### Leadership

Chair:	Jonathan W. Friedberg, MD
Vice-Chair:	Sonali M. Smith, MD
Executive Officer:	Susan M. O'Brien, MD
Statisticians:	Michael LeBlanc, PhD
	Hongli Li, MS
	Shay Bellasea, MS

### **Scientific Leadership**

Translational Medicine:	Alexey Danilov, MD, PhD
Radiation Oncology:	Louis S. Constine, MD
Imaging:	Lawrence H. Schwartz, MD
Immunotherapeutics:	Sweetha Kambhampati, MD
Pathology:	Joo Y. Song, MD
Early Therapeutics:	Nasheed Mohammad Hossain, MD

### **Designates**

Cancer Control:	Hayder Saeed, MD
Digital Engagement:	Mazyar Shadman, MD
Veterans Affairs:	Helen Ma, MD
Data Coordinators:	Alex Rangel, BS
	Gabi Herbert, MS, BS
	Laura Wells, BA
Oncology Research Professionals:	
CRA:	Erin M. Cebula, MPH
Nurse:	TBD
Patient Advocate:	Hildy Dillon, MPH
Pharmaceutical Science:	Holly O. Chan, PharmD
	Martina Fraga, PharmD
Protocol Project Manager:	Katarina Gasic

#### Time/Location

Friday, October 13, 2023 8:30 a.m. - 10:30 a.m. Room: Crystal A (Lobby Level, West Tower)

### **Agenda**

Clinical Trials Program Manager: . . . . . . . . . . . . Crystal Miwa

Welcome and Introductions: Jonathan Friedberg, MD & Sonali Smith, MD

Spotlight on Relapsed DLBCL:

a.	New biologic observations	Dr. Hilton
b.	Current treatment landscape	Dr. Reagan
c.	S2207	Dr. Amengual

#### Review of Selected Studies:

a.	S2114	Dr. Hess
b.	S1918	Dr. Brem
C.	S1608	Dr. Barr
d.	S1925	Dr. Stephens
e.	EA4151	Dr. Till
f.	AHOD2131	Dr. Hu
g.	AO51902	Dr. Amengual
h.	ANHL1931	Dr. Kamdar

## **Proposed Studies**

**52308**, "Randomized Phase III Study of Mosunetuzumab vs. Rituximab for Low Tumor Burden Follicular Lymphoma." Drs. Ghosh and Friedberg.

#### **Active Studies**

**S1608**, "Randomized Phase II Trial in Early Relapsing or Refractory Follicular Lymphoma." Drs. Barr and Burack. Activated: 8/10/17.

**S1918**, "A Phase II/III Randomized Study of R-miniCHOP With or Without CC-486 (Oral Azacytidine) 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 and Smith. Activated: 3/19/21.

**52114**, "A Randomized Phase II Trial of Consolidation Therapy Following CD19 CAR T-Cell Treatment for Relapsed/Refractory Diffuse Large B-cell Lymphoma or Grade IIIB Follicular Lymphoma." Drs. Hess and Hossain. Activated: 2/23/2023.

**52207**, "Randomized phase II study of the addition of Targeted therapeutic agents to tafasitamab-based therapy in non-transplant-eligible patients with Relapsed/refractory Large B-cell Lymphoma." Drs. Amen-gual, Reagan, and Smith. Activated: 6/30/2023

CTSU/A051701, "Randomized Phase II/III Study of Venetoclax (ABT199)
Plus Chemoimmunotherapy for MYC/BCL2 Double-Hit and Double
Expressing Lymphomas." Dr. Abramson. SWOG Champion: Dr.
Vallurupalli. Activated: 8/7/19. Temporarily closed: 8/2/21.

CTSU/EA4151, "A Randomized Phase III Trial of Consolidation with Autologous Hematopoietic Cell Transplantation Followed by Maintenance Rituximab vs. Maintenance Rituximab Alone for Patients with Mantle Cell Lymphoma in Minimal Residual Disease-Negative First Complete Remission." Dr. Fenske. SWOG Champion: Dr. Till. Activated: 8/29/17.



CTSU/ANHL1931, "A Randomized Phase 3 trial of Nivolumab (NSC# 748726 IND# 125462) in Combination with Chemo-immunotherapy for the Treatment of Newly Diagnosed Primary Mediastinal B-cell Lymphoma." Dr. Roth. SWOG Champion: Dr. Kamdar. Activated 6/7/2021.

CTSU/A051902, "A Randomized Phase II Study of CHO(E)P vs Oral Azacitidine-CHO(E)P vs Duvelisib-CHO(E)P in Previously Untreated CD30 Negative Peripheral T-cell Lymphomas." Dr. Mehta-Shah. SWOG Champion: Dr. Amengual. Activated 7/30/2021.

### **Closed Studies**

CTSU/EA4181, "A Randomized 3-Arm Phase II Study Comparing 1.)
Bendamustine, Rituximab and High Dose Cytarabine (BR/CR) 2.)
Bendamustine, Rituximab, High Dose Cytarabine and Acalabrutinib (BR/CA-A), and 3.) Bendamustine, Rituximab and Acalabrutinib (BR-A) in Patients </= 70 years Old with Untreated Mantle Cell Lymphoma." Dr. Wagner-Johnson. SWOG Champion: Dr. Spurgeon. Activated: 10/3/19. Closed: 4/7/2023

### **Open Leukemia Studies**

<u>\$1925</u>, "A Randomized, Phase III Study of Early Intervention with Venetoclax and Obinutuzumab versus Delayed Therapy with Venetoclax and Obinutuzumab in Newly Diagnosed Asymptomatic High-Risk Pa-tients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL): EVOLVE CLL/SLL Study." Dr. Stephens. Activated: 12/14/20.

S1905, "A Phase I/II Study of AKR1C3-Activated Prodrug OBI-3424 (OBI-3424) in Patients with Re-lapsed/Refractory T-Cell Acute Lymphoblastic Leukemia (T-ALL)/T-Cell Lymphoblastic Lymphoma (T-LBL)." Drs. Advani and Papadantonakis. Activated: 8/17/20. Temporarily closed: 12/23/2022.

### **Open Cancer Care Delivery Study**

**S1912CD**, "A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)." Dr. Shankaran. Activated 7/26/2021.



## Accrual from trial opening through 6/30/2023 by Institution and Study

	<i>\$1608</i>	S1826	S1918	S2114	A051301	ANHL1931	E4412	EA4151	EA4181
Ascension Providence Hospitals - Southfield	-	5	-	-	-	-	-	-	-
Banner University Medical Center - Tucson	2	-	-	-	1	-	-	1	2
Baptist Memorial Health Care/Mid South Minority Underserved	-	3	-	-	-	-	-	-	-
Baylor College of Medicine/Duncan Comprehensive Cancer Center	-	-	-	-	1	-	-	-	-
Boston Medical Center	-	3	-	-	-	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	-	-	-	-	-	-	15	14
Cancer Research Consortium of West Michigan NCORP	3	13	-	-	-	-	-	-	-
Cancer Research for the Ozarks NCORP	1	5	-	-	-	-	-	-	-
Cancer Research of Wisconsin and Northern Michigan Consortium	-	2	-	-	-	-	-	-	-
Carle Cancer Center NCI Community Oncology Research Program	1	3	-	-	-	-	-	-	-
City of Hope Comprehensive Cancer Center	8	21	2	-	1	5	-	18	-
Columbia University Minority Underserved NCORP	-	2	2	-	-	-	1	-	-
Columbus NCI Community Oncology Research Program	1	2	-	-	-	-	-	-	-
CommonSpirit Health Research Institute	-	4	-	-	-	-	-	-	-
Essentia Health NCI Community Oncology Research Program	-	3	-	-	-	-	-	-	-
Fred Hutchinson Cancer Research Center LAPS	-	-	-	-	-	-	-	14	-
Georgia Cares Minority Underserved NCORP	-	6	2	-	-	-	-	-	-
Gulf South Minority Underserved NCORP	-	-	2	-	-	-	-	-	-
Hawaii Minority Underserved NCORP	-	-	1	-	-	-	-	-	-
Heartland Cancer Research NCORP	1	20	-	-	-	-	-	-	-
Henry Ford Hospital	-	8	-	-	-	-	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	2	11	2	-	-	-	11	-	13
King Faisal Specialist Hospital and Research Centre	-	-	-	-	4	-	-	-	-
Loyola University Medical Center	-	8	-	-	-	-	-	3	-
Medical University of South Carolina Minority Underserved NCORP	2	19	3	4	-	-	-	2	-
Michigan Cancer Research Consortium NCORP	1	6	4	-	-	-	-	-	-
Moffitt Cancer Center	-	15	-	-	-	-	-	-	-
Montana Cancer Consortium NCORP	-	8	-	-	-	-	-	-	-
NCORP of the Carolinas (Prisma Health NCORP)	-	11	-	-	-	-	-	2	-



## Accrual from trial opening through 6/30/2023 by Institution and Study

	S1608	S1826	S1918	S2114	A051301	ANHL1931	E4412	EA4151	EA4181
Nevada Cancer Research Foundation NCORP	-	2	-	-	-	-	1	-	-
Northwestern University LAPS	1	-	-	-	-	1	-	-	-
Oregon Health and Science University	-	4	-	-	-	-	-	6	5
Pacific Cancer Research Consortium NCORP	-	7	-	1	-	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	-	6	-	-	-	-	-	-	-
UC Davis Comprehensive Cancer Center LAPS	-	18	-	-	-	-	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	4	1	-	-	1	-	-	-
UC San Diego Moores Cancer Center	-	8	-	-	-	-	-	1	-
U of Alabama at Birm/Deep South Res Consort LAPS	-	12	-	-	-	-	7	5	-
University of Arkansas for Medical Sciences	-	1	-	-	-	-	-	-	-
University of Cincinnati Cancer Center-UC Medical Center	-	9	-	-	-	-	-	2	3
University of Colorado Cancer Center LAPS	-	4	-	-	1	-	-	-	-
University of Kansas Cancer Center - MCA Rural MU NCORP	-	-	-	-	-	-	-	-	1
University of Kentucky/Markey Cancer Center	-	2	-	-	-	-	-	1	-
University of Mississippi Medical Center	-	1	-	-	-	-	-	-	-
University of Rochester LAPS	14	33	-	1	3	3	-	10	17
University of Texas Health Science Center at San Antonio	-	17	-	-	-	-	-	12	-
University of Texas MD Anderson Cancer Center LAPS	3	34	-	-	-	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	1	14	2	-	-	-	-	18	12
Upstate Carolina Consortium Community Oncology Research Progra	m 1	7	-	-	-	-	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	-	4	-	-	1	-	-	1	6
Wisconsin NCI Community Oncology Research Program	-	11	-	-	-	-	-	-	-
Yale University - Yale Cancer Center LAPS	-	7	-	-	-	-	-	4	-
ALLIANCE	15	134	24	-	-	-	-	-	-
CCTG	-	30	-	-	-	-	-	-	-
COG	-	313	-	-	-	-	-	-	-
ECOG-ACRIN	5	83	10	-	-	-	-	-	-
NRG	11	51	3	-	-	-	-	-	-
Total	73	994	58	6	12	10	20	115	73

