

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
 Shay Bellasea, 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 (Medical Oncology)
 Mohamed E. Salem, MD (Medical 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)
 Digital Engagement: Heloisa Soares, MD, PhD
 Data Coordinators: Christine Magner
 Brian Zeller
 Ojasvi Mittal

Oncology Research Professionals:

CRA: Sandy Annis, CCRP
 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: Michelle Maxim

Time/Location

Friday, April 8, 2022 3:00 - 5:00 pm
 Room: Elwha B, Level 5

Agenda

1. Welcome

2. Announcements & Introductions

3. SWOG led trials (15 minutes)

- | | |
|--------------------------|----------------|
| a. S2104 | Soares, Ahmed |
| b. S2107 | Morris, Kopetz |
| c. S2001 | Chung |

4. Select NCTN Studies championed by SWOG (25 minutes)

- | | |
|---|---------|
| a. EA2174 perioperative eso/GEJ | Kelly |
| b. A021806 perioperative PDA | Behrman |
| c. EA2192 adjuvant PDA | Kasi |
| d. EA2176 1st line met anal | Morris |
| e. EA2197 perioperative gallbladder | Rocha |

Gastroesophageal Cancers (12 minutes) Iqbal, Wainberg

- Recent highlights
- Ongoing NCTN studies
- Future plans

Hepatobiliary (12 minutes)

El-Khoueiry, Shroff

- Recent highlights
- Ongoing NCTN studies
- Future plans

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Pancreatic (12 minutes)

Lowy, Sohal

closed: 06/15/21.

- a. Recent highlights
- b. Ongoing NCTN studies
- c. Future plans

Colon (12 minutes)

Fakih, Gold, Gholami

- a. Recent highlights
- b. Ongoing NCTN studies
- c. Future plans

Anal and Rectal (12 minutes)

Kachnic, Kennecke

- a. Recent highlights
- b. Ongoing NCTN studies
- c. Future plans

Neuroendocrine (12 minutes)

Strosberg, Dasari

- a. Recent highlights
- b. Ongoing NCTN studies
- c. Future plans

5. Patient advocates (5 minutes)

6. Other business

7. Adjourn

Gastroesophageal

Proposed Studies

S2214, "A Randomized Phase II Trial of Perioperative Trastuzumab and Atezolizumab given with FLOT or FOLFOX vs. FLOT or FOLFOX alone in Resectable HER2-Overexpressing Gastric/GEJ Adenocarcinoma." Dr. Chao.

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

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

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S2109, "A Phase II Study of Neoadjuvant Nivolumab plus Ipilimumab for Patients with Resectable Hepatocellular Carcinoma." Dr. Kaseb.

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: 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

Proposed 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.

Active Studies

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.

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

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 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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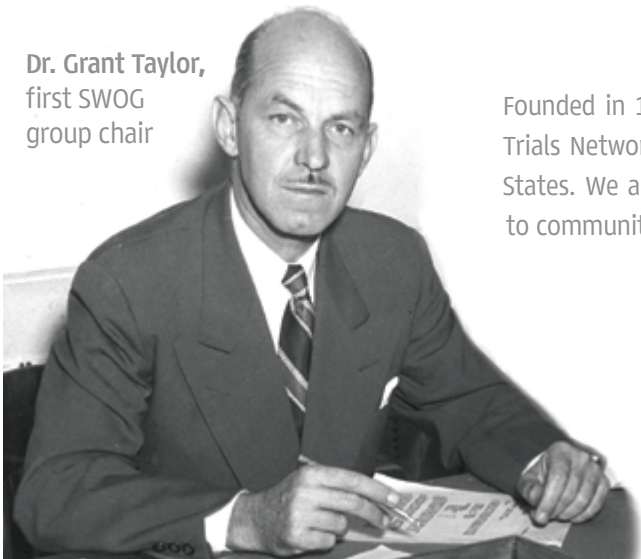
Accrual from trial opening through 12/31/2021 by Institution and Study

	S1613	S1815	S1922	S2001	A021502	A021602	A021703	A021806	EA2142	EA2165
Ascension Prov Hospitals - Southfield	-	-	-	1	2	-	-	-	-	1
Ascension Via Christi Hospitals Wichita	-	1	-	-	-	-	-	-	-	-
Banner U Med Ctr - Tucson	-	13	-	-	2	-	-	1	-	-
Baylor Coll Med/Dan L Duncan CCC	-	6	-	-	-	-	-	-	-	-
Boston Med Ctr	-	-	-	-	1	3	-	1	-	1
CWRU Case CCC LAPS	-	-	-	-	3	-	-	1	-	-
Ca Res Consortium West Mich NCORP	-	2	-	-	-	-	-	-	-	-
Ca Res for the Ozarks NCORP	-	3	-	-	-	-	-	-	-	-
Ca Res of Wisconsin & N Mich Consort	-	2	-	-	-	-	-	-	-	-
City of Hope CCC	-	4	-	1	-	1	-	-	-	-
Columbus NCORP	-	3	-	-	-	-	-	-	-	-
CommonSpirit Health Research Inst	3	4	-	-	-	-	-	-	-	-
Dayton NCORP	-	2	-	-	3	-	-	-	-	-
Fred Hutchinson Ca Res Ctr LAPS	-	-	-	-	3	-	-	-	-	3
Gulf South MU NCORP	-	4	-	-	-	-	-	-	-	1
Hawaii MU NCORP	-	11	-	-	-	-	-	-	-	-
Heartland Ca Res NCORP	3	7	-	-	-	-	-	-	-	-
Henry Ford Hospital	-	2	-	-	-	-	-	-	1	-
Kaiser Permanente NCORP	2	-	-	-	14	-	-	-	2	6
Lahey Hospital & Med Ctr	1	-	-	-	-	-	-	-	-	-
Loyola U Med Ctr	1	-	-	-	-	-	-	-	-	-
Michigan Ca Res Consortium NCORP	1	-	1	-	-	-	-	-	-	-
Moffitt CC	-	-	-	-	-	4	-	-	-	-
Montana Cancer Consortium NCORP	-	4	-	-	-	-	-	-	-	-
NCORP Carolinas (Prisma Hlth NCORP)	-	11	-	-	-	-	-	-	-	1
New Mexico MU NCORP	-	9	-	-	-	-	-	-	-	-
Northwell Health NCORP	-	-	-	-	-	-	6	1	-	-
Northwestern U LAPS	1	17	1	-	-	-	4	-	-	-
Oregon Health & Science U	-	3	-	-	-	-	-	-	-	4

Our History

Founded in 1956 by the National Cancer Institute, we are part of the NCI's National Clinical Trials Network, the largest and oldest publicly funded cancer research network in the United States. We are also part of NCI's Community Oncology Research Program, which connects us to community hospitals and clinics across the nation – and the diverse populations they serve.

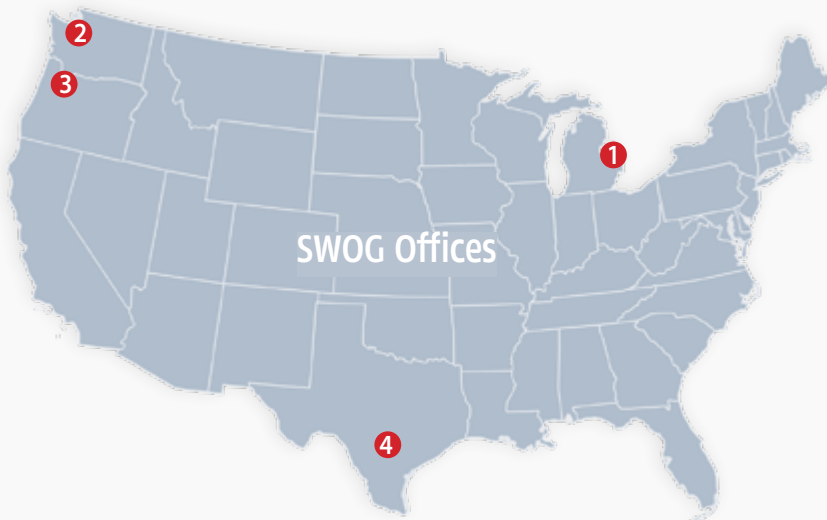
Dr. Grant Taylor,
first SWOG
group chair



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Accrual from trial opening through 12/31/2021 by Institution and Study

	S1613	S1815	S1922	S2001	A021502	A021602	A021703	A021806	EA2142	EA2165
Pacific Ca Res Consortium NCORP	3	9	-	-	-	-	-	-	-	-
SCL Health Saint Joseph Hospital	-	-	-	-	-	-	-	-	-	1
Southeast Clin Onc Res Consort NCORP	1	1	-	1	-	-	-	-	-	-
Sutter Ca Res Consortium	-	-	-	-	3	-	-	-	-	2
West Clinic - Wolf River	-	1	-	-	-	-	-	-	-	-
UC Davis CCC LAPS	2	4	-	-	4	-	-	-	-	5
UC Irvine Health/Chao Family CCC	-	3	-	-	-	-	-	-	-	-
USC Norris CCC LAPS	1	9	-	-	1	-	1	-	-	-
U Alabama Birm/Deep South RC LAPS	-	-	-	-	-	-	-	-	-	1
U Arkansas for Medical Sciences	-	2	-	-	-	-	-	-	-	7
U Cincinnati CC-UC Med Ctr	-	2	-	-	-	-	3	-	-	1
U Colorado CC LAPS	1	-	-	-	6	-	1	-	-	-
U Kansas CC - MCA Rural MU NCORP	4	-	-	-	3	-	1	-	-	-
U Michigan CCC LAPS	1	3	2	-	-	2	-	4	3	-
U Rochester LAPS	-	9	1	-	2	4	-	2	-	-
U Texas HSC at San Antonio	-	1	-	-	-	-	-	3	-	-
U Texas MD Anderson CC LAPS	13	22	5	-	-	-	-	-	-	-
U Utah - Huntsman Ca Inst LAPS	-	5	-	1	-	-	-	-	-	-
Upstate Carolina Consortium NCORP	-	1	-	-	-	-	-	-	-	-
Vanderbilt U - Ingram CC LAPS	-	4	-	-	-	-	-	-	-	-
Virginia Mason Med Ctr	-	-	-	-	4	2	-	-	-	-
Wayne State U - Karmanos Ca Inst LAPS	-	2	-	-	2	-	-	-	-	3
William Beaumont Hosp-Royal Oak	-	-	-	-	1	-	-	-	-	-
Wisconsin NCORP	-	1	-	-	-	-	-	-	-	-
Yale U - Yale CC LAPS	-	10	-	-	2	-	3	-	-	-
ALLIANCE	6	122	6	1	-	-	-	-	-	-
ECOG-ACRIN	4	92	1	-	-	-	-	-	-	-
NRG	5	41	2	-	-	-	-	-	-	-
Total	53	452	19	5	56	16	19	13	6	37



Where We Are

- 1 The Hope Foundation for Cancer Research, Ann Arbor, MI
- 2 Fred Hutch Cancer Research Center and Cancer Research And Biostatistics, Seattle, WA
- 3 SWOG Group Chair's Office, Knight Cancer Institute, Oregon Health & Science University, Portland, OR
- 4 SWOG Operations, San Antonio, TX

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Accrual from trial opening through 12/31/2021 by Institution and Study

	EA2174	EA2176	EA2186	EA2187	EA2197	NRGG005
<i>Ascension Prov Hospitals - Southfield</i>	-	-	2	-	-	1
<i>Ascension Via Christi Hospitals Wichita</i>	-	-	-	-	-	-
<i>Banner U Med Ctr - Tucson</i>	-	-	-	-	-	-
<i>Baylor Coll Med/Dan L Duncan CCC</i>	-	-	-	-	-	-
<i>Boston Med Ctr</i>	-	-	-	-	-	-
<i>CWRU Case CCC LAPS</i>	-	-	-	3	-	-
<i>Ca Res Consortium West Mich NCORP</i>	-	-	-	-	-	-
<i>Ca Res for the Ozarks NCORP</i>	-	-	-	-	-	-
<i>Ca Res of Wisconsin & N Mich Consort</i>	-	-	-	-	-	-
<i>City of Hope CCC</i>	-	-	1	-	-	-
<i>Columbus NCORP</i>	-	-	-	-	-	-
<i>CommonSpirit Health Research Inst</i>	-	-	-	-	-	-
<i>Dayton NCORP</i>	-	-	-	-	-	-
<i>Fred Hutchinson Ca Res Ctr LAPS</i>	-	-	-	-	-	-
<i>Gulf South MU NCORP</i>	-	-	-	-	-	-
<i>Hawaii MU NCORP</i>	-	-	2	-	-	-
<i>Heartland Ca Res NCORP</i>	-	-	-	-	-	-
<i>Henry Ford Hospital</i>	-	-	-	-	-	1
<i>Kaiser Permanente NCORP</i>	-	2	-	-	-	4
<i>Lahey Hospital & Med Ctr</i>	-	-	-	-	-	-
<i>Loyola U Med Ctr</i>	-	-	-	-	-	-
<i>Michigan Ca Res Consortium NCORP</i>	-	-	-	-	-	-
<i>Moffitt CC</i>	-	-	-	-	-	-
<i>Montana Cancer Consortium NCORP</i>	-	-	-	-	-	-
<i>NCORP Carolinas (Prisma Hlth NCORP)</i>	-	-	-	-	-	-
<i>New Mexico MU NCORP</i>	-	-	-	-	-	-
<i>Northwell Health NCORP</i>	-	-	1	-	-	-
<i>Northwestern U LAPS</i>	-	-	1	-	-	-
<i>Oregon Health & Science U</i>	-	-	-	-	1	-

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Accrual from trial opening through 12/31/2021 by Institution and Study

	EA2174	EA2176	EA2186	EA2187	EA2197	NRGG1005
Pacific Ca Res Consortium NCORP	-	-	-	-	-	-
SCL Health Saint Joseph Hospital	-	-	-	-	-	-
Southeast Clin Onc Res Consort NCORP	-	-	-	-	-	-
Sutter Ca Res Consortium	-	-	-	1	-	-
West Clinic - Wolf River	-	-	-	-	-	-
UC Davis CCC LAPS	-	-	-	-	-	1
UC Irvine Health/Chao Family CCC	-	-	-	-	-	-
USC Norris CCC LAPS	1	-	-	-	-	-
U Alabama Birm/Deep South RC LAPS	-	-	-	-	-	-
U Arkansas for Medical Sciences	-	-	-	-	-	-
U Cincinnati CC-UC Med Ctr	-	-	-	-	-	-
U Colorado CC LAPS	-	-	1	-	-	-
U Kansas CC - MCA Rural MU NCORP	-	-	-	1	-	1
U Michigan CCC LAPS	-	-	-	-	-	-
U Rochester LAPS	-	-	4	2	-	-
U Texas HSC at San Antonio	-	-	2	-	-	-
U Texas MD Anderson CC LAPS	-	3	-	-	-	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	-	-	-	-	-	-
William Beaumont Hosp-Royal Oak	-	-	-	-	-	-
Wisconsin NCORP	-	-	-	-	-	-
Yale U - Yale CC LAPS	-	-	-	-	-	4
ALLIANCE	-	-	-	-	-	-
ECOG-ACRIN	-	-	-	-	-	-
NRG	-	-	-	-	-	-
Total	1	5	14	7	1	13