intensity modulated radiation therapy (IMRT) and cisplatin. EA3161 will provide robust, biologically significant, and correlated studies in this patient population. As this study focuses on HPV-related disease, it also avoids intensification of concurrent therapy and relies instead on abrogating the risk of recurrence through a maintenance approach.

EA3161 (phase II) is assessing the efficacy of concurrent definitive therapy followed by nivolumab compared with concurrent definitive therapy followed by observation in terms of progression-free survival (PFS). EA3161 (phase III) is assessing the efficacy of concurrent definitive therapy followed by nivolumab compared with concurrent definitive therapy followed by observation in terms of overall survival (OS). Additional objectives include assessing the efficacy of nivolumab compared to observation in terms of relationship to baseline PD-L1 expression and the 12-week post therapy FDG PET/CT. Eligible patients must be at least 18 years of age with ECOG PS 0 or 1, and must have oropharynx cancer that is p16-positive by immunohistochemistry with smoking status: 10 pack-years, stage T1-2N2-N3 or T3-4N0-3 OR <10 pack-years, stage T4N0-N3 or T1-3N2-3.

Though it is quite probable that adding ICI to the backbone standard concurrent regimens will be proven effective for locally advanced SCCHN, the question of whether intensification specifically for the HPV-related OPSCC is the correct approach, and the degree to which this specific group will benefit from maintenance ICI, will continue to be relevant. EA3161 is uniquely positioned to answer these important questions for a healthier group of patients with better prognosis yet equivalent risk of distant metastases.

Learn more about trial EA3161.
NEWS IN BRIEF

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

EA TRIAL RESULTS IN HIGH-IMPACT JOURNALS

The NCI-MATCH trial was recently featured in the Journal of the National Cancer Institute. The manuscript, The Molecular Analysis for Therapy Choice (NCI-MATCH) Trial: Lessons for Genomic Trial Design, highlights how NCI-MATCH is helping researchers and physicians navigate the complexities of molecular profiling for targeted therapies. View the article.

Results from trial E1609, led by Ahmad Tarhini, MD (Moffitt Cancer Center), were published in the Journal of Clinical Oncology in January. The study demonstrated an overall survival advantage with adjuvant ipilimumab at 3 mg/kg — but not at 10 mg/kg — compared to high-dose interferon alfa-2b in patients with resected high-risk cutaneous melanoma. This is the first time in melanoma adjuvant therapy that a study has shown a significant improvement in overall survival against an active control regimen. Learn more.

EDITH MITCHELL, MD APPOINTED TO THE PRESIDENT’S CANCER PANEL

In December, Edith Mitchell, MD, co-chair of ECOG-ACRIN’s Health Equity Committee, was appointed to the President’s Cancer Panel. Established in 1971, the panel is an independent advisory group that reports to the President on barriers to progress in reducing the cancer burden and develops recommendations. Learn more.

INTRODUCING CONSIDERING CLINICAL TRIALS: A BLOG ABOUT CANCER TREATMENT OPTIONS

Together with the Cancer Research Advocates Committee, ECOG-ACRIN has launched a new blog featuring news, editorials, and perspectives by cancer research advocates. Updated quarterly, the blog highlights issues important to patients and survivors, new and ongoing ECOG-ACRIN trials, and results from completed trials. View the blog, and please share it with your site staff, outreach coordinators, and local advocacy groups.

REGISTRATION NOW OPEN FOR SPRING 2020 GROUP MEETING

Register now for the ECOG-ACRIN Spring 2020 Group Meeting, taking place Wednesday, April 29 – Friday, May 1 at the Baltimore Marriott Waterfront in Baltimore, Maryland. Please note that this meeting marks a departure from the usual Thursday – Saturday schedule and takes place Wednesday – Friday.

After registering, you will be connected to the hotel reservation page. You will also receive a confirmation email with a link to book your hotel room in the ECOG-ACRIN block. The hotel reservation deadline is Wednesday, April 1, but our room block may sell out prior to that date.

For those planning further ahead, the Fall 2020 Group Meeting will take place Wednesday, October 21 – Friday, October 23 at the Marriott Harbor Beach Hotel in Fort Lauderdale, Florida.

GROUP MEETING TRAVEL FUNDS AVAILABLE FOR CLINICAL RESEARCH ASSOCIATES

The ECOG-ACRIN CRA Core Committee has limited funds available to provide travel assistance to the Spring Group Meeting. Four candidates will be selected to receive a travel expense reimbursement award of up to $1,000. These funds are intended to facilitate attendance for CRAs with no other form of travel support. Data managers, clinical research associates or clinical research coordinators/nurses (who enter their own data) are eligible to apply. Only one candidate per institution will be supported.

Applications must be submitted no later than Friday, March 20. Apply now.