Cancer and Aging Research Group Teleconference  
February 12th, 2019

Present: Andrew Artz, Vijaya Bhatt, Shelley Bluethman, Beverly Canin, Kelley Covington, Clark Dumontier, Shakira Grant, Addie Hill, Tina Hsu, Li-Wen Haung, Vani Katheria, Kelly Kenzik, Heidi Klepin, Jessica Krok, Elizabeth Levin, Melissa Loh, LisaLowenstein, Amy MacKenzie, Allison Magnuson, Hussai Nuristani, Sukesh Patel, Mackenzi Pergolotti, Carolyn Presley, Melody Schiaffino, Mina Sedrak, Manvi Sharma, John Shen, Harpreet Singh, Enrique Soto, Ishwaria Subbiah, Canlan Sun, Virginia Sun, Tanya, Wilides, Kelly Trevino, Grant Williams, Melisa Wong  (36 total participants)

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<td>Announcement</td>
<td>Drs. Heidi Klepin and Allison Magnuson co-lead the call. Thank you for joining the call! Dr. Klepin mention the JGO Special Issue in dedication to Dr. Arti Hurria. In this Call for Papers for the Journal of Geriatric Oncology, JGO invites the submissions of original research, brief reports, and focused reviews on topics in geriatric oncology that highlight Dr. Arti Hurria’s work. Submissions should explicitly highlight how her research has influenced the original research or review topic. This JGO special issue is to celebrate Dr. Hurria’s academic and leadership accomplishments. The deadline for submission of papers for the issue is May 1, 2019. Please refer to the attachment for more information.</td>
<td>The Annual American Geriatrics Society (AGS) Conference will be held on May 2-4, 2019 in Portland, Oregon. Congratulations on the AGS New Investigator Award to Dr. Carolyn Presley! This award will be presented at 2019 AGS Annual Meeting Award Ceremony on Friday, May 3rd. The deadline for submission of papers for the issue is May 1, 2019. Please refer to the attachment for more information.</td>
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<td>Submit AGS abstracts to <a href="mailto:CARinG@coh.org">CARinG@coh.org</a>. AGS post-conference update on a CARG call in May.</td>
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<td>Update on ASCO Eligibility Projects</td>
<td>ASCO Eligibility Projects are looking to broaden eligibility criteria to make clinical trials more representative. The working group for eligibility requirements 1) Recognize that there is tide shifting to make clinical trials more reflective on the population and 2) discuss as a group and open discussion. In 2016, ASCO and Friends of Cancer Research (Friends) began a joint project to develop and advance specific strategies to change the exclusionary nature of eligibility criteria. ASCO-Friends working groups composed of patient advocates, drug/biotech</td>
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manufacturers, investigators, and regulators developed consensus recommendations for eligibility criteria on the following topics: 1) Brain Metastases, 2) HIV/AIDS, 3) Organ Dysfunction and Prior and Concurrent Malignancies, and 4) Minimum Age for Enrollment.

ASCO and Friends are now working to advance broad implementation of the recommendations. On August 8, 2018, ASCO and Friends submitted recommended language for five guidance documents on ways to broaden eligibility criteria for cancer clinical trials to the U.S. Food and Drug Administration (FDA). The five guidance documents contain the recommendations published in the October 2017 JCO Special Series. FDA plans to review the ASCO-Friends recommended language as the agency finalizes draft guidance documents to release for public comment. ASCO and Friends will announce when the draft guidance documents are available for comment and develop comments for submission.

Dr. Klepin reaches out to the group for feedback:
- Dr. Harpreet Singh shares her experience working with the ASCO eligibility project. An extension cohort may be the most appropriate representative. It would be difficult to standardize the eligibility requirement for a more liberal constraint which would depend on the clinical trial.
- Dr. Grant Williams mentions the issue of subjectivity and it does depend on the eye of the beholder on how to set an eligibility requirement for all clinical trials.
- Dr. Tina Hsu agrees that there more precise way to broaden eligibility criteria for cancer clinical trials and how to distinguish the performance status with older adults. Next steps are to present to cooperative groups about this information and to reach out to individuals in prominent clinical trials specialist who may help to overcome the implementation issues.
- Questions around how to generalize older adults in performance status.
- Many agreed that more study focus on this topic and support an adaptive trial design and extension cohort for a trial.
- One recommendation for sponsors to open clinical trials to the community.

For any additional feedback, please reach out to Dr. Heidi Klepin at hklepin@wakehealth.edu.

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**Next steps for ASCO Cancer Research Committee (building on ASCO/FDA workshop recommendations)**

The current chair of ASCO Cancer Research Committee is Dr. Klepin. Dr. Hurria paved the way for cancer and aging and how ASCO can contribute this change.
**TOPIC**

Ongoing efforts to address the lack of clinical research on older adults with cancer, the American Society of Clinical Oncology (ASCO) and the US Food and Drug Administration cosponsored a public workshop on geriatric oncology in November 2017. The goals were to review progress, build collaborations across stakeholders, and generate new action items for increasing the evidence base for treating older adults with cancer. It built on previous work of the Institute of Medicine, ASCO, and the U13 Conferences convened by the Cancer and Aging Research Group, the National Cancer Institute, and the National Institute of Aging between 2010 and 2015.

Based on the workshop discussions, four new action items to move the field forward were developed:
1) increase enrollment of older adults in clinical trials,
2) collect more information on older adults enrolled on clinical trials,
3) expand the use of real-world data in research on older adults, and
4) Strengthen collaboration between stakeholders to develop advocacy and policy solutions.

Two major recommendations include:
1) FDA Could Work With Sponsors to Outline Development Plans for New Drugs to Enroll Representative Numbers of Older Adults
2) FDA and NCI Should Work With Sponsors to Design Trials That Collect More Information on Treating Older/Frail Adults Sponsors and Researchers Should Work With Statisticians to Design More Trials with Coprimary or Composite Endpoints, Including PROs, Elements of GAs, and Endpoints Important to Older Adults

Discussed any feedback on how do we work together to expand the base of geriatric oncology that related to ASCO FDA and other stakeholder.

**Mentoring Discussion: Grant Resubmission**

Dr. Magnuson leads the mentoring discussion for this call. The topic is grant resubmission process by two examples from CARG members – Drs. Grant Williams and Heidi Klepin.

Dr. Grant Williams explain his process. He uses a table provided by his mentor Dr. Supriya Mohile. It is a grading table that helps to break down the comments and how to address the comments. By taking the comments, he drafts the response point by point. The comments and feedback in the table help to find any overlap and make changes before changing the overall grant.
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<td>Dr. Heidi Klepin shares her experience in grant resubmission. 1. Digest the review and accept the comments 2. Send to mentors for feedback for suggestions from the comments 3. Improve the research plan and need to reconcile with the feedback 4. Spend time with mentors and what you need to change or alter the comments.</td>
<td>Having a mentor will help to support and help to depersonalize from the grant feedback and their grant experiences can help the grant resubmission process.</td>
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<td><strong>CARG Virtual Lab Meeting Brainstorming</strong></td>
<td>Dr. Melisa Loh announces that the first Virtual Lab Call is on February 28th. We will create sign-in link similar to the CARG calls. We are currently working on setting up a system through the mycarg website.</td>
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**Next Conference Call: February 26th, 2019**