

# Melanoma Committee

## Leadership

Chair: ..... Sapna P. Patel, MD  
 Vice-Chair: ..... Roger S. Lo, MD, PhD  
 Executive Officer: ..... Christopher W. Ryan, MD  
 Statisticians: ..... Michael Wu, PhD  
 ..... Megan Othus, PhD  
 ..... James Moon, MS  
 ..... Hongli Li, MS

## Scientific Leadership

Translational Medicine: ..... William E. Carson, III, MD  
 Radiation Oncology: ..... Evan J. Wuthrick, MD  
 Surgery: ..... John Robert Hyngstrom, MD  
 Dermatology: ..... Clara Curiel-Lewandrowski, MD  
 Imaging: ..... Ari M. VanderWalde, MD  
 Medical Oncology: ..... Sapna Pradyuman Patel, MD  
 Pathology: ..... TBD  
 Non-Melanoma Skin Cancer: ..... Nikhil I. Khushalani, MD  
 Early Therapeutics: ..... Jeffrey A. Sosman, MD  
 SWOG's ECOG Liaisons: ..... Thach-Giao Truong, MD  
 ECOG's SWOG Liaisons: ..... David H. Lawson, MD  
 ..... Andrew Poklepovic, MD  
 Digital Engagement: ..... Zeynep Eroglu, MD

## Designates

Cancer Control Liaison: ..... Sancy Leachman, MD, PhD  
 ..... Thach-Giao Truong, MD (Survivorship)  
 Data Coordinator: ..... Tonya Johnson  
 ..... Laura Kingsbury, MRT  
 ..... Leah Everhart  
 ..... Hannah Hale  
 Oncology Research Professionals:  
 CRA: ..... Kathryn Allen, BA, CCRP  
 Nurse: ..... Lisa S. Morgan, RN, OCN  
 Patient Advocate: ..... Samantha Guild, J.D.  
 Pharmaceutical Science: ..... Sun "Coco" Yang, PharmD, PhD  
 ..... Kimberly McConnell, PharmD  
 Protocol Project Manager: ..... Catrina De Los Santos-Mireles  
 Clinical Trials Program Manager: ..... TBD

## Time/Location

Friday, October 21, 2022 2:30 pm - 4:30 pm  
 Room: Crystal C (Lobby Level, West Tower)

## Agenda

- 2:30 - 2:40 pm Welcome and Introduction:** Sapna Patel, MD
- 2:40 - 3:20 pm Keynote Speaker: Treating Mucosal Melanoma: Progress and Challenges in the PD-1 Era** - Alexander Shoushtari, M.D., Memorial Sloan Ketterin Cancer Center
- 3:20 - 3:35 pm Active Studies update - Study design, eligibility criteria, endpoints, accrual to date**
- S2015**, A Phase III, Multi-centre Randomised Controlled Trial Investigating 1cm vs. 2cm Wide Excision Margins for Primary Cutaneous Melanoma, MASC  
 PI: Joshua Mammen, M.D., Ph.D. (University of Nebraska)
- S2000**, A Randomized Phase II Trial Of Encorafenib + Binimetinib + Nivolumab Vs Ipilimumab + Nivolumab In Braf-V600 Mutant Melanoma With Brain Metastases.  
 PI: Zeynep Eroglu, M.D. (Moffit)  
 Biostatisticians: Michael Wu, Ph.D. & James Moon, M.S.
- 3:35 - 4:10 pm Closed to Patient Accrual, Manuscript & Translational Medicine Updates**
- S1801**, A Phase II Randomized Study of Adjuvant Versus Neo-Adjuvant Pembrolizumab (MK-3475) for Clinically Detectable Stage III-IV High-risk Melanoma. Sapna Patel (MDACC). Activated PI: Sapna Patel, M.D. (MD Anderson)  
 Biostatisticians: Megan Othus, Ph.D. & James Moon, M.S.
- S1616**, A Phase II Study of Ipilimumab and Nivolumab in Advanced Melanoma Following Progression on a PD-1 Inhibitor Alone  
 PI: Ari VanderWalde, M.D., M.P.H. (West Cancer Clinic)  
 Biostatisticians: Michael Wu, Ph.D. & James Moon, M.S.
- S1512**, A Study of PD-1 Blockade with Pembrolizumab In Patients with Primary Desmoplastic Melanoma (DM), Locally Advanced, Locally Recurrent, or Metastatic Desmoplastic Melanoma (DM)  
 PI: Kari Kendra, M.D. (Ohio State) and Siwen Hu-Lieskovan, M.D., Ph.D. (Huntsman Cancer Institute)  
 Biostatisticians: Michael Wu, Ph.D. & James Moon, M.S.
- S1607**, A Phase II Study of Combining T-VEC and PD-1 Blockade With Pembrolizumab In Patients With Advanced Melanoma Who Have Progressed On Anti-PD1 Therapy.  
 PI: Siwen Hu-Lieskovan, M.D., Ph.D. (Huntsman Cancer Institute)  
 Biostatisticians: Michael Wu, Ph.D. & James Moon, M.S.

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**S1404**, A Phase III Randomized Study of MK3475 versus High-Dose Interferon alfa-2b for Resected High-Risk Melanoma  
 PI: Sapna Patel, M.D. (MD Anderson)  
 Biostatisticians: Megan Othus, Ph.D., James Moon, M.S., & Hongli Li, M.S.

**S1320**, A Randomized Phase II Trial of Intermittent Versus Continuous Dosing of Dabrafenib and Trametinib in BRAFV600E/K Mutant Melanoma  
 PI: Alain Algazi, M.D. (University of California San Francisco)  
 Biostatisticians: Megan Othus, Ph.D., James Moon, M.S.

**S1221**, Phase I/II Study of the Safety and Efficacy of the AKT Inhibitor GSK2141795 in Combination with the BRAF Inhibitor Dabrafenib and Trametinib in Patients with BRAF Mutant Cancer  
 PI: Alain Algazi, M.D. (University of California San Francisco) and Antoni Ribas (UCLA)  
 Biostatisticians: Megan Othus, Ph.D. & James Moon, M.S.

**4:10 - 4:20 pm**      **ECOG / ALLIANCE Updates:** David Lawson, MD

**4:20 - 4:25 pm**      **Advocate Update:** Remarks (Samantha Guild, JD, AIM at Melanoma)

**4:25 - 4:30 pm**      **Closing**

## Other Active Studies

**CTSU/EA6174**, "STAMP: Surgically Treated Adjuvant Merkel Cell Carcinoma with Pembrolizumab, a Phase III Trial." SWOG Champion: Dr. Hsu. Activated: 10/1/18.

**CTSU/EA6141**, "Randomized Phase II/III Study of Nivolumab plus Ipilimumab plus Sargramostim versus Nivolumab plus Ipilimumab in Patients with Unresectable Stage III or Stage IV Melanoma." SWOG Champion: Dr. K. Kim. Activated: 9/10/15.

**CTSU/EA6192**, "The BAMB2 (BRAF, Autophagy, MEK Inhibition in Melanoma) Study: A Randomized Double Blind Phase II Study of Dabrafenib and Trametinib with or Without Hydroxychloroquine in Advanced BRAF V600E/K Melanoma with Elevated LDH". SWOG Champion: Dr. Truong. Activated:10/23/20.

## Other Closed Studies

**CTSU/EA6134**, "DREAMseq (Doublet, Randomized Evaluation in Advanced Melanoma Sequencing) a Phase III Trial." SWOG Champion: Dr. Chmielowski. Activated: 7/13/15. Closed: 9/30/2021.

## Studies in Development

**S2300**, "A Phase 3 Randomized Trial of Complete Circumferential Peripheral and Deep Margin Assessment for Excision of Localized Cutaneous Melanoma: The CAEC ("Cake") Trial" Dr. Yu.

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### Accrual from trial opening through 6/30/2022 by Institution and Study

	S1512	S1801	S2000	S2015	EA6134	EA6141	EA6174	EA6192
Banner MD Anderson CC	-	3	-	-	-	-	-	-
Banner U Med Ctr - Tucson	-	7	-	-	-	-	3	-
Baptist Mem Hlth Care/Mid South MU NCORP	-	1	-	-	-	-	-	-
Boston Med Ctr	-	1	-	-	-	-	-	-
CWRU Case CCC LAPS	-	-	-	-	6	-	14	-
Ca Res Consort of W Mich NCORP	-	26	-	8	-	-	-	-
Ca Res for the Ozarks NCORP	-	-	1	-	-	1	-	-
Ca Res of Wisconsin & N Mich Consort	-	2	-	-	-	-	-	-
Carle CC NCORP	-	1	1	-	-	-	-	-
City of Hope CCC	-	6	-	-	2	3	-	-
Columbus NCORP	-	1	-	-	-	-	-	-
Dayton NCORP	-	-	-	-	-	2	-	-
Georgia NCORP	1	-	-	-	-	-	-	-
Gulf South MU NCORP	-	1	-	-	-	-	-	-
Hawaii MU NCORP	-	2	-	-	2	-	-	-
Heartland Ca Res NCORP	-	6	-	-	-	-	-	-
Intermountain Med Ctr	1	-	-	-	-	-	-	-
Kaiser Permanente NCORP	-	14	-	-	19	23	-	-
Loma Linda U Med Ctr	-	2	-	-	-	-	-	-
Massachusetts Vet Epi Res & Info Ctr	-	5	-	-	-	-	-	-
Medical U South Carolina MU NCORP	-	1	-	-	-	-	-	-
Michigan Ca Res Consort NCORP	-	5	-	-	-	-	-	-
Moffitt CC	19	-	4	-	-	-	-	-
Montana Cancer Consort NCORP	-	4	-	-	-	-	-	-
NCORP Carolinas (Prisma Hlth NCORP)	-	-	-	-	2	-	-	-
Nevada Ca Res Foundation NCORP	-	-	-	-	-	-	1	-
New Mexico MU NCORP	-	1	-	-	-	-	-	-
Northwell Hlth NCORP	-	7	-	-	-	-	-	-

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Accrual from trial opening through 6/30/2022 by Institution and Study

	S1512	S1801	S2000	S2015	EA6134	EA6141	EA6174	EA6192
Northwestern U LAPS	1	13	-	-	-	-	-	2
Ohio State U CCC LAPS	6	13	-	-	4	-	3	1
Pacific Ca Res Consort NCORP	-	3	-	-	-	-	-	-
SCL Hlth Saint Joseph Hospital	-	-	-	-	-	-	1	-
Southeast Clin Onc Res Consort NCORP	1	-	-	-	-	-	-	-
Sutter Ca Res Consort	-	-	-	-	2	5	1	-
The Don and Sybil Harrington CC	-	3	-	-	-	-	-	-
UC Irvine Hlth/Chao Family CCC	-	3	-	-	-	2	7	-
UCLA / Jonsson CCC	4	6	-	-	7	-	-	-
USC Norris CCC LAPS	5	8	-	-	-	-	2	-
U Alabama Birm/Deep South RC LAPS	-	1	-	-	-	-	-	-
U Arkansas for Medical Sciences	-	-	-	-	3	-	-	-
U Cincinnati CC-UC Med Ctr	-	-	-	-	-	2	3	-
U Colorado CC LAPS	-	-	-	-	1	-	-	-
U Kansas CC - MCA Rural MU NCORP	2	8	-	-	2	-	-	-
U Kentucky/Markey CC	-	4	-	-	-	-	-	-
U Michigan CCC LAPS	-	15	1	-	-	-	-	-
U Rochester LAPS	-	4	-	-	2	-	1	-
U Texas Hlth Science Ctr at San Antonio	-	-	-	-	-	1	-	-
U Texas MD Anderson CC LAPS	-	10	-	-	-	-	-	-
U Utah - Huntsman Ca Inst LAPS	10	20	-	-	-	-	6	-
Wayne State U - Karmanos Ca Inst LAPS	-	-	-	-	2	-	-	-
Western States Ca Res NCORP	-	-	-	-	-	1	-	-
Wisconsin NCORP	-	9	-	-	-	-	-	-
Yale U - Yale CC LAPS	-	-	-	-	-	6	-	-
ALLIANCE	1	32	1	-	-	-	-	-
ECOG-ACRIN	2	50	3	-	-	-	-	-
NRG	4	47	1	-	-	-	-	-
<b>Total</b>	<b>57</b>	<b>345</b>	<b>12</b>	<b>8</b>	<b>54</b>	<b>46</b>	<b>42</b>	<b>3</b>