Leadership

Co-Chairs: Michael J. Fisch, MD, MPH Norah Lynn Henry, MD, PhD

Time/Location

Thursday, October 20, 2022 1:30 pm - 3:30 pm Room: Regency A (Ballroom Level, West Tower)

Agenda

- The Translational Spectrum in Symptom Control: From Measurement Science to Biological Correlates
- Patient-Reported Outcomes What is a Meaningful Change? Plenary speaker: Salene Jones, PhD
- Opportunities and Challenges as a Translational Symptom Scientist at SWOG

Plenary speaker: Daniel Hertz, PhD

Active Studies

- S1600, "A Randomized Phase III Double-Blind Clinical Trial Evaluating the Effect of Immune-Enhancing Nutrition on Radical Cystectomy Outcomes (SIMmune)." Drs. Hamilton-Reeves, Holzbeierlein, Kukreja, et al. Activated: 2/21/19; Temporarily closed: 8/9/22.
- <u>S1614</u>, "A Phase III Randomized Trial of Prophylactic Antiviral Therapy in Patients with Current or Past Hepatitis B Virus (HBV) Infection Receiving Anti-Cancer Therapy for Solid Tumors." Drs. Hwang, Lok, Gehring, et al. Activated: 2/21/19.
- <u>S2013</u>, "Immune Checkpoint Inhibitor Toxicity (I-CHECKIT): A Prospective Observational Study." Drs. Gunturu, Hershman, Kuderer, et al. Activated: 8/16/21.

Other Concepts in Development (Soon to activate)

- S2010, "A Randomized Phase III Trial Comparing Active Symptom Monitoring Plus Patient Education Versus Patient Education Alone to Improve Persistence with Endocrine Therapy in Young Women with Stage I-III Breast Cancer (ASPEN)." Drs. Henry, Hershman, and Skaar.
- <u>S2205</u>, "ICE COMPRESS: Randomized Trial of Limb Cryocompression Versus Continuous Compression Versus Low Cyclic Compression for the Prevention of Taxane-Induced Peripheral Neuropathy." Drs. Accordino, Pennington, Hershman, et al.

Closed Studies

- <u>\$1714</u>, "A Prospective Observational Cohort Study To Develop A Predictive Model Of Taxane-Induced Peripheral Neuropathy In Cancer Patients"-Drs. Trivedi, Hershman, Brannagan, et al. Activated 3/1/19.
- <u>S0702</u>, "A Prospective Observational Multicenter Cohort Study to Assess the Incidence of Osteonecrosis of the Jaw (ONJ) in Cancer Patients with Bone Metastases Starting Zoledronic Acid Treatment." Dr. Van Poznak and Dr. Gralow M.D. Activated 12/15/2008. Closed to Accrual 06/01/19.
- <u>S1200</u>, "Randomized Blinded Sham- and Waitlist-Controlled Trial of Acupuncture for Joint Symptoms Related to Aromatase Inhibitors in Women with Early Stage Breast Cancer." Drs. Hershman and Crew. Activated: 3/27/12. Closed: 2/15/17.

Committee Business

- 1. What is happening with our open studies?
- 2. What other studies are we planning?
- 3. What other updates should we know about?
 - Patient Advocate update
 - Statistical Center update

Other SWOG Studies with Symptom Control and QOL Component

Breast

<u>S1706</u>, "A Phase II Randomized, Double-Blinded, Placebo-Controlled Trial of Olaparib Administered Concurrently with Radiotherapy for Inflammatory Breast Cancer." Dr. Jagsi. Activated: 9/12/18.

Cancer Care Delivery

- 51703, "Randomized Non-Inferiority Trial Comparing Overall Survival of Patients Monitored with Serum Tumor Marker Directed Disease Monitoring (Stmddm) Versus Usual Care in Patients with Metastatic Hormone Receptor Positive Her-2 Negative Breast Cancer." Drs. Accordino, Hershman, and Ramsey. Activated: 7/16/18.
- <u>S1912CD</u>, "A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)." Drs. Shankaran, Carlos, Hershman, et al. Activated: 7/26/21.



<u>S2108CD</u>, "A Cluster Randomized Trial Comparing an Educationally Enhanced Genomic Tumor Board (EGTB) Intervention to Usual Practice to Increase Evidence-Based Genome-Informed Therapy." Drs. Reuter, Trivedi, Symington, et al. Activated: 8/22/22.

GU

- <u>S1802</u>, "Phase III Randomized Trial of Standard Systemic Therapy (SST) Versus Standard Systemic Therapy Plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer." Dr. Chapin. Activated: 9/17/18.
- <u>**S1806</u>**, "Phase III Randomized Trial of Concurrent Chemoradiotherapy with or Without Atezolizumab in Localized Muscle Invasive Bladder Cancer." Dr. Singh. Activated: 4/19/18.</u>

Leukemia

<u>S1925</u>, "Randomized, Phase III Study of Early Intervention with Venetoclax and Obinutuzumab Versus Delayed Therapy with Venetoclax and Obinutuzumab in Newly Diagnosed Asymptomatic High-Risk Patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL): EVOLVE CLL/SLL Study." Drs. Stephens, Hill, Pagel, et. al. Activated: 12/14/20.

Lung

- <u>\$1914</u>, "A Randomized Phase III Trial of Induction/Consolidation Atezolizumab (NSC#783608) + SBRT Versus SBRT Alone in High Risk, Early Stage NSCLC." Drs. Daly, Simone, Kelly, et al. Activated: 3/25/20.
- <u>S1827</u>, "MRI Brain Surveillance Alone Versus MRI Surveillance and Prophylactic Cranial Irradiation (PCI): A Randomized Phase III Trial in Small-Cell Lung Cancer (MAVERICK)." Drs. Rusthoven, Brown, Wefel, et al. Activated: 1/10/20.

Lymphoma

- S1826, "A Phase III, Randomized Study of Nivolumab (Opdivo) Plus AVD or Brentuximab Vedotin (Adcetris) Plus AVD in Patients (Age >/= 12 Years) with Newly Diagnosed Advanced Stage Classical Hodgkin Lymphoma." Drs. Herrera, Friedberg. Activated: 7/19/19.
- S1918, "A Phase II/III Randomized Study of R-miniCHOP with or without Oral Azacitidine (CC-486) in Participants Age 75 Years or Older with Newly Diagnosed Diffuse Large B Cell Lymphoma, Grade IIIb Follicular Lymphoma, Transformed Lymphoma, and High-Grade B-cell Lymphomas with MYC and BCL2 and/or BCL6 Rearrangements." Drs. Brem, Smith, Henry, et al. Activated: 3/19/21.

Myeloma

<u>S1803</u>, "Phase III Study of Daratumumab/rHuPH20 (NSC- 810307) + Lenalidomide or Lenalidomide as Post-Autologous Stem Cell Transplant Maintenance Therapy in Patients with Multiple Myeloma (MM) Using Minimal Residual Disease to Direct Therapy Duration (DRAMMATIC Study)." Drs. Krishnan, Chhabra, and Callander. Activated: 6/27/19.

Prevention and Epidemiology

- **S0820**, "A Double-Blind Placebo-Controlled Trial of Eflornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon or Rectal Cancer, Phase III – Preventing Adenomas of the Colon with Eflornithine and Sulindac (PACES)." Drs. Zell, Brown, Lance, et al. Activated: 3/1/13.
- <u>S1904</u>, "Cluster Randomized Controlled Trial of Patient and Provider Decision Support To Increase Chemoprevention Informed Choice Among Women with Atypical Hyperplasia or Lobular Carcinoma in Situ -Making Informed Choices on Incorporating Chemoprevention into Care (MiCHOICE)." Drs. Crew, Kukafka, Hershman, et al. Activated: 9/1/20.

NCTN Studies

CTSU/NRG-GI004, "Colorectal Cancer Metastatic dMMR Immunotherapy (COMMIT) Study: A Randomized Phase III Study of mFOLFOX6/ Bevacizumab Combination Chemotherapy with or Without Atezolizumab or Atezolizumab Monotherapy in the First Line Treatment of Patients with Deficient DNA Mismatch Repair (dMMR) Metastatic Colorectal Cancer." Dr. Overman. Activated: 11/7/17; Temporarily closed: 6/4/20; Reactivated: 1/29/21.



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

	51600	S1614	51714	52013	A221505	A221602	A221702	A221805	A222004	EAQ202	EAZ171
Ascension Prov Hospitals - Southfield	-	-	-	7	-	-	-	-	-	-	-
Ascension Via Christi Hospitals Wichita	-	-	1	-	-	-	-	-	-	-	-
CWRU Case CCC LAPS	-	-	-	-	3	-	1	-	-	-	-
Ca Res Consortium of West Mich NCORP	-	-	146	-	-	-	-	-	-	-	-
Ca Res for the Ozarks NCORP	-	-	10	1	-	-	-	-	-	-	-
Ca Res of Wisconsin and N Mich Consort	-	-	-	26	-	-	-	-	-	-	-
Carle CC NCORP	-	-	б	3	-	-	-	-	-	-	-
City of Hope CCC	4	-	-	-	-	-	-	-	-	-	-
Columbia University MU NCORP	-	-	27	8	-	3	-	-	-	-	-
Columbus NCORP	-	-	-	7	-	-	-	-	-	-	-
CommonSpirit Hlth Res Inst	-	-	71	б	-	-	-	-	-	-	-
Dayton NCORP	-	-	-	-	-	1	-	1	-	-	-
Desert Regional Med Ctr	-	-	3	-	-	3	-	-	-	-	-
Fred Hutchinson Ca Res Ctr LAPS	10	-	-	-	-	-	-	-	-	-	-
Georgia NCORP	-	-	18	12	-	-	-	-	-	-	-
Grupo Onc Cooperativo de Invest	-	-	10	-	-	-	-	-	-	-	-
Gulf South MU NCORP	1	-	26	7	1	-	-	-	-	-	1
Hawaii MU NCORP	-	-	70	-	-	-	-	-	-	-	-
Heartland Ca Res NCORP	-	-	38	54	-	-	-	-	-	-	-
Henry Ford Hospital	7	-	-	-	-	-	-	-	-	-	-
Instituto Nacional De Cancerologia	-	-	10	-	-	-	-	-	-	-	-
Instituto Nacional De Cancerologia de Mexico	-	-	60	-	-	-	-	-	-	-	-
Kaiser Permanente NCORP	-	2	65	1	-	-	-	-	-	-	-
Lahey Hospital and Med Ctr	-	-	22	19	-	-	-	-	-	-	-
Loyola University Med Ctr	-	-	2	-	-	-	-	-	-	-	-
Massachusetts Vet Epi Res & Info Ctr	-	-	-	4	-	-	-	-	-	-	-



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

	51600	51614	51714	52013	A221505	A221602	A221702	A221805	A222004	EAQ202	EAZ171
Medical U South Carolina MU NCORP	-	-	-	-	-	-	-	-	-	-	2
Montana Cancer Consortium NCORP	-	-	-	2	-	-	-	-	-	-	-
NCORP Carolinas (Prisma Hlth NCORP)	-	-	30	-	-	-	-	-	-	29	-
Nevada Ca Res Foundation NCORP	-	-	-	-	-	-	-	-	-	3	-
Northwell Health NCORP	-	-	-	-	2	3	-	-	-	-	-
Oregon Health & Science U	-	-	-	10	-	-	-	-	-	-	-
Pacific Ca Res Consortium NCORP	-	-	2	-	-	-	-	-	-	-	-
Southeast Clin Onc Res Consort NCORP	-	-	278	36	-	-	-	-	-	-	-
The West Clinic - Wolf River	-	-	-	-	б	-	-	-	-	-	-
Tulane U Hlth Sciences Ctr	-	-	1	-	-	-	-	-	-	-	-
UC Irvine Hlth/Chao Family CCC	-	-	-	-	1	4	-	-	-	-	-
USC Norris CCC LAPS	59	-	-	-	-	-	-	-	-	-	-
U Arkansas for Medical Sciences	-	-	68	5	-	-	-	-	-	-	-
U Colorado CC LAPS	б	-	2	-	16	-	1	2	-	-	-
U Kansas CC - MCA Rural MU NCORP	37	-	24	-	-	-	-	2	-	-	-
U Kentucky/Markey CC	-	-	-	-	-	10	-	-	-	-	-
U Rochester LAPS	10	-	-	-	-	-	14	-	-	-	-
U Texas Hlth Science Ctr San Antonio	-	-	14	5	-	-	-	-	-	-	-
U Texas MD Anderson CC LAPS	-	1	-	-	-	-	-	-	-	-	-
U Utah - Huntsman Ca Inst LAPS	-	-	-	-	-	8	-	-	2	-	-
Upstate Carolina Consortium NCORP	-	-	118	-	1	-	-	-	-	-	-
Wayne State U - Karmanos Ca Inst LAPS	-	-	-	-	-	-	1	-	-	-	-
Wisconsin NCORP	-	-	-	5	-	-	-	-	-	-	-
ALLIANCE	5	-	44	39	-	-	-	-	-	-	-
ECOG-ACRIN	-	-	80	23	-	-	-	-	-	-	-
NRG	1	1	90	28	-	-	-	-	-	-	-
Total	140	4	1,336	308	30	32	17	5	2	32	3

