



Annual Report 2019

hcosierSM
CANCER RESEARCH NETWORK

Board of Directors



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Bert O'Neil, MD



Timothy Ratliff, PhD



Ted Stansbury



Richard Zellars, MD

Hoosier Cancer Research Network's vision and mission is to form **unparalleled** relationships between academic, community, pharmaceutical, and biotech collaborators with the goal of **advancing** cancer research, education, and patient advocacy.

Our **highly qualified** team provides **comprehensive** study management and support, from conception and study design through project completion and publication.

A MESSAGE FROM OUR Chairman of the Board

As the books closed on 2019, Hoosier Cancer Research Network approached a familiar juncture. The organization's steady growth, both in numbers as well as in the range and quality of service we provide, have led us to full capacity in our present location. There is only so much creative reorganizing you can do in a limited space.

I am pleased to announce that this spring, HCRN will move to its new home at 7676 Interactive Way, on the northwest side of Indianapolis. This new location, visible from I-465 between the 71st and 86th Street exits, nearly doubles the square footage of our space in the 500 North Meridian building, and offers ample room to expand in certain key areas of immediate and future need, such as:

- Additional storage space and resources for the biorepository and correlative research team.
- Additional conference rooms to accommodate the active schedules of Clinical Trial Working Groups and study-specific teleconferences.
- Additional offices and cubicles for our growing staff.

In many ways, HCRN has come full circle, experiencing familiar challenges that come with growth. While it may feel like we've been here before, viewing our "story" in perspective shows each cycle has led the organization to a new stage in its development.

Let's look back on where we've been and how far we've come, and in the process pay tribute to some of our greatest champions.

Legend has it that the vision for Hoosier Oncology Group began in the mid-1980s with a "HOG" logo sketched on the back of a cocktail napkin. Dr. Patrick Loehrer, distinguished professor at the Indiana University School of Medicine and director of the IU Simon Comprehensive Cancer Center, and Dr. Lawrence Einhorn, distinguished professor at the IU School of Medicine whose research led to the cure for testicular cancer, envisioned a collaboration that would bring together academic researchers and community oncologists to offer novel clinical trials to patients within their own communities.



**Christopher A. Fausel,
PharmD, MHA, BCOP**

Clinical Manager, Oncology Pharmacy
Indiana University School of Medicine

Very soon, a group of community oncologists across the Hoosier state — Drs. R. Prasad Mantravadi, Rafat Ansari, Kenneth Pennington, and William Fisher — joined their academic colleagues. Rounding out the early executive committee were the late Dr. Steve Williams, then director of the IU Simon Cancer Center, and Sandra Turner, who would steer the early growth of the HOG as its first executive director, until she herself faced a cancer diagnosis that ultimately claimed her life.

A MESSAGE FROM OUR

Chairman of the Board



From the mid-1980s to 2007, the HOG operated under the umbrella of the Walther Cancer Institute (now known as the Walther Cancer Foundation), with offices located in the spacious and historic home of Dr. Joseph E. Walther on North Meridian Street in Indianapolis. HOG investigators were prolific, initiating 130+ studies in more than 15 cancer types and supportive care with 40+ sites participating in the HOG network. Several studies during this era resulted in significant findings that established the HOG as a valued research collaborator among funders and key academic institutions alike. As the HOG's reputation grew, so too did its footprint, with new sites continually dotting the map from coast to coast.

The years 2007 through 2014 brought a series of transitions. Change was not always comfortable, but it was necessary to build the foundation for the growth that would follow. In 2007, the HOG became an independent 501(c)(3) non-profit organization under the leadership of then executive director Jake Vinson. With that change, the HOG made its first big move, to the Indiana University Research Technology Center on West 10th Street, near the IU School of Medicine. The new facility allowed the HOG to establish its first dedicated biorepository room, with space for both ambient and frozen sample storage.

The move to West 10th Street coincided with a transition to the HOG's first electronic data capture (EDC) system. Gone were the days of paper-based case report forms. The speed and efficiency of data input grew tremendously

during this time. With greater efficiency came greater demand for the HOG's services, and the network continued its growth as Cyndi Burkhardt took the reins as executive director in 2012. Recognizing the organization's maturity into a nationwide, full-service clinical research organization, the HOG's leaders chose to rebrand as Hoosier Cancer Research Network (HCRN) in 2014. By that time, HCRN employed nearly 30 full-time staff members and had reached capacity. It was time for another move, and in December 2014 the doors opened at HCRN's new offices at 500 North Meridian Street.



In the years since the move to "500 North," HCRN has added strategic staff positions in several depart-

A MESSAGE FROM OUR Chairman of the Board

ments, including finance and contracting, research development, research operations, safety and regulatory, data management, informatics, and correlative services. Under Burkhardt's steady leadership, HCRN's growth has accelerated at an unprecedented pace. Consider the following metrics from 2014 compared with 2019:

	2014	2019
Studies (<i>current + active development</i>)	15+	80+
Sponsor-investigators (<i>lead PIs</i>)	10+	55+
Number of clinical sites	130+	450+
Number of study funders	10+	30+



HCRN co-founder Lawrence H. Einhorn, MD, visited the HCRN offices in February 2019.

As 2019 drew to a close, HCRN had once again come full circle, reaching capacity at 500 North, and final negotiations were underway to secure a new office location.

We anticipate opening our new offices in May. Knowing that change can be disruptive, we've worked hard to ensure this transition will be as seamless as possible. HCRN has put together a fact sheet about the move for our members, funders, and study teams. The fact sheet may be viewed at hoosiercancer.org/move/. HCRN staff are happy to answer your questions. Visit hoosiercancer.org/contact/, send an email to contact@hoosiercancer.org, or call the HCRN offices at 317-921-2050 at any time.

Thank you to all our member sites, investigators, study teams, funders, and champions who have been a part of the HOG/HCRN story. We are grateful for your collaboration and support over the years.



Chief Scientific Officer



Shadia I. Jalal, MD

Associate Professor of Medicine
Indiana University School of Medicine

As a member of the Hoosier Cancer Research Network, I am grateful to collaborate with outstanding investigators in the development of multi-center, investigator-initiated clinical trials. I've seen the value of this collaboration throughout my own professional development: from my oncology fellowship under the mentorship of Dr. Larry Einhorn and Dr. Nasser Hanna to my current role as a lead investigator for a number of early-stage therapeutic clinical trials. HCRN has been a trusted and valuable resource every step of the way. In my new role as HCRN's chief scientific officer, it is my goal to ensure HCRN's research portfolio continues to reflect the scientific excellence and relevance for which it is highly regarded.

This mark of excellence begins and ends with the community of veteran thought leaders and young investigators — from leading cancer centers across the United States — who participate in HCRN's Clinical Trial Working Groups. Our members bring their expertise, a passion for discovery, and the conviction that we do our best work in the company of our peers. Within the context of Clinical Trial Working Groups, these investigators share a common purpose: to develop the next generation of clinical trials that will lead to safer, more effective treatments for our patients, and improved quality of life for cancer survivors.

So, how do we move from aspiration to achievement? I believe HCRN has answered this question exceptionally well through its clinical trial development and management processes.

It begins when an investigator submits a Letter of Intent to Hoosier Cancer Research Network. The investigator presents the study concept to their Clinical Trial Working Group peers, where group members provide valuable feedback on design, objectives, eligibility, feasibility, funding, and other critical aspects of the study.

Once a working group has approved an LOI, the study concept moves into an intense period of development. HCRN staff assist the sponsor-investigator with the development of the study protocol and informed consent, while contracting and regulatory discussions take place between the sponsor-investigator's institution, study funders, and HCRN. Feasibility surveys are conducted to identify the best participating sites for the trial, and regular teleconferences begin to keep all study teams apprised of the study's development.

As development and contract negotiations conclude, the HCRN data team finalizes a custom EDC for the study, while regulatory staff support the sponsor-investigator's IND submission and prepare documents for IRB review. Finally, as the study is activated, HCRN provides all necessary training to participating sites, and ongoing project, data, safety, regulatory, and correlative management throughout the life of the study.

HCRN's support continues through final publication of the study. But as those who have led clinical trials know all too well, the completion of a study is rarely the end of the story, as study results lead to new lines of inquiry. With this reality in mind, HCRN integrates planning for correlative sample collection and future research at the earliest stages of study development.

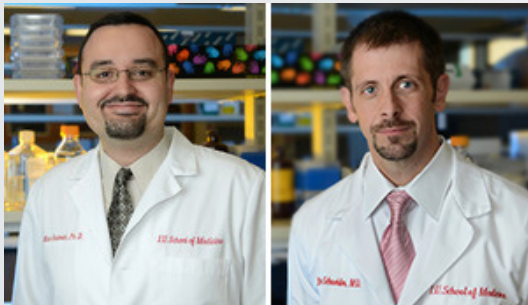
As the next few pages of this report demonstrate, HCRN researchers delivered significant accomplishments in 2019. I am thankful to each member for their contributions and look forward to our continued work together.



BREAST CANCER Clinical Trial Working Group

Researchers predict which TNBC patients may avoid recurrence and which are at high-risk of relapse

Indiana University School of Medicine researchers have discovered how to predict whether triple negative breast cancer will recur, and which women are likely to remain disease-free. They presented their findings on December 13, 2019, at the San Antonio Breast Cancer Symposium.



Milan Radovich, PhD (left), and Bryan Schneider, MD, discovered that women whose plasma contained genetic material from a tumor – referred to as circulating tumor DNA – had only a 56 percent chance of being cancer-free two years following

chemotherapy and surgery. Patients who did not have circulating tumor DNA, or ctDNA, in their plasma had an 81 percent chance that the cancer would not return after the same amount of time. The study also examined the impact of circulating tumor cells, or CTCs, which are live tumor cells that are released from tumors somewhere in the body and float in the blood.

Radovich and Schneider are researchers in the Indiana University Melvin and Bren Simon Comprehensive Cancer Center and the Vera Bradley Foundation Center for Breast Cancer Research. They lead the Precision Health Initiative's triple negative breast cancer team.

The researchers, along with colleagues from the Hoosier Cancer Research Network, analyzed plasma samples taken from the blood of 142 women with triple negative breast cancer who had undergone chemotherapy prior to surgery. Utilizing the FoundationOne Liquid Test, circulating tumor DNA was identified in 90 of the women; 52 were negative.

The women were participants in BRE12-158, a clinical study that tested genomically directed therapy versus treatment of the physician's choice in patients with stage I, II, or III triple negative breast cancer.

The authors say the next step is a new clinical study expected to begin in early 2020, which utilizes this discovery to enroll patients who are at high risk for recurrence and evaluates new treatment options for them.

Co-chairs



Carey Anders, MD
University of North Carolina



Filipa Lynce, MD
Georgetown University

Breast Cancer CTWG *at a glance*

40+

member investigators

25+

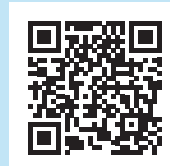
institutions represented

1

study approved in 2019

Learn more:

hoosercancer.org/breast



GASTROINTESTINAL Clinical Trial Working Group

Studies Open to Accrual

- CUP16-268:** Single-arm phase 2 study to examine pembrolizumab and concurrent radiation to induce an abscopal effect in patients with previously treated carcinoma of unknown primary
- ESO17-325:** A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma
- GI15-225:** A Pilot Study of Pembrolizumab in Combination With Y90 Radioembolization in Subjects With Poor Prognosis Hepatocellular Carcinoma With Preserved Liver Function
- GI16-288:** A Phase II Trial of Perioperative CV301 Vaccination in Combination With Nivolumab and Systemic Chemotherapy for Resectable Hepatic-Limited Metastatic Colorectal Cancer
- GI17-319:** A single arm, multi-center Phase 2 trial of mFOLFOX6 + trastuzumab + avelumab in first-line, metastatic, HER2-amplified gastric and esophageal adenocarcinoma

Studies Closed to Accrual

- GI14-186:** A Multi-Center, Single Arm, Phase II study of Pembrolizumab (MK-3475) in Combination with Chemotherapy for Patients with Advanced Colorectal Cancer
- GI14-198:** Phase II Randomized, Double-Blind Study of mFOLFIRINOX Plus Ramucirumab versus mFOLFIRINOX plus placebo in Advanced Pancreatic Cancer Patients
- GI16-263:** A phase II multi-center study evaluating combination immunotherapy for advanced cholangiocarcinoma with pembrolizumab and Sylatron (peginterferon alfa-2b)

Posters and Publications

GI14-198

TIP Poster at Gastrointestinal Cancers Symposium
(Jan. 18, 2019)

Title: Phase II randomized, double-blind, study of mFOLFIRINOX plus ramucirumab versus mfolfirinox plus placebo in advanced pancreatic cancer patients.

Authors: Walid Labib Shaib (pictured), Bert O'Neil, Bassel F. El-Rayes, Steven J. Cohen, Tina Ashley Khair, Erwin L. Robin, Timothy K. Huyck, Rebecca A. Redman, Ashwin Reddy Sama, Mohamad Kassir, Tarios S. Bekaii-Saab.



Co-chairs



Steven J. Cohen, MD
Abingdon - Jefferson Health



Bassel El-Rayes, MD
Emory University



Autumn J. McRee, MD
University of North Carolina

GI CTWG *at a glance*

65+
member investigators

35+
institutions represented

2
studies approved in 2019

Learn more:
hoosiercancer.org/gi



GENITOURINARY Clinical Trial Working Group

Studies Open to Accrual

- GU15-215:** A Phase II Trial of Atezolizumab and Bevacizumab in Cisplatin-ineligible Patients with Advanced/Unresectable Urothelial Cancer
- GU15-262:** Phase 2 Trial of Olaparib in Patients with Metastatic Urothelial Cancer Harboring DNA Damage Response Gene Alterations
- GU16-243:** Phase I/II Study of Modern Immunotherapy in BCG-Relapsing Urothelial Carcinoma of the BLADDER – (ADAPT-BLADDER)
- GU16-260:** Phase II study of front line therapy with nivolumab and salvage nivolumab + ipilimumab in patients with advanced renal cell carcinoma
- GU16-287:** Randomized phase 2 trial of gemcitabine + carboplatin + nivolumab versus gemcitabine + oxaliplatin + nivolumab in cisplatin-ineligible patients with metastatic urothelial cancer
- GU17-289:** Phase II Randomized, Open label Study of High Dose Interleukin 2 vs High Dose Interleukin 2 plus Entinostat in Untreated Adv Renal Cell Carcinoma
- GU17-294:** Phase 2 Trial of Tremelimumab in Patients With Metastatic Urothelial Cancer Previously Treated With PD-1/PD-L1 Blockade
- GU17-295:** A Phase II Trial of Atezolizumab plus Chemotherapy after Progression on Single Agent PD-1 or PD-L1 Inhibitor in Cisplatin-ineligible Patients with Advanced Urothelial Carcinoma
- GU17-326:** Phase II Study to Evaluate the Safety, Pharmacodynamics, and Efficacy of Entinostat in Combination with Nivolumab plus Ipilimumab in Patients with Renal Cell Carcinoma Previously Treated with Nivolumab plus Ipilimumab

Co-chairs



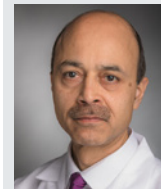
Matthew Galsky, MD

Icahn School of Medicine
at Mount Sinai



Noah M. Hahn, MD

Johns Hopkins University



Guru Sonpavde, MD

Dana-Farber Cancer
Institute

Posters and Publications

GU14-188

Podium Session at American Urological Association Annual Meeting (May 5, 2019)

Authors: Hristos Kaimakliotis, Costantine Albany, Jean Hoffman-Censits, Edouard Trabulsi, W. Kevin Kelly, Joel Picus, Nabil Adra, Clint Cary, Michael Koch, Mark Fleming, Radhika Walling, J. Luke Godwin, Robert Abouassaly, Matthew Cooney, Pingfu Fu, Ariel Nelson, Lee Ponsky, and Christopher Hoimes (pictured).



GU14-182

Oral Abstract at American Society of Clinical Oncology Annual Meeting (June 3, 2019)

Authors: Matt D. Galsky (pictured), Sumanta K. Pal, Amir Mortazavi, Matthew I. Milowsky, Saby George, Sumati Gupta, Mark T. Fleming, Long H. Dang, Daniel M. Geynisman, Radhika Walling, Robert S. Alter, Erwin L. Robin, Jue Wang, Shilpa Gupta, David D. Chism, Joel Picus, George Philips, David I. Quinn, Noah M. Hahn, Menggang Yu.



GU CTWG

at a glance

70+

member investigators

45+

institutions represented

2

studies approved in 2019

Learn more:

hoosiercancer.org/gu



THORACIC Clinical Trial Working Group

Studies Open to Accrual

- LUN15-299:** Phase II Study of Nivolumab and Ramucirumab for Patients with Previously-Treated Mesothelioma
- LUN17-302:** A Phase II Study Evaluating Efficacy and Safety of Hypomethylating Agent Guadecitabine in Combination with Carboplatin in Extensive Stage Small Cell Lung Cancer
- LUN17-321:** A Phase II Study of Concurrent Chemoradiation Plus Durvalumab (MEDI4736) Followed by Surgery Followed by Adjuvant Durvalumab (MEDI4736) in Medically Operable Patients With Surgically Resectable Stage III (N2) Non-Small Cell Lung Cancer
- LUN18-335:** An Open-Label Randomized Phase II Study of Combining Osimertinib with and without Ramucirumab in TKI-naïve EGFR-mutant Locally Advanced or Metastatic NSCLC

Co-chairs



**Karen Reckamp,
MD, MS**
Cedars-Sinai



**Rachel E. Sanborn,
MD**
Providence Cancer Ctr

Posters and Publications

LUN14-179

Poster at IACSLC World Conference on Lung Cancer
(Sept. 7-10, 2019)

Title: ChemoXRT w/ Consolidation Pembrolizumab in Unresectable Stage III NSCLC: Long-Term Survival Update and Analysis of Post-Progression Therapy.

Authors: G. Durm (pictured); S. Althouse; A. Sadiq; S. Jalal; S. Jabbour; R. Zon; G. Kloecker; M. Williamson; K. Reckamp; E. Kio; R. Langdon; B. Adesunloye; R. Gentzler; W. Harb; R. Walling; C. Yeon; M. Koczywas; N. Hanna.



LUN13-175

Poster at IACSLC World Conference on Lung Cancer
(Sept. 7-10, 2019)

Title: Ph I/II Carboplatin, Nab-Paclitaxel and Pembrolizumab for Advanced NSCLC (HCRN LUN13-175): Outcomes by Nab-Paclitaxel Dose.

Authors: R. Gentzler (pictured); N. Mohindra; S. Jalal; K. Reckamp; R. Hall; N. Hanna; Y.K. Chae; V. Villafior; M. Koczywas; I. Helenowski; A. Rademaker; J. Patel.



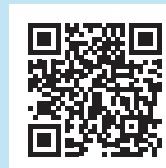
Thoracic CTWG *at a glance*

45+
member investigators

30+
institutions represented

3
studies approved in 2019

Learn more:
hoosercancer.org/thoracic



MELANOMA Clinical Trial Working Group

Studies Open to Accrual

MEL16-252: Single Arm Phase II Study of Ipilimumab and Nivolumab as Adjuvant Therapy for Resected Mucosal Melanoma (SALVO Study)

MEL17-309: Phase II single-arm multi-center study of adjuvant ipilimumab in combination with nivolumab in subjects with high-risk ocular melanoma

Studies Closed to Accrual

MEL16-252: Single Arm Phase II Study of Ipilimumab and Nivolumab as Adjuvant Therapy for Resected Mucosal Melanoma (SALVO Study)

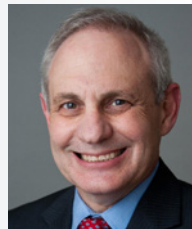
Posters and Publications

MEL17-309

**Poster at Society for Melanoma Research
16th International Congress** (Nov. 20-23, 2019)

Title: Phase II single-arm multi-center study of adjuvant ipilimumab in combination with nivolumab in subjects with high-risk ocular melanoma.

Authors: Suthee Rapisuwon, Sapna P. Patel, Richard D. Carvajal, Leonel F. Hernandez-Aya, Katy Tsai, Sunandana Chandra, Ming T. Tan, Adil Daud, Jeffrey A. Sosman, and Michael B. Atkins (pictured).

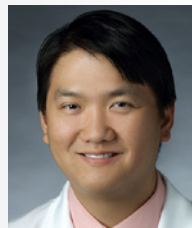


MEL17-309

**Poster Session at American Society of Clinical
Oncology Annual Meeting** (June 3, 2019)

Title: Phase II single-arm multicenter study of adjuvant ipilimumab in combination with nivolumab in subjects with high-risk ocular melanoma.

Authors: Suthee Rapisuwon (pictured), Sapna Pradyuman Patel, Richard D. Carvajal, Leonel Fernando Hernandez-Aya, Katy K. Tsai, Sunandana Chandra, Ming Tony Tan, Adil Daud, Jeffrey Alan Sosman, Michael B. Atkins.



Co-chairs



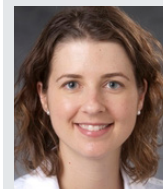
Ragini R. Kudchadkar, MD

Emory University



Timothy Kuzel, MD

Rush University



April Salama, MD

Duke University

Melanoma CTWG *at a glance*

30+

member investigators

20+

institutions represented

Learn more:

hoosercancer.org/melanoma



Clinical Trial Working Groups

Correlative Sciences CTWG



30+ members

15+ institutions

hoosercancer.org/correlative

Thomas G. Sors, PhD (co-chair)
Purdue University

HCRN Biorepository and Correlative Research Services

HCRN recognizes the importance of correlating clinical and laboratory data with the goal of identifying factors that are associated with response and/or toxicity to treatment. Samples collected from consented patients participating in HCRN studies are shipped to our biorepository for storage and management.

Dedicated correlative managers at HCRN:

- Oversee all sample processing and tracking, site training, and support throughout the life of each study.
- Maintain two -80 freezers and a -140 mechanical cryogenic freezer.
- Create study procedure manuals with detailed instructions for collection, labeling, processing, and shipping samples.
- Assemble and ship study-specific sample collection kits to participating institutions.
- Manage complete chain of custody.

Learn more about our services:
hoosercancer.org/services

Myeloid CTWG

Co-chairs



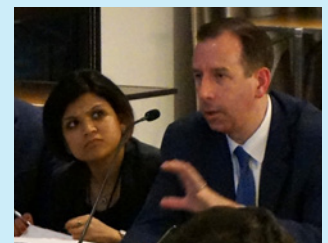
Matthew Foster, MD
University of North Carolina



Joshua Zeidner, MD
University of North Carolina

8 members **7** institutions
hoosercancer.org/myeloid

THANK YOU to all investigators who participated in HCRN research and Clinical Trial Working Groups during 2019.



Investigators: Discover the benefits of participating in HCRN Clinical Trial Working Groups. Learn more and join today at hoosercancer.org/join/.



Research Collaborations

Hoosier Cancer Research Network collaborates with several research consortia, including the Big Ten Cancer Research Consortium, the Translational Breast Cancer Research Consortium, the Bladder Cancer Genomics Consortium, and the Midwest Melanoma Partnership.

Big Ten Cancer Research Consortium (Big Ten CRC)

The Big Ten Cancer Research Consortium was created in 2013 to transform the conduct of cancer research through collaborative, hypothesis-driven, highly translational oncology trials that leverage the scientific and clinical expertise of Big Ten universities. The goal of the Big Ten CRC is to create a unique team-research culture to drive science rapidly from ideas to new approaches to cancer treatment. Within this innovative environment, today's research leaders collaborate with and mentor the research leaders of tomorrow with the unified goal of improving the lives of all patients with cancer. Learn more: bigtencrc.org.

HCRN serves as administrative headquarters for the Big Ten CRC.

Translational Breast Cancer Research Consortium (TBCRC)

The Translational Breast Cancer Research Consortium is a collaborative group founded in 2005 to conduct innovative and high-impact clinical trials for breast cancer. The TBCRC is composed of 19 clinical sites; five core working groups focusing on correlative science and breast cancer phenotypes; two interest groups focusing on patient-reported outcomes and immuno-oncology; working groups for patient advocates, study coordinators, and contracts/administrators; and a central office. Collectively, these groups work to foster trial development in a collegial environment that enhances cross-institutional collaboration. Learn more: pub.emmes.com/study/bcrc/.

HCRN provides trial management and support to the TBCRC.

Bladder Cancer Genomics Consortium (BCGC)

The Bladder Cancer Advocacy Network launched the Bladder Cancer Genomics Consortium in 2017. The BCGC's ultimate goal is to provide the opportunity for every patient to be an exceptional responder to personalized therapy while advancing collaborative research to support the development of life-saving treatments for bladder cancer. Learn more: bcn.org/bladder-cancer-genomics-consortium/.

HCRN developed and manages a genomically driven sample collection study for the BCGC.

Midwest Melanoma Partnership (MMP)

The Midwest Melanoma Partnership (MMP) is a multi-institutional collaboration of physicians, scientists, and patient advocates dedicated to the development of improved therapies for patients with malignant melanoma. Learn more: midwestmelanoma.org.

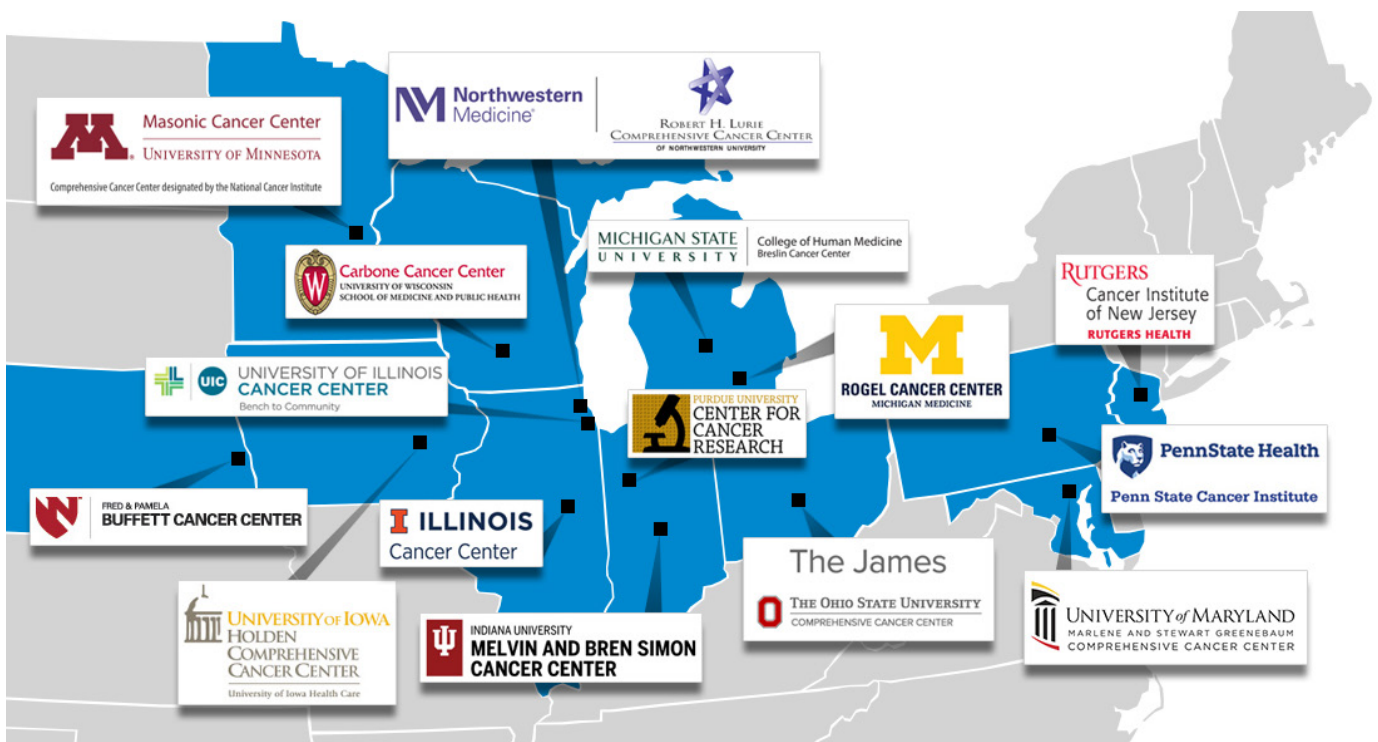
HCRN provides trial management and support to the MMP.

Big Ten Cancer Research Consortium

The Big Ten cancer centers create a uniquely powerful collaboration built on a robust history of research and an extensive research infrastructure. Leveraging geographical location and existing relationships among the cancer centers, collaboration flows from shared research visions and goals.

Member Institutions

University of Illinois Cancer Center (University of Illinois at Chicago)
The Cancer Center at Illinois (University of Illinois at Urbana-Champaign)
Indiana University Melvin and Bren Simon Comprehensive Cancer Center
Holden Comprehensive Cancer Center, University of Iowa
The University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center
University of Michigan Rogel Cancer Center
Michigan State University Breslin Cancer Center
Masonic Cancer Center, University of Minnesota
Fred & Pamela Buffett Cancer Center (University of Nebraska)
Robert H. Lurie Comprehensive Cancer Center of Northwestern University
The Ohio State University Comprehensive Cancer Center – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute
Penn State Cancer Institute
Purdue University Center for Cancer Research
Rutgers Cancer Institute of New Jersey
University of Wisconsin Carbone Cancer Center



Big Ten Cancer Research Consortium

Studies Open to Accrual

BTCRC-AML17-113: Phase Ib study of the safety and efficacy of Gemtuzumab Ozogamicin (GO) and Venetoclax in patients with relapsed or refractory CD33+ AML

BTCRC-AML18-342: Phase I trial of azacitidine plus nivolumab following reduced-intensity allogeneic PBSC transplantation for patients with AML and high-risk myelodysplasia

BTCRC-BRE15-024: A phase I/II, single arm, non-randomized study of ribociclib (LEE011), a CDK 4/6 inhibitor in combination with bicalutamide, an androgen receptor (AR) inhibitor, in advanced AR+ triple-negative breast cancer

BTCRC-BRE16-042: A Phase II Study of Pembrolizumab Plus Fulvestrant in Hormone Receptor Positive, HER-2 Negative Advanced/Metastatic Breast Cancer Patients

BTCRC-BRE18-337: Phase 2 Trial With Safety Run-In of Gedatolisib Plus Talazoparib in Advanced Triple Negative or BRCA1/2 Positive, HER2 Negative Breast Cancers

BTCRC-GI15-015: Phase II Study of FOLFOX combined with Nab-Paclitaxel (FOLF-OX-A) in the Treatment of Metastatic or Advanced Unresectable Gastric, Gastro-Esophageal Junction Adenocarcinoma

BTCRC-GU16-043: Single Arm Phase Ib/II Study of Durvalumab and Guadecitabine in Advanced Kidney Cancer

BTCRC-HEM15-027: Phase I Study of Nivolumab in Combination with Ruxolitinib in Relapsed or Refractory Classical Hodgkin Lymphoma

BTCRC-HEM15-028: Phase I/II Study of Ixazomib and Romidepsin in Relapsed/Refractory Peripheral T-cell Lymphoma (PTCL)

BTCRC-HEM17-092: Phase I/II study augmenting TAK-659 action in relapsed/refractory AML by addition of the proteasome inhibitor Ixazomib

BTCRC-HN17-111: Phase II Trial of Androgen Deprivation Therapy (ADT) and Pembrolizumab for Advanced Stage Androgen Receptor-positive Salivary Gland Carcinoma

BTCRC-LUN15-017: A Phase Ib/II Study of Anti-PD-1 Antibody Pembrolizumab and Imprime PGG for Patients with Metastatic Non-small Cell Lung Cancer After Progression on First-Line Chemotherapy

BTCRC-LUN16-081: Phase II Study of Consolidation Immunotherapy w/ Nivolumab and Ipilimumab or Nivolumab alone following Concurrent Chemoradiotherapy for Unresectable Stage IIIA/IIIB NSCLC

BTCRC-LUN17-127: A Phase I/II Study of Nivolumab, Ipilimumab and Plinabulin in Patients With Recurrent Small Cell Lung Cancer

BTCRC-LUN17-139: A Phase II Study of Carboplatin Plus Pemetrexed Plus Atezolizumab Plus Bevacizumab in Chemotherapy and Immunotherapy-naïve Patients With Stage IV Non-squamous Non-small Cell Lung Cancer

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Big Ten Cancer Research Consortium

Posters and Publications

BTCRC-ESO14-012

Rapid Abstract Session at Gastrointestinal Cancers Symposium (Jan. 17-19, 2019)

Title: Safety and efficacy of durvalumab following trimodality therapy for locally advanced esophageal and GEJ adenocarcinoma: Early efficacy results from Big Ten Cancer Research Consortium study.

Authors: Hirva Mamdani (pictured), Bryan J. Schneider, Laith I. Abushahin, Thomas J. Birdas, Kenneth Kesler, Heather Burney, Susan Perkins, Shadia Ibrahim Jalal.



BTCRC-ESO14-012

Poster Session at American Society of Clinical Oncology Annual Meeting (May 31-June 4, 2019)

Title: Safety and efficacy of durvalumab following multimodality therapy for locally advanced esophageal and GEJ adenocarcinoma: Results from Big Ten Cancer Research Consortium study.

Authors: Hirva Mamdani, Bryan J. Schneider, Laith I. Abushahin, Thomas J. Birdas, Kenneth Kesler, Heather Burney, Susan M. Perkins, Shadia Ibrahim Jalal (pictured).

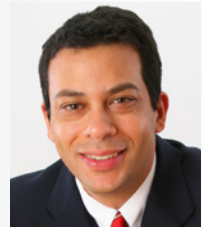


BTCRC-LUN16-081

Poster Session at American Society of Clinical Oncology Annual Meeting (May 31-June 4, 2019)

Title: Interim safety analysis of consolidation nivolumab and ipilimumab versus nivolumab alone following concurrent chemoradiation for unresectable stage IIIA/IIIB NSCLC.

Authors: Melissa Yan, Greg Andrew Durm, Hirva Mamdani, Apar Kishor Ganti, Borys Hinczenko, Salma K. Jabbour, Lawrence Eric Feldman, Goetz H. Kloecker, Ticiana Leal, Salah Almokadem, Jarushka Naidoo, Naomi Fujioka, Nasser H. Hanna (pictured).



BTCRC-BRE15-016

Poster Session at San Antonio Breast Cancer Symposium (Dec. 10-14, 2019)

Title: Safety results from a phase 2 study of Palbociclib in combination with Tamoxifen as first line therapy for metastatic hormone receptor positive breast cancer.

Authors: Oana C. Danciu (pictured), Kent Hoskins, Cristina Truica, Anne Blaes, Deimante Tamkus, Jatin Rana, Pavankumar Tandra, Lauren Green, Li Liu, Menggang Yu, Deborah Toppmeyer, Ruth O'Regan, Kari Wisinski.



BTCRC-BRE18-337

Ongoing Trials Session at San Antonio Breast Cancer Symposium (Dec. 10-14, 2019)

Title: Phase 2 trial with safety-run in of gedatolisib plus talazoparib in advanced triple negative or BRCA1/2 positive HER2 negative breast cancer.

Authors: Sneha Phadke, Menggang Yu, Kathy Miller, Ami Shah, Oana Danciu, Kari Wisinski (pictured).



Our Contributors

Thank you to all who have contributed to Hoosier Cancer Research Network. We are grateful for your commitment of time and resources to help us fulfill our mission. Your generous support strengthens our ability to fund investigator-initiated research. Learn how you can contribute at www.hoosiercancer.org/make-a-difference/.

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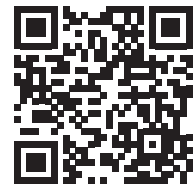
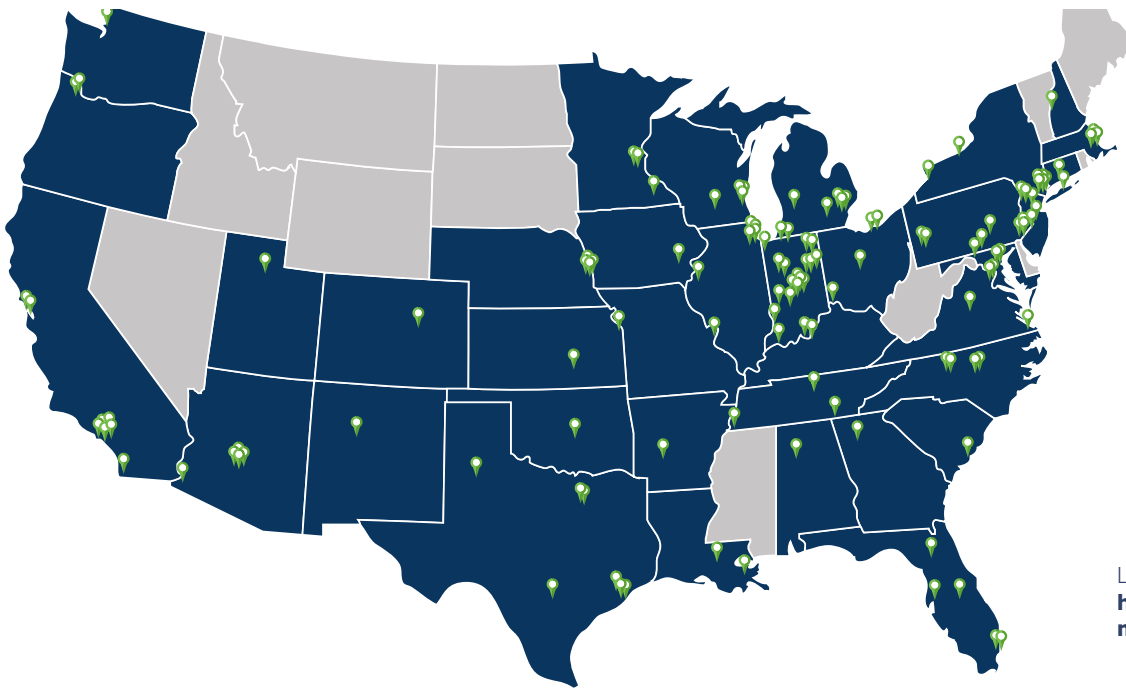
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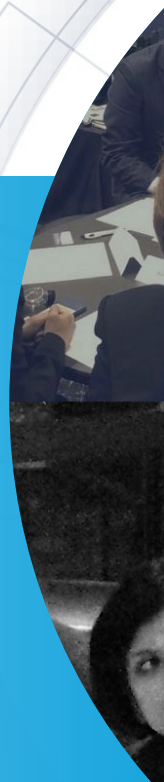
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