



hcoosierSM
CANCER RESEARCH NETWORK

Annual Report *2021*



Board of Directors



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PharmD, MHA, BCOP
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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.

Christopher Fausel, PharmD, MHA, BCOP

Chair

These last two years have presented challenges for all organizations, but I want to express my utmost admiration to Cyndi Burkhardt and the entire team at Hoosier Cancer Research Network as we endured another year of challenges. The growth I have seen of Hoosier Cancer Research Network throughout my almost decade as chairman has been a product of Cyndi's leadership. We would not have our highly qualified team, our reach as a network, and our strong collaborations if not for her leadership and guidance.

Hoosier Cancer Research Network remains equipped to support impactful clinical trials that answer crucial questions for cancer patients in communities nationwide.

As we continue to make meaningful gains in cancer research, it is a privilege to witness the important work of the HCRN staff in all areas of responsibility. Through their efforts, we are making real, measurable progress against cancer. It takes a team with vision to make such an impact.



As the pursuit of our goal to beat cancer continues, the key to our success is collaboration. Each year, the number and strength of investigators, institutions, community sites, pharmaceutical and biotech companies with whom we collaborate increases.

The strength of our collaborations and the leadership exhibited by our working groups and administrative team have powered our sails through these uncertain times. With these strengths, Hoosier Cancer Research Network is positioned for many strong years ahead.



One team. Infinite possibilities.

Hoosier Cancer Research Network (HCRN) remains as active as ever in developing and opening new investigator-initiated cancer clinical trials and continues to develop our relationships with sites, investigators and funders. Cancer does not stall and patients do not stop needing treatment. And so, research must continue despite the challenges of our time.



As a network, we are in a strong position. I am grateful that Hoosier Cancer Research Network has maintained a consistent level of staffing and activity. 2021 was another strong year for HCRN in terms of the quality of engagement with our network collaborators. More top academic research institutions and key opinion leaders joined our network in 2021, enriching the scientific strength and energy of each of our disease-specific clinical trial working groups. Throughout the year we have seen a steady inflow of ideas and look forward to continuing the trend in 2022. Across our network we have added 108 investigators to our clinical trial working groups and have seen 54 concepts presented during these working group meetings. HCRN's clinical trial working groups provide an ideal venue for investigators to develop their concepts in a supportive, collegial environment.

I would like to thank our excellent, hardworking staff and our leadership team for continuing to support our mission. I want to express my profound appreciation to all of our sponsor-investigators, your study teams, and collaborators for all that you do individually and collectively to advance our vision. Together we are making a difference across our communities, and I hope this gives you a sense of pride and inspiration, as it does for me. To all our collaborators, we look forward to continuing our work together in 2022.

Cyndi Burkhardt, RN
Executive Director



Genitourinary Clinical Trial Working Group

The Genitourinary Clinical Trial Working Group has been tremendously active over the past year. Despite the ongoing pandemic, our group has strived to increase collaborations with our investigators and partners. We continue to bring forward novel concepts with integrated correlative studies to advance the treatment of genitourinary malignancies.

Our mission is to ensure the 1) development of novel and clinically relevant clinical trial concepts across the continuum of genitourinary malignancies, 2) mentorship of junior faculty and fellows in the process of clinical trial development, and 3) integration of tissue, blood, and urine based biomarkers to improve prognostication and therapy selection.

As cancer care delivery has been dramatically impacted during the COVID-19 pandemic, a top priority for our group has been to continue to provide access to clinical trials. We have worked to develop solutions to challenges brought on through the pandemic to continue to support our investigators in clinical trial development, activation, and accrual.

We have an open, collaborative culture and encourage the continued participation of fellows and junior faculty. Additionally, we encourage multidisciplinary partnerships across all disciplines including urology, medical oncology, radiation oncology, pathology, and radiology.

2021 Publications & Presentations

ASCO Annual Meeting:

- **Poster:** A phase 2 study of cabozantinib in combination with atezolizumab as neoadjuvant treatment for muscle-invasive bladder cancer (HCRN GU18-343) ABATE study.
- **Poster Discussion Session:** Phase II study of nivolumab and salvage nivolumab + ipilimumab in treatment-naive patients (pts) with advanced non-clear cell renal cell carcinoma (nccRCC) (HCRN GU16-260-Cohort B).
- **Oral Abstract Session:** Phase 2 trial of gemcitabine, cisplatin, plus nivolumab with selective bladder sparing in patients with muscle-invasive bladder cancer (MIBC): HCRN GU 16-257.

AACR Annual Meeting:

- **Poster:** Urothelial cancer-GENOMIC analysis to improve patient outcomes and research (UC-GENOME): a bladder cancer advocacy network (BCAN) led collaborative research study (HCRN GU15-217)

Co-chairs



Shilpa Gupta, MD
Cleveland Clinic



Rana McKay, MD
University of California
San Diego

19

active studies & approved LOI
as of 12/31/2021

45+

Institutions represented

75+

Member investigators



Correlative Sciences

Clinical Trial Working Group

The HCRN Correlative Sciences Working Group advises investigators on the correlative research objectives for HCRN studies that are in development. The group introduced the HCRN Translational Research Seminars series in late 2021 to provide opportunities for investigators

to present innovative biomarker research and discuss potential collaboration. The seminars are open to all investigators at HCRN member institutions. Aadel Chaudhuri, MD, PhD, of the Washington University School of Medicine, presented the inaugural seminar in December,

highlighting clinical data that supports circulating tumor DNA as a biomarker that predicts progression-free survival. HCRN plans three seminars in 2022. Investigators may sign up to receive seminar invitations at <https://hoosiercancer.org/seminars/>.



Co-chairs



Gaorav Gupta,
MD, PhD
*University of
North Carolina*



David J. McConkey,
PhD
*Johns Hopkins
University*



Hatem Sabaawy, MD,
PhD
Rutgers University



20+

Institutions represented

35+

Member investigators



Breast Cancer *Clinical Trial Working Group*

In 2021, the Breast Cancer Clinical Trial Working Group saw increased multidisciplinary participation. The group also began including local and systemic therapies. The group saw an increased geographic reach and complementary expertise across the breast cancer disease trajectory from neoadjuvant to the metastatic setting.

Our highlights include the completion of our first protocol, followed by an influx of activity in concepts in development and studies actively recruiting. In our working group, we are seeing many protocols focused on the clinical challenge of brain metastases. This is in parallel to the first FDA-approved treatment in this setting, tucatanib.

Our team is focused on opening and accruing to the studies carefully planned in 2021. We look forward to seeing the fruits of the team's labor in the form of abstracts disseminated to the larger oncology audience as the working group continues to contribute to advances in breast oncology.

2021 Publications & Presentations

npj Breast Cancer:

- **Manuscript:** M Kalra, Y Tong, DR Jones, T Walsh, MA Danso, CX Ma, P Silverman, M King, SS Badve, SM Perkins, KD Miller. Cisplatin +/- rucaparib after preoperative chemotherapy in patients with triple-negative or BRCA mutated breast cancer. *npj Breast Cancer* 7, 29 (2021). <https://doi.org/10.1038/s41523-021-00240-w>. (HCRN BRE-09-149)

Journal of Clinical Oncology:

- **Manuscript:** Schneider BP, Jiang G, Ballinger TJ, Shen F, Chitambar C, Nanda R, Falkson C, Lynce FC, Gallagher C, Isaacs C, Blaya M, Paplomata E, Walling R, Daily K, Mahtani R, Thompson MA, Graham R, Cooper ME, Pavlick DC, Albacker LA, Gregg J, Solzak JP, Chen YH, Bales CL, Cantor E, Hancock BA, Kassem N, Helft P, O'Neil B, Storniolo AMV, Badve S, Miller KD, Radovich M. BRE12-158: A Postneoadjuvant, Randomized Phase II Trial of Personalized Therapy Versus Treatment of Physician's Choice for Patients With Residual Triple-Negative Breast Cancer. *J Clin Oncol*. Epub 2021 Dec 15. doi: 10.1200/JCO.21.01657.org/10.1038/s41523-021-00240-w. (HCRN BRE12-158)

Co-chairs



Erica Stringer-Reasor, MD
University of Alabama at Birmingham



Carey Anders, MD
Duke Cancer Institute

6

active studies & approved
LOI as of 12/31/2021

30+

Institutions
represented

60+

Member investigators



Myeloid Clinical Trial Working Group

The Myeloid CTWG is collaborative group of investigators who are invested in working together to advance treatment options for the most challenging patient populations with acute myeloid leukemia. On a quarterly basis this group discusses clinical trial concepts, ideas, and proposals among investigators to determine optimal strategies for drug development in AML and MDS.

This year the group saw its first clinical trial proposal approved, a Phase 2 Study of Tagraxofusp with or without Azacitidine in Newly Diagnosed AML after Previous Exposure to Hypomethylating Agents. Investigators in the myeloid working group are interested in designing biomarker-based novel

therapeutic strategies for select subgroups of patients with MDS and AML with limited effective treatment options. The Myeloid CTWG prioritizes translational correlative analyses built into the study design to advance our understanding and knowledge of the mechanism of clinical activity and resistance of novel agents in MDS/AML.

In 2022 the group will work to continue to expand our network with invested investigators across the country. We anticipate that our first approved clinical trial will be a linchpin for the design and implementation of drug development strategies within HCRN to advance treatment options for patients with MDS/AML.



Matthew Foster, MD
University of North Carolina



Joshua Zeidner, MD
University of North Carolina



8

Institutions represented

10+

Member investigators

1

Approved LOI as of
12/31/2021

Melanoma

Clinical Trial Working Group



Alan Tan, MD
Rush University



Timothy Kuzel, MD
Rush University



Ragini R. Kudchadkar, MD
Emory University

4

active studies & approved LOI
as of 12/31/2021

25+

Institutions represented

35+

Member investigators



Gastrointestinal

Clinical Trial Working Group



Bassel El-Rayes, MD
University of Alabama at
Birmingham



Patrick Boland, MD
Rutgers University



Richard Kim, MD
Moffitt Cancer Center

2021 Publications & Presentations

Cancer Immunology, Immunotherapy:

- **Manuscript:** Herting, C.J., Farren, M.R., Tong, Y. et al. A multi-center, single-arm, phase Ib study of pembrolizumab (MK-3475) in combination with chemotherapy for patients with advanced colorectal cancer: HCRN GI14-186. *Cancer Immunol Immunother* 70, 3337–3348 (2021). <https://doi.org/10.1007/s00262-021-02986-5>

AACR Annual Meeting:

- **Poster:** Phase II study of avelumab and trastuzumab with FOLFOX chemotherapy in previously untreated HER2-amplified metastatic gastroesophageal adenocarcinoma (HCRN GI17-319)

Gastrointestinal Cancers Symposium:

- **Poster:** Phase II randomized, double-blind study of mFOLFIRINOX plus ramucirumab versus mFOLFIRINOX plus placebo in advanced pancreatic cancer patients (HCRN GI14-198).
- **Trials in Progress:** A phase II study of atezolizumab (ATEZO) and bevacizumab (Bev) in combination with Y90 TARE in patients (Pts) with hepatocellular carcinoma (HCC). (HCRN GI19-405)

19

active studies & approved
LOI as of 12/31/2021

45+

Institutions
represented

75+

Member investigators



Thoracic Clinical Trial Working Group

9

active studies &
approved LOI as of
12/31/2021

40+

Institutions
represented

60+

Member
investigators



Gregory A. Durm, MD
Indiana University



Mary Jo Fidler, MD
Rush University



Ryan Gentzler, MD
University of Virginia

2021 Publications & Presentations

IASLC World Conference on Lung Cancer:

- **Poster: RAMOSE: An Open-Label Randomized Phase II Study of Osimertinib with or without Ramucirumab in TKI-Naïve EGFR-Mutant Metastatic NSCLC (HCRN LUN18-335)**

Studies Closed to Accrual in 2021

- **LUN17-321**, led by Greg Durm, MD
- **LUN15-299**, led by Arkadiusz Dudek, MD, PhD



Research Collaborations



The Big Ten Cancer Research Consortium was created in 2013 to transform the conduct of cancer research through collaborative, clinical trials and observational studies that seek to improve the lives of cancer patients in the diverse communities we serve by leveraging the scientific and clinical expertise of Big Ten universities. The goal of the Big Ten Cancer Research Consortium creates a unique team-research culture to drive science rapidly from ideas to new approaches to treatment and prevention. Within this innovative environment, today's research leaders collaborate with and mentor the research leaders of tomorrow. Learn more: www.bigtenrc.org.



Translational **Breast Cancer** Research Consortium

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/.

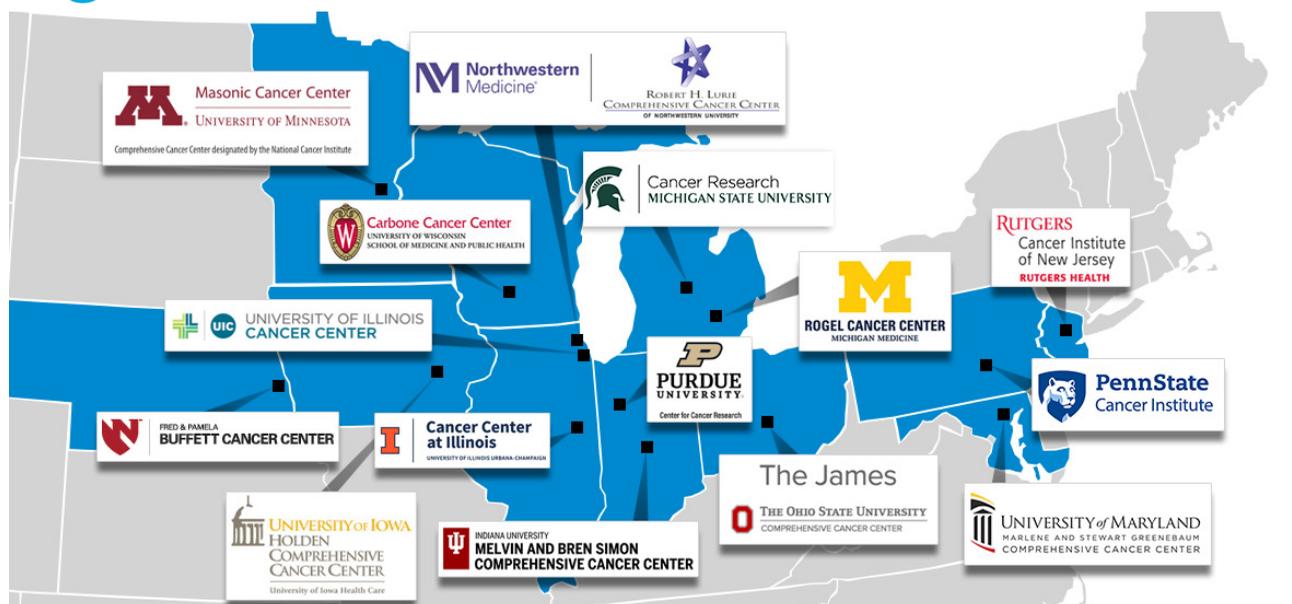


The Bladder Cancer Advocacy Network launched the Bladder Cancer Genomics Consortium in 2017. The BCGC's ultimate goal is to provide the opportunity for every patient to be an exceptional responder to personalized therapy while advancing collaborative research to support the development of life-saving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



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. The mission of the Midwest Melanoma Partnership is to facilitate the sharing of ideas, clinical trials and resources in an effort to improve the diagnosis, treatment, and long-term care of melanoma patients. Learn more: midwestmelanoma.org.

Big Ten Cancer Research Consortium



Competitors on the Field, Partners in Curing Cancer

A consortium’s collaboration speeds the integration of the latest discoveries from academic laboratories into clinical research. Through collaborative working groups, researchers from Big Ten cancer centers refine scientific curiosity into novel studies, honed by some of the brightest minds in cancer research. This means advances in the fight against cancer translate more efficiently into new treatments for patients.

Publications & Presentations 2021

European Urology Focus:

- Manuscript (BTCRC-GU16-051)

Gastrointestinal Cancers Symposium:

- 2 posters (BTCRC-ESO14-012, BTCRC-GI18-149)

Genitourinary Cancers Symposium:

- 1 poster (BTCRC-GU16-043)

ASCO Annual Meeting:

- 6 posters (BTCRC-BRE15-016 (2 posters), BTCRC-LUN15-029, BTCRC-LUN17-127, BTCRC-LUN18-153)

IASLC 2021:

- 2 posters (BTCRC-LUN15-017 and BTCRC-LUN19-396)

AACR:

- 1 poster (BTCRC-AML17-113)

400+

Researchers participate in working groups

600+

Patients have enrolled in studies

30+

Studies have opened to accrual

15,000+

Samples collected for correlative research

Our Member Network

Alabama

- UAB Comprehensive Cancer Center, Birmingham

Arizona

- BCG Oncology, P.C., Phoenix
- Ironwood Cancer & Research Centers, Phoenix
- University of Arizona Cancer Center
- Yuma Regional Cancer Center, LLC, Yuma

Arkansas

- Genesis Cancer Center, Hot Springs

California

- Cedars-Sinai Medical Center, Los Angeles
- City of Hope, Duarte
- Marin Cancer Care, Greenbrae
- Moores Cancer Center at UC San Diego Health
- Prostate Oncology Specialists, Inc., Marina Del Rey
- Salinas Valley Memorial Healthcare System, Salinas
- Stanford University, Stanford
- USC Norris Comprehensive Cancer Center, Los Angeles

Colorado

- University of Colorado Cancer Center, Aurora

Connecticut

- Yale Cancer Center, New Haven

Florida

- Memorial Breast Cancer Center at Memorial Regional Hospital, Hollywood
- Moffitt Cancer Center, Tampa
- Sylvester Comprehensive Cancer Center at the University of Miami
- UF Health Cancer Center, Orlando
- University of Florida Health Cancer Center, Gainesville

Illinois

- Illinois CancerCare, PC, Galesburg
- Robert H. Lurie Comprehensive Cancer Center of Northwestern University, Chicago
- Rush University Medical Center, Chicago
- The University of Chicago Medical Center
- University of Illinois Cancer Center, Chicago

Indiana

- American Health Network, Indianapolis
- Ascension St. Vincent Evansville Cancer Center, Evansville
- Baptist Health Floyd Cancer Care Center, New Albany
- Community Health Network, Inc. Cancer Centers, Indianapolis
- Community Healthcare System, Munster
- Fort Wayne Medical Oncology & Hematology
- Goshen Center for Cancer Care
- Horizon Oncology Research LLC, Lafayette
- Indiana University Melvin and Bren Simon Comprehensive Cancer Center, Indianapolis
- IU Health Arnett Cancer Centers, Lafayette
- IU Health Ball Memorial Cancer Center, Muncie
- IU Health Cancer Centers Bloomington
- IU Health Central Indiana Cancer Centers, Indianapolis
- Memorial Hospital of South Bend and Elkhart General Hospital
- Parkview Research Center, Fort Wayne
- St. Vincent, Indianapolis
- St. Vincent Anderson Regional Hospital, Anderson

Iowa

- University of Iowa Holden Comprehensive Cancer Center, Iowa City

Kansas

- Cancer Center of Kansas, Wichita
- University of Kansas Medical Center, Kansas City

Kentucky

- Univ. of Louisville/James Brown Cancer Center, Louisville

Louisiana

- Ochsner, New Orleans

Maryland

- Meritus Center for Clinical Research / John R. Marsh Cancer Center, Hagerstown
- Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore
- University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center, Baltimore

Massachusetts

- Beth Israel Deaconess Medical Center, Boston
- Boston Medical Center, Boston
- Dana-Farber Cancer Institute, Boston
- Tufts Medical Center, Boston

Michigan

- Barbara Ann Karmanos Cancer Center, Detroit
- Henry Ford Health System, Detroit
- Michigan Center of Medical Research, Farmington Hills
- The Cancer Center at Metro Health Village, Wyoming
- University of Michigan Rogel Cancer Center, Ann Arbor

Minnesota

- HealthPartners Institute, Minneapolis
- Masonic Cancer Center, Univ. of Minnesota, Minneapolis

Missouri

- Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine, St. Louis

Nebraska

- Fred & Pamela Buffett Cancer Center (University of Nebraska), Omaha
- Methodist Hospital, Omaha
- Nebraska Cancer Specialists, Omaha
- Urology Cancer Center and GU Research Network, Omaha

New Hampshire

- Dartmouth-Hitchcock Norris Cotton Cancer Center, Lebanon

New Jersey

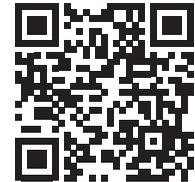
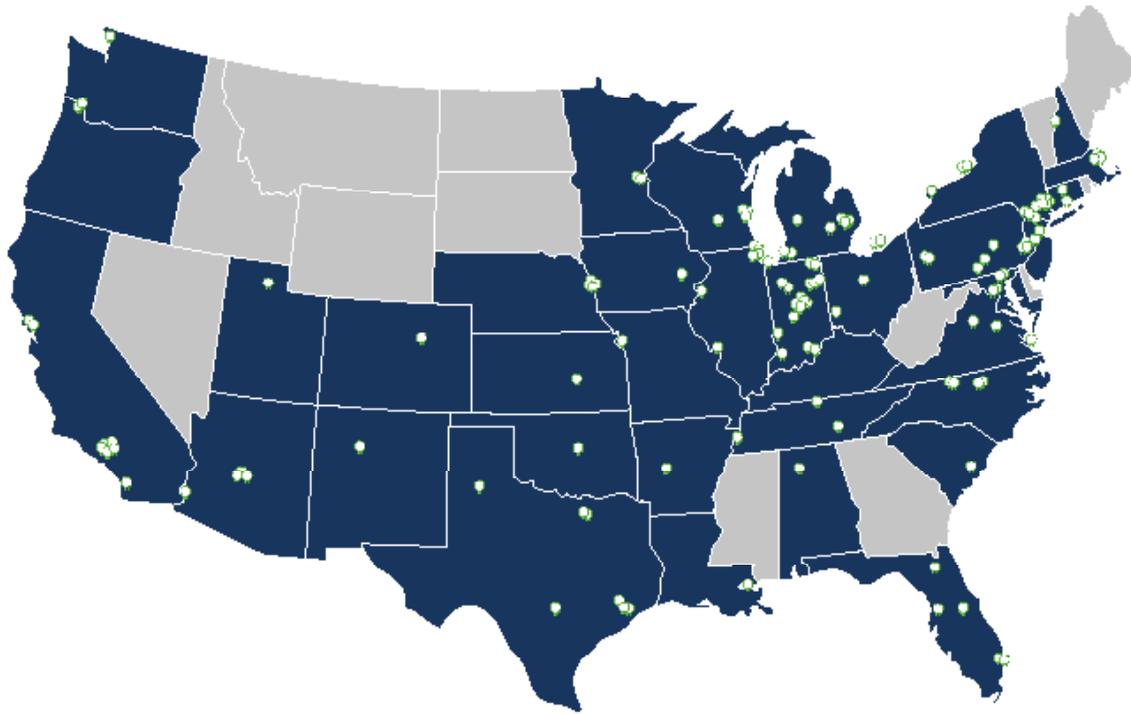
- Atlantic Health System, Morristown
- John Theurer Cancer Center at Hackensack Meridian Health, Hackensack
- Penn Medicine | Virtua Cancer Program
- Regional Cancer Care Associates, LLC, Cherry Hill
- Rutgers Cancer Institute of New Jersey, New Brunswick
- Summit Medical Group Cancer Center, Florham Park

New Mexico

- University of New Mexico Comprehensive Cancer Center, Albuquerque

New York

- Columbia University Irving Medical Center, New York
- Icahn School of Medicine at Mount Sinai, New York
- Integrated Medical Professionals, PLLC, Melville



Learn more at:
[hoosiercancer.org/members](https://www.hoosiercancer.org/members)

- 📍 Jacobs School of Medicine and Biomedical Sciences at the University at Buffalo
- 📍 Memorial Sloan Kettering Cancer Center, New York
- 📍 Montefiore Medical Center
- 📍 New York University Cancer Institute, New York
- 📍 Roswell Park Cancer Institute, Buffalo
- 📍 University of Rochester - Wilmot Cancer Institute
- 📍 Weill Cornell Medicine, New York

North Carolina

- 📍 Duke Cancer Institute
- 📍 Novant Health Oncology Specialists, Winston-Salem
- 📍 University of North Carolina Lineberger Comprehensive Cancer Center, Chapel Hill
- 📍 Wake Forest Baptist Medical Center Comprehensive Cancer Center, Winston-Salem

Ohio

- 📍 Cleveland Clinic Cancer Center
- 📍 The Ohio State University, Columbus
- 📍 University Hospitals Seidman Cancer Center, Cleveland
- 📍 University of Cincinnati Cancer Center

Oklahoma

- 📍 Stephenson Cancer Center at the Univ. of Oklahoma, Oklahoma City

Oregon

- 📍 Knight Cancer Institute at Oregon Health & Science University, Portland
- 📍 Providence Cancer Institute, Portland

Pennsylvania

- 📍 Allegheny Health Network, Pittsburgh
- 📍 Fox Chase Cancer Center, Philadelphia
- 📍 Gettysburg Cancer Center, Gettysburg
- 📍 Penn Medicine Abramson Cancer Center, Philadelphia
- 📍 Penn State Cancer Institute, Hershey
- 📍 Thomas Jefferson University / Sidney Kimmel Cancer Center, Philadelphia
- 📍 UPMC Hillman Cancer Center, Pittsburgh

South Carolina

- 📍 Medical University of South Carolina / Hollings Cancer Center, Charleston

Tennessee

- 📍 Erlanger Health System, Chattanooga
- 📍 Vanderbilt-Ingram Cancer Center, Nashville
- 📍 West Cancer Center, Memphis

Texas

- 📍 Baylor College of Medicine, Houston
- 📍 Joe Arrington Cancer Research and Treatment Center, Lubbock
- 📍 MD Anderson Cancer Center, Houston
- 📍 Texas Oncology - Baylor Charles A. Sammons Cancer Center, Dallas
- 📍 UT Health San Antonio MD Anderson Cancer Center
- 📍 UT Medical Branch at Galveston
- 📍 UT Southwestern Harold C. Simmons Comp. Cancer Center, Dallas

Utah

- 📍 Huntsman Cancer Institute at University of Utah, Salt Lake City

Virginia

- 📍 University of Virginia Cancer Center, Charlottesville
- 📍 Virginia Commonwealth University, Richmond
- 📍 Virginia Oncology Associates, Norfolk

Washington

- 📍 Fred Hutchinson Cancer Research Center, Seattle
- 📍 Swedish Health Service, Seattle

Washington, D.C.

- 📍 George Washington University Cancer Center
- 📍 Georgetown University Lombardi Comprehensive Cancer Center

Wisconsin

- 📍 Aurora Research Institute, LLC, Milwaukee
- 📍 Clement J. Zablocki VA Medical Center, Milwaukee
- 📍 Froedtert & the Medical College of Wisconsin, Milwaukee
- 📍 University of Wisconsin Carbone Cancer Center, Madison

📍 Academic site

One Team.

Infinite Possibilities.

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