

# Gastrointestinal Committee

## Leadership

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

## Scientific Leadership

Gastroesophageal: ..... Syma Iqbal, MD  
 ..... Zev A. Wainberg, MD  
 Pancreatic: ..... Davendra P.S. Sohal, MD  
 ..... Andrew M. Lowy, MD (Surgical representative)  
 Hepatobiliary: ..... Anthony B. El-Khoueiry, MD  
 ..... Rachna T. Shroff, MD  
 ..... Syed A. Ahmad, MD (Surgical representative)  
 Colon: ..... Marwan G. Fakih, MD  
 ..... Philip J. Gold, MD  
 ..... Sepideh Gholami, MD (Surgical representative)  
 Neuroendocrine Tumors: ..... Nageshwara Arvind Dasari, MD  
 ..... Jonathan R. Strosberg, MD  
 Ano-Rectal: ..... Lisa A. Kachnic, MD  
 ..... Hagen F. Kennecke, MD  
 Imaging: ..... Anthony F. Shields, MD, PhD  
 Pathology: ..... Mary Kay Washington, MD, PhD  
 Radiation Oncology: ..... Lisa A. Kachnic, MD  
 Surgery: ..... Stephen W. Behrman, MD  
 ..... Syed A. Ahmad, MD  
 ..... Flavio Rocha, MD  
 Translational Medicine: ..... Christopher lieu, MD (interim)

## Designates

Cancer Control Liaisons: ..... Jason A. Zell, DO (Prevention)  
 ..... Afsaneh Barzi, MD (CCD)  
 Community Liaisons: .. Gary Buchsacher, MD, PhD (Medical Oncology)  
 ..... Mohamed E. Salem, MD (Medical Oncology)  
 ..... Flavio Rocha, MD (Surgical)  
 ..... David Horowitz, MD (Radiation Oncology)  
 ..... Mark A. O'Rourke, MD (Palliative Care)  
 DEI Champion: ..... Colmar Figueroa-Moseley, PhD, MPH  
 ..... Rachael Ann Safyan, MD  
 Digital Engagement: ..... Heloisa Soares, MD, PhD  
 Data Coordinators: ..... Christine Magner  
 ..... 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: ..... Laura Gildner, MS

## Time/Location

Friday, May 12, 2023 4:30 pm - 6:30 pm  
 Room: Grand Ballroom A (Street Level)

## Agenda

1. Welcome
2. Announcements & Introductions  
 Philip Philip  
 E. Gabriella Chiorean
3. GI Committee DEI initiatives  
 Rachel Safyan  
 Colmar Figueroa-Moseley
4. SWOG GI Committee Led trials
  - a. S1922 Michael Overman
  - b. S2001 Vincent Chung
  - c. S2104 Heloisa Soares/Syed Ahmad
  - d. S2107 Van Morris
  - e. S0802 Jason Zell
  - f. S2012 David Zhen
  - E. Gabriella Chiorean
  - Anwaar Saeed/Paul Oberstein
  - g. S2303
5. SWOG GI Committee Co-Led Trials
  - a. A022104 Arvind Dasari
  - b. A022001 Heloisa Soares
  - c. EA2192 Anup Kasi
  - d. NRG-GI004 Michael Overman
  - e. NRG-GI008 Christopher Lieu
6. NCI/CTEP ctDNA working group update Philip Philip
7. Highlighted NCTN Trials
  - a. A021806 Steven Behrman
  - b. EA2176 Van Morris
  - c. NRG-GI005 Aaron Scott
8. Anal and Rectal Hagen Kennecke, Lisa Kachnic
  - a. Highlights of recent clinical trials
  - b. Future plans

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9. Colon  
 Marwan Fakih, Philip Gold,  
 Sepideh Gholami
- a. Highlights of recent clinical trials  
 b. Future plans
10. Gastroesophageal Cancers  
 Syma Iqbal, Zev Wainberg
- a. Highlights of recent clinical trials  
 b. Future plans
11. Hepatobiliary  
 Anthony El-Khoueiry  
 Rachna Shroff
- a. Highlights of recent clinical trials  
 b. Future plans
12. Neuroendocrine  
 Jon Strosberg, Arvind Dasari
- a. Highlights of recent clinical trials  
 b. Future plans
13. Pancreatic  
 Davendra Sohal, Andrew Lowy
- a. Highlights of recent clinical trials  
 b. Future plans
14. 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/A022102, "Randomized Phase III Trial of mFOLFIRINOX +/- Nivolumab vs. FOLFOX +/- Nivolumab for First-Line Treatment of Metastatic HER2-Negative Gastroesophageal Adenocarcinoma." Dr. Oberstein. Activated: 1/17/19.

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: 2/6/20. Temporarily closed: 6/15/21.

## 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.

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.

## 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.

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## Hepatobiliary

### Active Studies

CTSU/NRG-GI003, "A Phase III Randomized Trial of Protons Versus Photons for Hepatocellular Carcinoma." Dr. El-Khoueiry. Activated: 6/21/17.

CTSU/EA2197, "Optimal Perioperative Therapy for Incidental Gallbladder Cancer (OPT-IN): A Randomized Phase II/III Trial." Dr. Rocha. Activated: 12/22/20.

CTSU/EA2187, "A Phase 2 Study of Pevonedistat in Combination with Carboplatin and Paclitaxel in Advanced Intrahepatic Cholangiocarcinoma." Dr. Stein. Activated: 1/31/20. Temporarily closed: 3/31/21.

### 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: 6/6/22.

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## Accrual from trial opening through 12/31/2022 by Institution and Study

	S1613	S1922	S2001	S2104	S2107	A021502	A021602	A021703	A021806
Ascension Providence Hospitals - Southfield	-	-	1	-	-	3	-	-	-
Banner University Medical Center - Tucson	-	-	-	3	-	2	2	-	1
Baptist Memorial Health Care/Mid South Minority Underserved NCORP	-	-	2	-	-	-	-	-	-
Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center	-	-	-	-	-	-	-	1	-
Boston Medical Center	-	-	-	-	-	1	3	-	1
CWRU Case Comprehensive Cancer Center LAPS	-	-	-	-	-	6	-	-	2
City of Hope Comprehensive Cancer Center	-	-	2	-	-	-	1	-	-
Columbia University Minority Underserved NCORP	-	-	1	-	-	-	-	-	-
CommonSpirit Health Research Institute	3	-	-	-	-	-	-	-	-
Dayton NCI Community Oncology Research Program	-	-	-	-	-	3	-	-	-
Fred Hutchinson Cancer Research Center LAPS	-	-	-	-	-	4	-	-	-
Gulf South Minority Underserved NCORP	-	-	-	-	-	-	-	-	-
Hawaii Minority Underserved NCORP	1	-	-	-	-	-	-	-	-
Heartland Cancer Research NCORP	3	-	-	-	2	-	-	-	-
Henry Ford Hospital	-	-	1	-	-	-	-	-	-
Houston Methodist Hospital	-	-	-	-	-	-	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	2	-	-	-	1	16	-	-	-
Lahey Hospital and Medical Center	1	-	-	-	-	-	-	-	-
Loyola University Medical Center	1	-	-	-	-	-	-	-	-
Medical University of South Carolina Minority Underserved NCORP	-	-	-	1	-	-	-	-	-
Michigan Cancer Research Consortium NCORP	1	1	-	-	-	-	-	-	-
Moffitt Cancer Center	-	-	-	-	-	-	4	-	-
NCORP of the Carolinas (Prisma Health NCORP)	-	-	-	-	-	-	-	-	-
Northwell Health NCORP	-	-	-	-	-	-	-	9	1
Northwestern University LAPS	1	1	-	-	-	1	-	8	-
Oregon Health and Science University	-	-	-	-	-	-	-	-	-
Pacific Cancer Research Consortium NCORP	3	-	-	-	-	-	-	-	-
SCL Health Saint Joseph Hospital	-	-	-	-	-	-	-	-	-

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**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.

**CTSU/NRG-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.

**CTSU/A021703**, "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.

**CTSU/A021502**, "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.

**CTSU/NRG-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.

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### Accrual from trial opening through 12/31/2022 by Institution and Study

	S1613	S1922	S2001	S2104	S2107	A021502	A021602	A021703	A021806
Southeast Clinical Oncology Research Consortium NCORP	1	-	2	1	1	-	-	-	-
Sutter Cancer Research Consortium	-	-	-	-	-	3	-	-	-
The Don and Sybil Harrington Cancer Center	-	-	-	-	-	-	-	-	2
UC Davis Comprehensive Cancer Center LAPS	2	-	-	-	-	4	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	-	1	-	-	-	-	-	-
USC Norris Comprehensive Cancer Center LAPS	1	-	-	-	-	2	-	1	-
University of Alabama at Birmingham/Deep South Research Consortium LAPS	-	-	-	-	-	-	-	-	-
University of Arkansas for Medical Sciences	-	-	-	-	-	-	-	-	-
University of Cincinnati Cancer Center-UC Medical Center	-	-	-	-	-	-	-	3	-
University of Colorado Cancer Center LAPS	1	-	1	-	-	6	-	1	-
University of Kansas Cancer Center - MCA Rural MU NCORP	4	-	-	-	-	3	-	1	-
University of Kentucky/Markey Cancer Center	-	-	-	2	-	-	-	-	-
University of Michigan Comprehensive Cancer Center LAPS	1	3	-	-	-	-	2	-	4
University of Rochester LAPS	-	1	-	-	-	2	6	-	4
University of Texas Health Science Center at San Antonio	-	-	-	-	-	-	-	-	3
University of Texas MD Anderson Cancer Center LAPS	13	9	-	-	1	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	-	-	1	1	-	-	-	-	-
University of Wisconsin Carbone Cancer Center	-	-	-	-	-	-	-	-	-
Vanderbilt University - Ingram Cancer Center LAPS	-	-	1	-	-	-	-	-	-
Virginia Mason Medical Center	-	-	-	-	-	4	2	-	-
Wayne State University - Karmanos Cancer Institute LAPS	-	-	1	-	-	2	-	-	-
William Beaumont Hospital-Royal Oak	-	-	-	-	-	1	-	-	-
Wisconsin NCI Community Oncology Research Program	-	-	-	-	1	-	-	-	-
Yale University - Yale Cancer Center LAPS	-	-	-	-	-	3	-	8	-
ALLIANCE	6	8	4	-	2	-	-	-	-
ECOG-ACRIN	4	1	4	-	-	-	-	-	-
NRG	5	2	1	2	-	-	-	-	-
<b>Total</b>	<b>54</b>	<b>26</b>	<b>23</b>	<b>10</b>	<b>8</b>	<b>66</b>	<b>20</b>	<b>32</b>	<b>18</b>

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## 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: 1/1/22.

## Anal

## Active Studies

**CTSU/EA2176**, "Randomized Phase III Study of Immune Checkpoint Inhibition with Chemotherapy in Treatment-Naïve Metastatic Anal Cancer Patients." Dr. Morris. Activated: 10/15/20.

**CTSU/EA2182**, "A Randomized Phase II Study of De-Intensified ChemoRadiation for Early-Stage Anal Squamous Cell Carcinoma (DECREASE)." Dr. Murphy. Activated: 11/12/19.

**CTSU/EA2201**, "A Phase II Study of Neoadjuvant Nivolumab Plus Ipilimumab and Short-Course Radiation in MSI-H/dMMR Locally

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## Accrual from trial opening through 12/31/2022 by Institution and Study

	EA2165	EA2174	EA2176	EA2182	EA2186	EA2187	EA2197	NRGGI004	NRGGI005
Ascension Providence Hosp - Southfield	1	-	1	1	2	-	-	-	3
Banner U Med Ctr - Tucson	-	-	-	-	-	-	-	-	-
Baptist Mem Hlth Care/Mid South MU NCORP	-	-	-	-	-	-	-	-	3
Baylor College of Med/Dan L Duncan CCC	-	-	-	-	-	-	-	-	-
Boston Med Ctr	1	2	-	1	-	-	-	-	-
CWRU Case CCC LAPS	-	2	-	1	-	3	-	-	-
City of Hope CCC	-	-	-	-	1	-	-	-	-
Columbia U MU NCORP	-	-	-	-	-	-	-	-	-
CommonSpirit Hlth Res Inst	-	-	-	-	-	-	-	-	-
Dayton NCORP	-	-	-	-	1	-	-	-	1
Fred Hutchinson Cancer Res Ctr LAPS	3	-	-	-	-	-	-	-	-
Gulf South MU NCORP	1	-	-	-	-	-	-	-	-
Hawaii MU NCORP	-	-	-	-	2	-	-	-	-
Heartland Cancer Res NCORP	-	-	-	-	-	-	-	-	-
Henry Ford Hosp	-	-	-	-	-	-	-	-	1
Houston Methodist Hosp	-	-	-	-	-	-	-	1	-
Kaiser Permanente NCORP	6	-	3	-	-	-	-	-	8
Lahey Hosp and Med Ctr	-	-	-	-	-	-	-	-	-
Loyola U Med Ctr	-	-	-	-	-	-	-	-	-
Med U South Carolina MU NCORP	-	-	-	-	-	-	-	-	-
Michigan Cancer Res Consort NCORP	-	-	-	-	-	-	-	-	1
Moffitt CC	-	-	-	-	-	-	-	-	-
NCORP of the Carolinas (Prisma Hlth NCORP)	1	-	-	-	-	-	-	-	-
Northwell Hlth NCORP	-	1	-	-	2	-	-	-	1
Northwestern U LAPS	-	-	1	-	1	-	-	-	-
Oregon Hlth and Science U	4	-	1	1	-	-	1	-	1
Pacific Cancer Res Consort NCORP	-	-	-	-	-	-	-	-	-
SCL Hlth Saint Joseph Hosp	1	-	-	-	-	-	-	-	-
Southeast Clin Onc Res Consort NCORP	-	-	-	-	-	-	-	-	-

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Advanced Rectal Adenocarcinoma." Dr. Cho. Activated: 5/13/21.

Overman. Activated: 12/16/19.

## Other

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

## Active Studies

S2012, "Randomized Phase II/III Trial of First Line Platinum/Etoposide with or without Atezolizumab in Patients with Poorly Differentiated Extrapulmonary Small Cell Neuroendocrine Carcinomas." Dr. Zhen. Activated: 12/2/21

EAY131, "Molecular Analysis for Therapy Choice." Dr. Villalobos. Activated: 8/12/15.

S1922, "Randomized Phase II Selection Study of Ramucirumab and Paclitaxel Versus FOLFIRI in Refractory Small Bowel Adenocarcinoma." Dr.

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## Accrual from trial opening through 12/31/2022 by Institution and Study

	EA2165	EA2174	EA2176	EA2182	EA2186	EA2187	EA2197	NRGGI004	NRGGI005
Sutter Cancer Res Consort	2	-	-	-	-	1	-	-	-
Don and Sybil Harrington CC	-	-	-	-	-	-	-	-	-
UC Davis CCC LAPS	5	-	-	-	-	-	1	-	1
UC Irvine Hlth/Chao Family CCC	-	-	1	-	2	-	-	-	1
USC Norris CCC LAPS	-	1	-	-	-	-	-	-	-
U Alabama at Birm / Deep South Res Consort LAPS	1	-	-	-	-	-	-	-	-
U Arkansas for Med Sciences	7	-	1	-	-	-	-	-	-
U Cincinnati CC-UC Med Ctr	1	-	1	-	-	-	-	-	-
U Colorado CC LAPS	-	-	-	-	1	-	-	-	-
U Kansas CC - MCA Rural MU NCORP	-	-	-	-	-	1	-	-	2
U Kentucky/Markey CC	-	-	-	-	-	-	-	-	-
U Michigan CCC LAPS	-	-	-	-	-	-	-	-	-
U Rochester LAPS	-	-	-	-	4	2	-	1	-
U Texas Hlth Science Ctr at San Antonio	-	-	-	-	3	-	-	-	-
U Texas MD Anderson CC LAPS	-	-	7	-	-	-	-	12	1
U Utah - Huntsman Cancer Inst LAPS	-	-	-	-	-	-	-	-	-
U Wisconsin Carbone CC	-	-	-	-	-	-	-	1	-
Vanderbilt U - Ingram CC LAPS	-	-	-	-	-	-	-	-	1
Virginia Mason Med Ctr	-	-	-	-	-	-	-	-	-
Wayne State U - Karmanos Cancer Inst LAPS	3	-	-	1	-	-	-	-	-
William Beaumont Hosp-Royal Oak	-	-	-	-	-	-	-	-	-
Wisconsin NCORP	-	-	-	-	-	-	-	-	-
Yale U - Yale CC LAPS	-	-	-	-	-	-	-	-	4
ALLIANCE	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	-	-	-	-	-	-	-	-	-
NRG	-	-	-	-	-	-	-	-	-
<b>Total</b>	<b>37</b>	<b>6</b>	<b>16</b>	<b>5</b>	<b>19</b>	<b>7</b>	<b>2</b>	<b>15</b>	<b>29</b>