

Gastrointestinal Committee

Leadership

Chair: Philip A. Philip, MD, PhD, FRCP
 Vice-Chair: Elena G. Chiorean, MD
 Executive Officer: Christopher W. Ryan, MD
 Statisticians: Katherine A. Guthrie, PhD
 Sarah Colby, MS

Scientific Leadership

Phase I Studies: Sandip P. Patel, MD
 Gastroesophageal: Syma Iqbal, MD
 Zev A. Wainberg, MD
 Pancreatic: Elena Gabriela Chiorean, MD
 Andrew M. Lowy, MD (Surgical representative)
 Hepatobiliary: Anthony B. El-Khoueiry, MD
 Rachna T. Shroff, MD
 Syed Ahmad, MD (Surgical representative)
 Colon: Philip J. Gold, MD
 Wells A. Messersmith, MD
 Neuroendocrine Tumors: Nageshwara Arvind Dasari, MD
 Jonathan R. Strosberg, MD
 Ano-Rectal: Lisa A. Kachnic, MD
 Hagen F. Kennecke, MD
 Translational Medicine: Heinz-Josef Lenz, MD
 Christopher H. Lieu, MD
 Daniel Catenacci, MD
 Imaging: Anthony F. Shields, MD, PhD
 Pathology: Mary Kay Washington, MD, PhD
 Radiation Oncology: Lisa A. Kachnic, MD
 Surgery: Stephen W. Behrman, MD

Designates

Cancer Control Liaisons: Jason A. Zell, DO (Prevention)
 Afsaneh Barzi, MD (CCD)
 Community Liaisons: Gary L. Buchsacher, MD, PhD (Med Oncology)
 Mohamed E. Salem, MD (Med Oncology)
 Jeremiah Lee Deneve, DO (Surgical)
 Flavio Rocha, MD (Surgical)
 David Horowitz, MD (Radiation Oncology)
 Chan Shen, PhD, MS (Health Outcomes)
 Mark A. O'Rourke, MD (Palliative Care)
 DEI Champion: Colmar Figueroa-Moseley, PhD, MPH
 Digital Engagement: Heloisa Soares, MD, PhD
 Data Coordinators: Christine Wagner
 Brian Zeller
 Ojasvi Mittal

Oncology Research Professionals:

CRA: Michelle A. Springer, BA
 Nurse: TBD
 Patient Advocate (Pancreatic): Carole Seigel, MBA
 Patient Advocate (Colon): Florence Kurttila, MS
 Pharmaceutical Science: Jane E. Rogers, PharmD
 Protocol Project Manager: Christy Klepetko
 Clinical Trials Program Manager: TBD

Time/Location

Friday, October 21, 2022 4:00 pm - 6:00 pm

Room: Regency B (Ballroom Level, West Tower)

Agenda

1. Welcome
2. Announcements & Introductions Philip Philip / Gabriella Chiorean
3. GI Committee DEI initiatives Rachel Safyan
Colmar Figueroa- Moseley
4. SWOG led trials (15 min)
 - a. S2104 Heloisa Soares/Syed Ahmed
 - b. S2107 Van Morris/ Steve Kopetz
 - c. S2001 Vincent Chung
 - d. S1992 Michael Overman
 - e. S0802 Jason Zell
5. CTEP ctDNA working group update Philip Philip
6. Select NCTN Studies and new approvals
 - a. EA2183 mGE cancers oligomet Paul Oberstein
 - b. EA2186 GIANT pancreatic David Zhen
 - c. A021602 NET cabo vs placebo Arvind Dasari
 - d. NRG GI-004 MSI-High 1L mCRC Michael Overman
 - e. EA2201 MSI-High rectal May Cho
7. Gastroesophageal Cancers (12 min) Syma Iqbal, Zev Wainberg
 - a. Highlights of major recent clinical trials
 - b. Ongoing NCTN studies
 - c. Future plans
8. Hepatobiliary (12 min) Anthony El-Khoueiry
Rachna Shroff
 - a. Highlights of major recent clinical trials

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- b. Ongoing NCTN studies
 - c. Future plans
9. Pancreatic (12 min) Andrew Lowy, Davendra Sohal
- a. Highlights of major recent clinical trials
 - b. Ongoing NCTN studies
 - c. Future plans
10. Colon (12 min) Marwan Fakih, Philip Gold, Sepideh Gholami
- a. Highlights of major recent clinical trials
 - b. Ongoing NCTN studies
 - c. Future plans
11. Anal and Rectal (12 min) Lisa Kachnic, Hagen Kennecke
- a. Highlights of major recent clinical trials
 - b. Ongoing NCTN studies
 - c. Future plans
12. Neuroendocrine (12 min) Jon Strosberg, Arvind Dasari
- a. Highlights of major recent clinical trials
 - b. Ongoing NCTN studies
 - c. Future plans
13. Adjourn

Gastroesophageal

Proposed Studies

S2303, "Phase II/III Trial of Nivolumab + Cabozantinib or Nivolumab + Paclitaxel + Ramucirumab versus Paclitaxel + Ramucirumab in Patients with PD-L1 CPS \geq 5 Advanced Gastric and Esophageal Adenocarcinoma." Dr. Saeed.

Active Studies

CTSU/EA2174, "A Phase II/III Study of Peri-Operative Nivolumab and Ipilimumab in Patients with Locoregional Esophageal and Gastroesophageal Junction Adenocarcinoma." Dr. Kelly. Activated: 1/17/19.

CTSU/EA2183, "A Phase III Study of Consolidative Radiotherapy in Patients with Oligometastatic HER2 Negative Esophageal and Gastric Adenocarcinoma (EGA)." Dr. Horowitz. Activated: 2/6/2020. Temporarily closed: 06/15/21.

Pancreatic

Active Studies

S2001, "Randomized Phase II Clinical Trial of Olaparib + Pembrolizumab

Alone as Maintenance Therapy in Metastatic Pancreatic Cancer Patients with Germline BRCA1 or BRCA2 Mutations." Dr. Chung. Activated: 12/4/20.

CTSU/A021804, "A Prospective, Multi-Institutional Phase II Trial Evaluating Temozolomide vs. Temozolomide and Olaparib for Advanced Pheochromocytoma and Paraganglioma." Dr. C. Lopez. Activated: 11/2/20.

CTSU/A021806, "A Phase III Trial of Perioperative Versus Adjuvant Chemotherapy for Resectable Pancreatic Cancer." Dr. Noel. Activated: 7/1/20.

CTSU/EA2186, "A Randomized Phase II Study of Gemcitabine and Nab-Paclitaxel Compared with 5-Fluorouracil, Leucovorin, and Liposomal Irinotecan in Older Patients with Treatment Naïve Metastatic Pancreatic Cancer (GIANT)." Dr. Zhen. Activated: 6/18/20.

CTSU/EA2192, "APOLLO: A Randomized Phase II Double-Blind Study of Olaparib Versus Placebo Following Adjuvant Chemotherapy in Patients with Resected Pancreatic Cancer and a Pathogenic BRCA1, BRCA2 or PALB2 Mutation." Drs. Chiorean and Philip. Activated: 4/29/21.

Proposed Studies

S2211, "Randomized Phase II/III Study of Gemcitabine and nab-paclitaxel with and without CEND-1 for 1st Line Treatment of Metastatic Pancreatic Cancer." Dr. Botta.

Neuroendocrine

Active Studies

S2104, "Randomized Phase II Trial of Postoperative Adjuvant Capecitabine and Temozolomide versus Observation in High-Risk Pancreatic Neuroendocrine Tumors." Dr. Soares. Activated: 10/14/21.

CTSU/A021602, "Randomized Double-Blinded Phase III Study of CABozantinib versus Placebo IN Advanced Neuroendocrine Tumors after Progression on Prior Therapy (CABINET)." Dr. Strosberg. Activated: 7/18/18.

Hepatobiliary

Proposed Studies

S2301, "Phase II Single Arm Study of Tremelimumab and Durvalumab (T300+D) in Advanced Hepatocellular Carcinomas with Child-Pugh-B Cirrhosis (STRIDE in CP-B)." Dr. Arora.

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Active Studies

[CTSUNRG-GI003](#), "A Phase III Randomized Trial of Protons Versus Photons for Hepatocellular Carcinoma." Dr. El-Khoueiry. Activated: 6/21/17.

[CTSUEA2197](#), "Optimal Perioperative Therapy for Incidental Gallbladder Cancer (OPT-IN): A Randomized Phase II/III Trial." Dr. Rocha. Activated: 12/22/20.

[CTSUEA2187](#), "A Phase 2 Study of Pevonedistat in Combination with Carboplatin and Paclitaxel in Advanced Intrahepatic Cholangiocarcinoma." Dr. Stein. Activated: 1/31/20. Temporarily closed: 03/31/21.

Closed Studies

[S1815](#), "A Phase III Randomized Trial of Gemcitabine, Cisplatin, and Nab-Paclitaxel Versus Gemcitabine and Cisplatin in Newly Diagnosed, Advanced Biliary Tract Cancers." Dr. Shroff. Activated: 12/3/18. Permanently Closed: 2/15/21.

Colorectal

Active Studies

[S2107](#), "Randomized Phase II Trial of Encorafenib and Cetuximab with or without Nivolumab for Patients with Microsatellite Stable, BRAFV600E Metastatic Colorectal Cancer." Dr. Morris. Activated: 6/06/22.

[CTSUNRG-GI005](#), "Phase II/III Study of Circulating Tumor DNA as a Predictive Biomarker in Adjuvant Chemotherapy in Patients with Stage IIA Colon Cancer (COBRA)." Dr. Scott. Activated: 12/16/19.

[CTSUA021703](#), "Randomized Double-Blind Phase III Trial of Vitamin D3 Supplementation in Patients with Previously Untreated Metastatic Colorectal Cancer (SOLARIS)." Dr. Cohen. Activated: 9/30/19.

[CTSUA021502](#), "Randomized Trial of Standard Chemotherapy Alone or Combined with Atezolizumab as Adjuvant Therapy for Patients with Stage III Colon Cancer and Deficient DNA Mismatch Repair." Dr. Lieu. Activated: 9/12/17.

[CTSUNRG-GI004](#), "Colorectal Cancer Metastatic dMMR/MSI-H Immunotherapy (COMMIT) Study: A Randomized Phase III Study of mFOLFOX6/Bevacizumab/Atezolizumab Combination versus Single Agent Atezolizumab in the First-Line Treatment of Patients with Deficient DNA Mismatch Repair (dMMR)/Microsatellite Instability-High (MSI-H) Metastatic Colorectal Cancer." Dr. Overman. Activated: 11/7/17.

[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)." Dr. Zell. Activated: 3/1/13.

Closed Studies

[S1613](#), "A Randomized Phase II Study of Trastuzumab and Pertuzumab (TP) Compared to Cetuximab and Irinotecan (CETIRI) in Advanced/Metastatic Colorectal Cancer (MCRC) with HER-2 Amplification." Dr. Raghav. Activated: 10/19/17. Step 1 closed to accrual: 1/1/2022.

Anal

Active Studies

[CTSUEA2176](#), "Randomized Phase III Study of Immune Checkpoint Inhibition with Chemotherapy in Treatment-Naïve Metastatic Anal Cancer Patients." Dr. Morris. Activated: 10/15/20.

[CTSUEA2182](#), "A Randomized Phase II Study of De-Intensified ChemoRadiation for Early-Stage Anal Squamous Cell Carcinoma (DECREASE)." Dr. Murphy. Activated: 11/12/19.

[CTSUEA2201](#), "A Phase II Study of Neoadjuvant Nivolumab Plus Ipilimumab and Short-Course Radiation in MSI-H/dMMR Locally Advanced Rectal Adenocarcinoma." Dr. Cho. Activated 5/13/21.

Other

Active Studies

[S1922](#), "Randomized Phase II Selection Study of Ramucirumab and Paclitaxel Versus FOLFIRI in Refractory Small Bowel Adenocarcinoma." Dr. Overman. Activated: 12/16/19.

[S1609](#), "DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors." Dr. Patel. Activated 1/13/17.

[EAY131](#), "Molecular Analysis for Therapy Choice." Dr. Villalobos. Activated: 8/12/15.

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

	EA2165	EA2174	EA2176	EA2182	EA2186	EA2187	EA2197	NRGG1004	NRGG1005
Ascension Prov Hospitals - Southfield	1	-	-	-	2	-	-	-	1
Ascension Via Christi Hospitals Wichita	-	-	-	-	-	-	-	-	-
Banner U Med Ctr - Tucson	-	-	-	-	-	-	-	-	-
Baptist Mem Hlth Care/Mid South MU NCORP	-	-	-	-	-	-	-	-	2
Baylor Coll Med/Dan L Duncan CCC	-	-	-	-	-	-	-	-	-
Boston Med Ctr	1	-	-	-	-	-	-	-	-
CWRU Case CCC LAPS	-	1	-	1	-	3	-	-	-
Ca Res Consortium West Mich NCORP	-	-	-	-	-	-	-	-	-
Ca Res for the Ozarks NCORP	-	-	-	-	-	-	-	-	-
Ca Res of Wisconsin & N Mich Consort	-	-	-	-	-	-	-	-	-
City of Hope CCC	-	-	-	-	1	-	-	-	-
Columbus NCORP	-	-	-	-	-	-	-	-	-
CommonSpirit Health Research Inst	-	-	-	-	-	-	-	-	-
Dayton NCORP	-	-	-	-	1	-	-	-	-
Fred Hutchinson Ca Res Ctr LAPS	3	-	-	-	-	-	-	-	-
Gulf South MU NCORP	1	-	-	-	-	-	-	-	-
Hawaii MU NCORP	-	-	-	-	2	-	-	-	-
Heartland Ca Res NCORP	-	-	-	-	-	-	-	-	-
Henry Ford Hospital	-	-	-	-	-	-	-	-	1
Houston Methodist Hospital	-	-	-	-	-	-	-	1	-
Kaiser Permanente NCORP	6	-	3	-	-	-	-	-	6
Lahey Hospital & Med Ctr	-	-	-	-	-	-	-	-	-
Loyola U Med Ctr	-	-	-	-	-	-	-	-	-
Michigan Ca Res Consortium NCORP	-	-	-	-	-	-	-	-	-
Moffitt CC	-	-	-	-	-	-	-	-	-
Montana Cancer Consortium NCORP	-	-	-	-	-	-	-	-	-
NCORP Carolinas (Prisma Hlth NCORP)	1	-	-	-	-	-	-	-	-
New Mexico MU NCORP	-	-	-	-	-	-	-	-	-
Northwell Health NCORP	-	-	-	-	1	-	-	-	-
Northwestern U LAPS	-	-	-	-	1	-	-	-	-

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	EA2165	EA2174	EA2176	EA2182	EA2186	EA2187	EA2197	NRGG004	NRGG005
Oregon Health & Science U	4	-	1	1	-	-	1	-	1
Pacific Ca Res Consortium NCORP	-	-	-	-	-	-	-	-	-
SCL Health Saint Joseph Hospital	1	-	-	-	-	-	-	-	-
Southeast Clin Onc Res Consort NCORP	-	-	-	-	-	-	-	-	-
Sutter Ca Res Consortium	2	-	-	-	-	1	-	-	-
The Don and Sybil Harrington CC	-	-	-	-	-	-	-	-	-
The West Clinic - Wolf River	-	-	-	-	-	-	-	-	-
UC Davis CCC LAPS	5	-	-	-	-	-	1	-	1
UC Irvine Health/Chao Family CCC	-	-	1	-	1	-	-	-	1
USC Norris CCC LAPS	-	1	-	-	-	-	-	-	-
U Alabama Birm/Deep South RC LAPS	1	-	-	-	-	-	-	-	-
U Arkansas for Medical Sciences	7	-	-	-	-	-	-	-	-
U Cincinnati CC-UC Med Ctr	1	-	1	-	-	-	-	-	-
U Colorado CC LAPS	-	-	-	-	1	-	-	-	-
U Kansas CC - MCA Rural MU NCORP	-	-	-	-	-	1	-	-	2
U Michigan CCC LAPS	-	-	-	-	-	-	-	-	-
U Rochester LAPS	-	-	-	-	4	2	-	1	-
U Texas HSC at San Antonio	-	-	-	-	2	-	-	-	-
U Texas MD Anderson CC LAPS	-	-	6	-	-	-	-	13	1
U Utah - Huntsman Ca Inst LAPS	-	-	-	-	-	-	-	-	-
Upstate Carolina Consortium NCORP	-	-	-	-	-	-	-	-	-
Vanderbilt U - Ingram CC LAPS	-	-	-	-	-	-	-	-	-
Virginia Mason Med Ctr	-	-	-	-	-	-	-	-	-
Wayne State U - Karmanos Ca Inst LAPS	3	-	-	-	-	-	-	-	-
William Beaumont Hosp-Royal Oak	-	-	-	-	-	-	-	-	-
Wisconsin NCORP	-	-	-	-	-	-	-	-	-
Yale U - Yale CC LAPS	-	-	-	-	-	-	-	-	4
ALLIANCE	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	-	-	-	-	-	-	-	-	-
NRG	-	-	-	-	-	-	-	-	-
Total	37	2	12	2	16	7	2	15	20