Sometimes it takes a dramatic event to shake loose new ideas. Sometimes people require a disruption to justify the time to reflect on the status quo.

The pandemic has afforded such an opportunity to many different organizations and industries, and ours is no exception. And if we’ve learned anything from this experience, it’s that our greatest goals can only be attained through earnest collaboration.

Viewed through that prism, 2021 was a rousing success for Advocate Aurora Research Institute. Since beginning our transformational journey in February 2021, our research team members – hailing from across the country and working in hospitals from Green Bay, Wisconsin, to southern Chicagoland – have come together to make great progress in positioning the Research Institute for success in an ever-changing health care environment.

We have launched and refined a new organizational structure that leverages our existing strengths, optimizes our operations and will foster future growth. We are working with our industry partners who have a demonstrated track record of success in order to prioritize high-impact clinical trials that align with Advocate Aurora Health’s clinical focus areas of cancer, cardiovascular, neuroscience, and child and family health. And we have rebuilt our academic research department to fully support our leading independent researchers, grow our priority research programs and collaborate with other top research enterprises on projects that will advance the fields of health equity, data science, population health, aging, health services research and behavioral health. We have integrated our laboratory and biorepository research services to bring high-quality research support to not only Advocate Aurora investigators, but also to facilitate collaboration with regional and national academic and industry partners to bolster scientific discoveries.

And, finally, we have joined together with our Advocate Aurora leaders to align our research vision with the long-term transformational goals of the larger health system, defining the value of research and renewing our focus on discoveries that directly improve the care and health outcomes of the patients and families we are privileged to serve within our Midwest communities and beyond.

Sincerely,

Amit Acharya, PhD
President, Advocate Aurora Research Institute
Chief Research Officer and System Vice President, Advocate Aurora Health
Research Institute overview

Helping people live well through research is our primary focus. At Advocate Aurora Research Institute, part of Advocate Aurora Health, we’re transforming care to improve health and quality of life across the entire life span, from infants to older adults.

We support hundreds of unique research projects, including groundbreaking clinical trials, that give Advocate Aurora patients access to innovative treatment options through research that otherwise wouldn’t be available to them.

Our success in translating scientific research into more effective care, prevention strategies and treatments are strengthening our communities and garnering national attention.

Centers of Excellence and Research Offices

- Clinical Trials Research
  - Center of Excellence in Cancer Research
  - Center of Excellence in Cardiovascular Research
  - Center of Excellence in Neuroscience Research
  - Clinical Trials Office

- Academic Research and Strategic Partnerships
  - Scientific Programs and Centers
  - Office of Academic Research Support
  - Center for Child and Family Research
  - Office of Research Analytics and Systems Computing

- Research Services
  - Office of Biorepository and Laboratory Services
  - Office of Sponsored Research
  - Office of Industry Engagement and Innovation

Health system partnerships

A successful research enterprise requires the commitment and foresight of Advocate Aurora leadership and the collaboration, expertise and dedication of our many health system partners. The Research Institute is grateful to our partners who have so strongly supported our transformation and continued growth:

- Advocate Charitable Foundation and Aurora Health Care Foundation
- Brand, Consumer Experience & Public Affairs
- Finance
- Graduate Medical Education
- Health Informatics and Technology
- Human Resources
- Legal
- Pharmacy
- Research Compliance
- Research Subject Protection Program

External research partners

The Research Institute works closely with our partners to generate real-world evidence, advance population health and conduct clinical trials of novel drugs and devices that benefit people living within the communities we serve and beyond.

In addition to working with many industry, academic and life science partners in evaluating new treatments and real-world outcomes, other active partnerships include:

- Center for Urban Population Health
- Chicagoland Children’s Health Alliance
- Health Care Systems Research Network
- Institute for Translational Medicine
- Institute for Advanced Clinical Trials for Children
- Wisconsin Network for Health Research

The Research Institute is a valued partner of industry sponsors, academic and life science collaborators, and other research organizations. Advocate Aurora cares for 3 million unique patients and offers more than 500 sites of care across Illinois and Wisconsin – more than any other health system in the Midwest. We also utilize one electronic health record across all system sites, enabling quick access to patient data for more coordinated, efficient care.

Board of Directors

The Advocate Aurora Research Institute board of directors consists of Advocate Aurora Health leaders who serve in an advisory capacity, helping to shape the Research Institute’s future.

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<thead>
<tr>
<th>Board Member</th>
<th>Role and Title</th>
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<tr>
<td>Amit Acharya, PhD</td>
<td>Chief Research Officer</td>
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<td>Jeffrey Bahr, MD</td>
<td>Chief Medical Group Officer</td>
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<td>Rachelle (Shelly) Hart</td>
<td>Senior Vice President, General Counsel</td>
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<td>Nan Nelson</td>
<td>Senior Vice President, Finance Operations</td>
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<td>Dennis Potts (Chair)</td>
<td>Executive Vice President, Operations WI Region</td>
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<td>Ajay Sahajpal, MD</td>
<td>Medical Director, Abdominal Transplant Program</td>
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Amara Sherko was only 2 years old when she underwent her third open heart surgery in June 2019. Born with only the right half of her heart fully developed and functioning, a condition known as hypoplastic left heart syndrome, Amara’s survival depended on a series of three unique surgeries to reconstruct her heart and reroute blood flow.

Although grateful for the care that extended their daughter’s life, Adrian and Jason Sherko worried that the procedures helping to keep Amara alive could prove traumatic for their toddler who was too young to understand. “Toddlers with her condition frequently have posttraumatic stress disorder and fear of doctors and hospitals,” Adrian said. “It’s understandable given all they experience. We would never want Amara to fear the people who literally saved her life and are going to be a part of her life forever.”

That’s why a pediatric clinical trial, which offered a study treatment option that would significantly reduce blood draws for an entire year after surgery, held special meaning for the Sherko family.

An alternative option through research

During the Fontan procedure – the final planned operation in the three-surgery series – surgeons reroute oxygen-poor blood from the lower part of the body directly to the lungs so oxygen is replenished before entering the heart. Although this ensures oxygen-rich blood reaches the body, the modified flow increases the risk for potentially life-threatening blood clots.

To reduce risk post-surgery, Amara was to receive standard treatment for one year with warfarin, an anticoagulant drug that prevents blood clots from forming. Unfortunately, warfarin requires frequent blood draws to monitor levels and adjust the amount given.

Around the time of Amara’s Fontan procedure, Advocate Children’s Hospital in Oak Lawn, Illinois, served as a site for the UNIVERSE clinical trial, which was evaluating anticoagulant drug XARELTO® for its effectiveness in helping to prevent blood clots in children following Fontan surgery. XARELTO® works differently compared to warfarin so frequent blood draws to monitor drug levels aren’t needed.

Pediatric cardiologist Andrew Van Bergen, MD, who led the Advocate Aurora Research Institute team, and Bonnie Hughes, BSN, who served as the lead senior research coordinator, presented the research and standard-of-care options to Amara’s parents. “I had numerous discussions with Dr. Van Bergen and Bonnie about the risks on both sides,” Adrian said. “XARELTO® and warfarin are both blood thinners, and all blood thinners come with risks for bleeding, which can be scary when giving to a 2-year-old. But with XARELTO®, Amara didn’t have to endure the physical and mental side effects of those frequent blood draws.”

Amara, one of 112 pediatric research participants who contributed to the UNIVERSE clinical trial, completed her participation in 2020.

Study leads to FDA approval

UNIVERSE trial results led to the December 2021 U.S. Food and Drug Administration (FDA) approval of XARELTO® for two pediatric indications, one being treatment to help prevent blood clots in children aged 2 years and older with congenital heart disease who have undergone the Fontan procedure. This was an important approval as, previously, it had only been approved for use in adults. “FDA approval means children now have access to valuable treatment options they didn’t have before,” Dr. Van Bergen said.

Young heart warriors and their families face intense and often harrowing health challenges. For Amara’s parents, access to a less-invasive treatment option through research spared their toddler from additional pain and fear after surgery. “I had this 2-year-old who endured far more than any child should ever have to do, and she’d just had her third extensive open heart surgery,” Adrian said. “Amara had post-op complications requiring readmission to the hospital, had to be spoon-fed thickened liquids every day and was on a multitude of medications post-surgery for weeks. It was all unimaginable. If we had the addition of those frequent blood draws directly post-op, it would have been horrendous.”

“I had this 2-year-old who endured far more than any child should ever have to do, and she’d just had her third extensive open heart surgery,” Adrian said. “Amara had post-op complications requiring readmission to the hospital, had to be spoon-fed thickened liquids every day and was on a multitude of medications post-surgery for weeks. It was all unimaginable. If we had the addition of those frequent blood draws directly post-op, it would have been horrendous.”

Adrian Sherko, mom of Amara, research participant

It is incredibly exciting for future heart warriors to have a drug that eases what they have to go through physically and mentally.
Includes industry-sponsored clinical trials, registries and other projects (e.g., expanded access protocols, humanitarian use devices) supported by the Clinical Trials Research team.

Includes investigator-initiated research, quality improvement and evaluation projects led by research scientists (independently or in collaboration with Advocate Aurora Health, university or industry partners) and data science studies and other projects supported by the Academic Research team; does not include graduate medical education or nursing research.

Includes research studies and other projects conducted or supported by the Research Institute's laboratories and biorepository.

Data inclusive of projects open at any point in 2021
Duplicate studies across multiple sites excluded
Child and family health study data inclusive of pediatric research only
Scientific Articles
Includes all Advocate Aurora Health-authored, peer-reviewed journal articles published; excludes abstracts and presentations

- Neuroscience (47) 9%
- Specialty (196) 36%
- Cancer (67) 12%
- Child and family health (97) 18%
- Cardiovascular (143) 26%

550

Grants Awarded
Includes all research grants awarded; grant-funded clinical trial awards excluded

- Cancer ($5,712,385) 43%
- Specialty ($5,797,475) 44%
- Child and family health ($722,033) 5%
- Neuroscience ($511,028) 4%
- Cardiovascular ($474,405) 4%
- Neuroscience ($20,000) 14%

$139K Internal
Cardiovascular ($118,571) 86%

$13.2M External

Research Funding Sources
Includes all research grants awarded; grant-funded clinical trial awards excluded

- Institutional investment ($17,378,909) 53%
- Philanthropic support ($2,939,018) 9%
- Other ($946,109) 3%
- External contracts and grants ($11,264,183) 35%

$32.5M
Our laboratories:

- **Biorepository and Specimen Resources Core**: Researchers and companies use biospecimens to better understand medical conditions, develop diagnostic tests and discover new or more effective treatments. At Biorepository and Specimen Resources Core (BSRC), our mission is to support research and medical product development by providing high-quality biospecimens to Advocate Aurora researchers, external research collaborators, and medical drug and device companies while maintaining Advocate Aurora’s high ethical standards.

- **Discovery Laboratory**: We designed this laboratory to facilitate multidisciplinary research. It has specialized capabilities for handling and analyzing human cells used to test treatments. Advocate Aurora Research Institute’s Glioblastoma Research Program, located at Discovery Laboratory, is pursuing pre-clinical evaluation of Zika Virus (ZIKV) as a candidate oncolytic virus for glioblastoma treatment. Currently, we are studying the oncolytic properties of ZIKV strains suitable for human use.

- **Endocrine Research Laboratory**: The team at our Endocrine Research Laboratory, located at Aurora St. Luke’s Medical Center in Milwaukee, partners with researchers around the country to investigate new endocrine diagnostic assays and measure biomarkers in specimens from humans, mice and rats.

- **Loeber Research Laboratory**: The Leona Loeber Memorial Cancer Research Laboratory is an extension of the Biorepository and Specimen Resources laboratory and provides a full scope of biospecimen services for clinical investigators and academic, industry and life science partners. The Loeber Research Laboratory was established to support cancer research thanks to a generous gift from the Loeber family in memory of Leona Loeber.

In addition, the office is developing new external partnerships to facilitate and support the translation of basic science research to clinical care. One of these new partnerships will provide Advocate Aurora Research Institute with extensive genomic data that will enable new areas of research to better understand disease and therapies.

Office of Research Analytics and Systems Computing

The Office of Research Analytics and Systems Computing provides high-quality, reproducible data from the electronic health record and other sources to provide evidence-based answers to research questions. The office serves as a data broker and ensures all policies, regulations and other processes are followed. Additionally, the team is building a research data infrastructure as part of the Research Institute’s knowledge and data strategy to support large, multisite collaborations and ensure efficient use of research data.

The Office of Research Analytics and Systems Computing works closely with our research scientists and investigators and the Office of Industry Engagement and Innovation, to enable industry partners to advance data analysis, software or algorithm evaluation and validation, as well as real-world evidence by connecting them with the information they need to execute their research studies.

Office of Industry Engagement and Innovation

The Office of Industry Engagement and Innovation helps grow industry collaborations and external partnerships across all three areas of our research enterprise: Clinical Trials Research, Academic Research and Strategic Partnerships, and Research Services.

The office supports industry engagement through the establishment of consistent processes for business development and account management that contribute to our success in deal structuring, negotiations, and coordination of industry-funded projects focused on biorepository, laboratory and data service offerings.

The office works with investigators to capture and administer intellectual property and provides the expertise for commercialization. It also liaises with teams within Advocate Aurora to help align research with health system priorities and the achievement of organizational goals.
Office of Sponsored Research

The Office of Sponsored Research (OSR) provides critical services to support research programs that are wholly or partially funded by federal, foundation or third-party sponsors. OSR provides comprehensive services for a variety of funded and unfunded contractual research relationships, grant submissions, budgeting, billing, and management of intramural funding. OSR has three specialty areas:

**Sponsored Program Services**

Sponsored Program Services supports and assists Advocate Aurora Health investigators with grant proposal development, budget development, proposal processing and submission, award acceptance, and reporting throughout the lifecycle of an award. Managing a diverse portfolio of federal and foundation sponsors, the Sponsored Program Services team provides pre- and post-award support and assists in ensuring compliance with funding regulations and requirements. The team also manages an intramural program designed to advance research that will lead to increased funding opportunities and expansion of Advocate Aurora’s research portfolio.

**Clinical Research Billing and Systems**

Clinical Research Billing and Systems provides pre- and post-award services for clinical trials. Pre-award activities include the review of clinical trial protocols to develop a Medicare Coverage Analysis, used to determine procedures eligible for reimbursement and to support clinical trial budgets. During the conduct of clinical trials, the Clinical Research Billing and Systems team carefully monitors all of the research participant’s charges to confirm appropriate routing and ensure Advocate Aurora’s compliance with research billing regulatory requirements. Additionally, Clinical Research Billing and Systems oversees critical systems, such as REDCap and our clinical trial management system, OnCore, which are used to perform data collection and analyses.

**Clinical Trials Business Services**

Clinical Trials Business Services ensures both timely research study start-up and fair reimbursement to Advocate Aurora for research services rendered by providing comprehensive support for clinical trial business activities, including contract negotiation, budgeting, cost assessments, reimbursement negotiations, coordination and oversight of purchasing agreements, and other trial-related business operations.

Journal of Patient-Centered Research and Reviews

Advocate Aurora Research Institute oversees the peer-reviewed medical journal titled Journal of Patient-Centered Research and Reviews (JPCRR). With new issues published quarterly, JPCRR is devoted to disseminating scholarly works that aim to advance patient-centered care delivery, health outcomes and patient experiences. Since its launch in 2014, JPCRR has been accepted into several prestigious indexes of scientific literature, including the National Library of Medicine’s PubMed Central, Web of Science’s Emerging Sources Citation Index, Directory of Open Access Journals, Google Scholar and Crossref.

In 2021, JPCRR published more works and attracted more readers than in any previous year. Over the 12-month period, articles published by JPCRR were downloaded more than 50,000 times from the journal website and accessed an additional 100,000 times on PubMed Central.

Chaired by family medicine physician Dennis Baumgardner, MD, the journal’s distinguished editorial board consists of national experts representing a diverse array of clinical fields, enabling JPCRR to consider studies on primary, specialty or multidisciplinary care.

Visit aah.org/jpcrr to access all current and archived articles or to submit an original manuscript for editorial review.
Reducing racial inequities in research participation

Research scientist receives $120K in funding to improve health equity

Advocate Aurora Research Institute scientist Veronica Fitzpatrick, DrPH, received $119,910 through Advocate Aurora Health Foundations’ COVID-19 Relief Fund for her research project, “A study to explore disparities in clinical trial participation.” The medical community has long documented the lack of diversity in clinical trials. Throughout history, people of color, women, children and people older than 65 years have been consistently underrepresented in clinical trials of novel medications and devices. This has led to serious patient safety issues, as some approved treatments were later found to negatively affect those in underrepresented groups because the treatment reacted with their bodies differently.

Most recently, the COVID-19 pandemic has amplified the need to improve health equity. So, Dr. Fitzpatrick and her research team are analyzing the racial diversity of patients who participated in COVID-19 clinical trials conducted at Advocate Aurora study sites and comparing this to the diversity pattern of the 3 million patients served by Advocate Aurora.

Additionally, the research team is interviewing people of color to learn what research participation means to them, obstacles to joining clinical trials and potential solutions for overcoming barriers. The team is also conducting interviews with clinician investigators to gain an understanding of their perceptions and experiences surrounding recruiting and retaining research participants of color and their importance to research findings and health outcomes.

Prior COVID-19 infections do not protect against repeat occurrences

16K health care worker study shows importance of continued infection prevention

Having a prior COVID-19 infection or viral exposure did not prevent health care workers from a repeat occurrence, according to an Advocate Aurora Research Institute study published in the scientific journal Annals of Epidemiology. This was true even when the person’s body had mounted a positive antibody response to fight the virus responsible, SARS-CoV-2, as confirmed by antibody testing.

“Our findings demonstrate that immunity from COVID-19 infection may not be protective in the long term, if someone is likely re-exposed,” said Veronica Fitzpatrick, DrPH, research scientist at the Research Institute and primary author. “Based on our results, herd immunity – when enough members of a group become immune so that the entire group is protected against a disease – can only be achieved through vaccination.”

Advocate Aurora Health coauthors included Dr. Fitzpatrick, Anne Rivelli, MPH, epidemiologist at the Research Institute, Kenneth Copeland, PhD, technical lab director at ACL Laboratories, and Jon Richards, MD, PhD, hematologist, oncologist and principal investigator of the study. “Although additional research on immunity is needed, our study demonstrates that to prevent the spread of COVID-19 and its variants, infection prevention measures must remain in place regardless of a health care worker’s prior infection,” Dr. Richards said.

The study was funded by Advocate Aurora.
Mobile app may help to improve health outcomes

Researchers partner with citizens to reduce COVID-19's impact

Researchers from Advocate Aurora Research Institute and University of California, San Francisco (UCSF) began a study to analyze COVID-19’s impact using a smartphone app. Their goal is to help stem transmission of the virus and its new variants, monitor vaccination efforts, and, ultimately, improve health outcomes for people living in the U.S. and around the world.

But they need everyone’s help to reach their goal, so researchers have been asking citizens across the globe to participate in the COVID-19 Citizen Science Study, including Advocate Aurora Health patients who comprise a diverse population of 3 million people living in urban, suburban and rural communities across Illinois and Wisconsin.

The study remains open to all people, with or without COVID-19 infections, who are over 18 years of age, own a smartphone and download the “UCSF Eureka Research” mobile app. The app makes it easy, quick and safe for participants to complete brief health surveys about COVID-19, such as symptoms, medications, vaccinations and social distancing practices.

The information is being used to provide early warnings of new transmission hot-spots to communities at risk, evaluate the effectiveness of prevention strategies and vaccinations, develop processes to predict health outcomes, and improve people’s access to public resources and testing.

Rasha Khatib, PhD, MHS, research scientist, serves as the Research Institute’s principal investigator for the study.

2021 COVID-19 PUBLICATIONS

Researchers author more than 60 COVID-19 publications in 2021

Advocate Aurora Health researchers published 63 COVID-19 scholarly articles in peer-reviewed scientific journals in 2021.

The peer-review process, conducted by experts within each health care specialty, is essential for conferring scientific merit and signifies to readership that an article has met the journal’s standards for scientific rigor and publication.

During a time when the global medical community continued to put forth the call for scientifically valid findings to better understand COVID-19 infections and to improve prevention, diagnostics, treatments and health outcomes, our research teams answered with COVID-19-focused publications related to cancer care, cardiovascular health, neuroscience, child and family health, and numerous other clinical specialties.
In 2021, Advocate Aurora Research Institute established a new and fully integrated organizational structure to unify our research enterprise, increase efficiencies, leverage our existing strengths and lay the foundation for fully aligning our research endeavors to Advocate Aurora Health system priorities.

Under the division of Clinical Trials Research, led by Vice President Nina Garlie, PhD, the Research Institute created three Centers of Excellence (CoE) – in cancer, neuroscience and cardiovascular research. Each CoE is built around a well-developed, robust, systemwide program of research that is of significant scientific value and clinical relevance to Advocate Aurora.

Clinical Trials Research encompasses the Clinical Trials Office, which integrates our research education, quality and regulatory programs across the system. This office is also an incubator for clinical trials research areas that have the potential of becoming a CoE in the future based on research strengths, capacity and system priorities.

A new stroke-prevention device for people with AFib

With two clinical trial sites, Advocate Aurora Health contributed to a research study that led to the recent U.S. Food and Drug Administration (FDA) approval of a new device to treat people with atrial fibrillation (AFib) who are at risk for ischemic stroke.

Advocate Aurora Research Institute enrolled study participants at Advocate Christ Medical Center in Oak Lawn, Illinois, and Aurora St. Luke’s Medical Center in Milwaukee, which was the only site in Wisconsin to join the study.

The FDA granted approval for the Amplatzer™ Amulet™ Left Atrial Appendage Occluder after the clinical trial found that the device offers immediate closure of the left atrial appendage (LAA) for patients with AFib, reducing their risk of stroke without the need for blood thinners.

“Amplatzer™ Amulet™ device furthers our ability to close complex left atrial appendage anatomy and allows more patients to receive the benefits of left atrial appendage occlusion for the risk reduction of stroke,” said electrophysiologist William Spear, MD, Advocate Christ’s principal investigator for the study. “Advocate Aurora is proud to participate in cardiovascular clinical trials such as this that directly improve care of our patients.”

AFib is the most common type of heart arrhythmia, affecting 2.7 million Americans, and is associated with a five-fold increased risk of stroke, according to the American Heart Association. Physicians can prescribe blood-thinning medications to reduce the risk of a stroke for some patients, but for those who cannot take blood thinners long term, physicians may recommend occlusion, or closure, of the LAA.

“We are unsure of its true function, however, in patients with AFib, their irregular heartbeat can result in blood collecting in the left atrial appendage, where blood clots can form. If one of these clots is then pumped out of the heart and to the brain, it can cause a stroke.”

“Advocate Aurora is proud to participate in cardiovascular clinical trials such as this that directly improve care of our patients.”
Advocate Aurora Research Institute researchers joined a clinical trial evaluating an innovative investigational vaccine, named UV1, as a treatment for advanced melanoma, a form of skin cancer, which has spread so far beyond the initial site that it can no longer be completely removed from the body through surgery.

UV1 is designed to help a person’s immune system recognize and attack cancer cells wherever they’ve spread. Specifically, it helps the immune system’s fighter T cells to identify a unique substance – hTERT peptide – that’s expressed in a majority of human tumors and cancer cell lines but is not detectable within most of the body’s normal, adult tissues. After activation by the vaccine, the T cells mount a defense against cells expressing hTERT as they travel throughout the body.

“In this trial, researchers are testing UV1’s safety and effectiveness when it’s given to patients in addition to the standard combination treatment for advanced melanoma, nivolumab and ipilimumab,” said hematologist and oncologist Sigrun Hallmeyer, MD, who leads the study at Advocate Lutheran General Hospital in Park Ridge, Illinois. “All three therapies work to strengthen the body’s immune response against cancer, just in different ways. The hope is that they have a synergistic effect when combined.”

Research participants will randomly receive either standard treatment with nivolumab and ipilimumab or standard treatment plus the UV1 investigational cancer vaccine. The clinical trial is sponsored by Ultimovacs ASA.

NCI COMMUNITY ONCOLOGY RESEARCH PROGRAM

Advocate Aurora Health is one of 53 community sites participating in the National Cancer Institute (NCI) Community Oncology Research Program (NCORP), which brings adult and pediatric cancer clinical trials to people in their own communities instead of only at major research institutions.

Conducting clinical trials in a range of communities small and large means that a more diverse patient population can participate. This expanded access to clinical trials, in turn, generates more broadly applicable evidence that contributes to improved patient outcomes and a reduction in health inequities related to cancer.

In 2019, NCI awarded Advocate Aurora a six-year, $10.2 million grant – the largest in the health system’s history – to increase patient access to clinical trials at 29 local cancer clinics in both Illinois and Wisconsin. The recognition builds on Aurora’s initial five-year NCORP funding award.

Sigrun Hallmeyer, MD, is Illinois’s principal investigator and Thomas Saphner, MD, is Wisconsin’s principal investigator for the NCORP grant.
Advocate Aurora Research Institute and Advocate Memory Center joined the phase 3 “TRAILBLAZER-ALZ 2” clinical trial evaluating the safety and effectiveness of donanemab, an investigational drug for Alzheimer’s disease recently fast-tracked by the U.S. Food and Drug Administration (FDA).

During an earlier phase 2 trial, donanemab was shown to slow cognitive decline 32% more than placebo after 18 months of treatment. The phase 2 findings prompted the FDA to award donanemab with breakthrough therapy designation, which is only awarded to investigational drugs shown to have a potential to substantially improve treatment for a serious condition compared with currently available therapies. The designation accelerates drug development and review processes.

Donanemab is designed to help eliminate abnormal protein buildup, known as amyloid plaques, found inside the brains of people with Alzheimer’s disease. Scientists believe amyloid plaques may be an early, causal factor and removal may slow cognitive decline.

“We are excited to be part of this highly anticipated trial, since donanemab has shown itself to be very effective in removing amyloid from the brain,” said Darren Gitelman, MD, behavioral neurologist, senior medical director of Advocate Memory Center in Park Ridge, Illinois, and site principal investigator for this trial.

Research participants joining the clinical trial are randomly assigned to 18 months of treatment with either donanemab or placebo. TRAILBLAZER-ALZ 2 is sponsored by Eli Lilly and Company.

Migraines are common during childhood and teen years and account for up to 18% of all pediatric emergency department visits. About one-fifth of children who experience migraines have their first episode before the age of 5.

“Current migraine-preventive therapies for children and teens are limited in number and effectiveness,” said Farha Tokarz, MD, pediatric neurologist at Advocate Children’s Hospital in Park Ridge, Illinois. “The goal is to find a safe and effective therapy to prevent migraine headaches and improve the lives of children and teens who live with this condition.”

Migraines negatively impact a child’s quality of life and affect their ability to participate in daily activities at school, home and socially, according to the American Academy of Neurology and American Headache Society.

Symptoms vary widely over the span of childhood and adolescence, but the most frequently reported migraine symptoms are a moderate-to-severe headache lasting between one and 48 hours, along with nausea, vomiting and sensitivity to light and sound.
Studying stem cell treatment for Crohn’s disease

Aurora St. Luke’s joins a regenerative medicine clinical trial

By working with the Regenerative Medicine Center at Aurora St. Luke’s Medical Center in Milwaukee, Advocate Aurora Research Institute was able to participate in a study of a stem cell treatment for people with Crohn’s disease, a chronic, disabling gastrointestinal condition that affects more than 3 million Americans.

Up to 40% of people with Crohn’s disease develop perianal fistulas, abnormal channels that form between the perianal tissue and the rectum and anus and frequently get infected and become painful.

Some fistulas can be treated with antibiotics or other medications while others are severe enough to require surgery in order to be drained and closed.

For this clinical trial, participants receive either a placebo or the study drug Cx601, a local injection of a solution containing stem cells derived from a healthy donor’s adipose tissue, or fatty connective tissue, which is an abundant source of adult stem cells. In previous studies, Cx601 has shown the potential to aid the body’s immune system in healing complex fistulas in people with Crohn’s disease. The drug has been approved for use in Europe but not yet in the U.S.

Gastroenterologist Nilay Kumar, MD, MPH, is site principal investigator for the study. The clinical trial is sponsored by Tigenix S.A.U., manufacturer of the study drug.

Can artificial intelligence detect mental health disorders?

AI platform integrates with telehealth services to analyze a patient’s words, voice and facial expressions

Advocate Aurora Research Institute was one of just three sites to initially join a clinical trial studying an artificial intelligence (AI)-powered telehealth platform designed to analyze a patient’s words, voice and facial expressions to detect signs of mental health conditions, such as depression, anxiety and suicidal thoughts.

Declining mental health is a deepening crisis in the U.S., with episodes of anxiety and depression increasing up to four-fold during the pandemic, according to the U.S. Centers for Disease Control and Prevention.

“Declining mental health is a deepening crisis in the U.S., with episodes of anxiety and depression increasing up to four-fold during the pandemic,” said Mindy Waite, PhD, senior staff scientist with the Research Institute and Aurora Behavioral Health Services and principal investigator for the study. “The crisis is particularly acute in Black and Brown communities served by Advocate Aurora Health.”

New technologies may be able to help screen for depression symptoms, which could lead to more accessible and timely mental health services. This clinical trial aims to train and validate a technology developed by AI company aibberry, the study sponsor, to detect depression in a diverse patient population.

The AI system takes a video of a patient during their interview with a mental health professional and analyzes multiple data channels – video, audio and speech content – both separately and in combination, to extract patterns specific to a particular mental health disorder. The system then assigns a score showing the likelihood the patient has a particular mental disorder.

Source: U.S. Centers for Disease Control and Prevention

Declining mental health is a deepening crisis in the U.S., with episodes of anxiety and depression increasing up to four-fold during the pandemic.
Academic Research and Strategic Partnerships

Under the leadership of Vice President Denise Angst, PhD, RN, Advocate Aurora Research Institute’s division of Academic Research and Strategic Partnerships comprises four key areas.

Led by a scientific director along with independent research and clinician scientists, our individual Scientific Programs and Centers focus on a select area of investigator-initiated research aligned with organizational priorities.

The Office of Academic Research Support assists individual investigators by overseeing the Research Support Core – which includes research associates, project managers, biostatisticians, epidemiologists and staff scientists – and the Research Institute’s research proposal intake process.

Built on the foundation of the Advocate Center for Pediatric Research, the newly created Center for Child and Family Research is dedicated to the oversight, management, conduct and implementation of child- and family-centered clinical trials and academic research.

Finally, the Office of Research Analytics and Systems Computing delivers high-quality, reproducible data from the electronic health record and other sources to provide evidence-based answers to research questions. See page 7 for more information about this team.

Researchers publish novel heart disease risk findings

Newly identified racial and ethnic differences may be key to preventing serious disease

Advocate Aurora Research Institute researchers identified racial and ethnic differences in risk factors for atherosclerotic cardiovascular disease (ASCVD) among people with high blood pressure, or hypertension, through a first-of-its-kind study published in the American Journal of Hypertension.

"ASCVD – a narrowing of arteries from plaque buildup that often results in heart attack or stroke – is the leading cause of death worldwide," said Rasha Khatib, PhD, MHS, primary author and research scientist at the Research Institute. "We know ASCVD is more prevalent in people of color and designed our study to determine if this inequity also exists for ASCVD risk factors, which is critical information for developing successful prevention strategies that save lives."

Researchers conducted a comparative data analysis, from the health records of 5,227 people with hypertension cared for at Advocate Aurora Health Chicagoland clinics, on four ASCVD risk factors: ineffective hypertension control, smoking, diabetes (using HbA1c lab values) and elevated cholesterol levels. Findings revealed African Americans had the least controlled ASCVD risk factors overall, along with higher rates of uncontrolled hypertension and lack of cholesterol-reducing prescriptions. Additionally, Hispanics, Latinas and Latinos showed a greater trend toward uncontrolled HbA1c levels.

The results underscore a need to help people of color bring these risk factors under control, so the researchers are beginning a clinical trial in 2022 evaluating several new strategies that may ultimately lead to better ASCVD prevention and health equity.

Advocate Aurora Health coauthors include Nicole Glowacki, MPH, epidemiologist at the Research Institute, and Alvia Siddiqi, MD, vice president of Population Health.
Male and the elderly may be underserved in cancer clinical trial enrollment, according to a new study from Advocate Aurora Research Institute that looked at the gender, age, race, ethnicity and socioeconomic status of research participants in Wisconsin.

The investigators analyzed 772 patients participating in National Cancer Institute (NCI) trials among the 40,000 patients with cancer in the Aurora Cancer Registry. The project was initiated to evaluate the diversity of patient participation in Advocate Aurora Health’s NCI Community Oncology Research Program (NCORP).

The study found that only 38.3% of patients with cancer who were age 65 and older participated in clinical trials, compared to 61.7% of patients younger than age 65. The study also found that only 37.6% of men with cancer participated in clinical trials, compared to 62.2% of women with cancer. Race and ethnicity were not statistically significant factors in clinical trial participation in univariable analysis.

Research Institute co-authors include Thomas Saphner, MD, the study’s lead author and co-principal investigator of Advocate Aurora’s NCORP, Andy Marek, manager of research analytics and systems computing, Jennifer Homa, research biostatistician, and Neha Glandt, NCORP administrator, as well as Lisa Robinson, director of Aurora Clinical Data Registries. Karen Cheek, RN, cancer clinical trials manager, was a collaborator. The researchers published their findings in the journal Contemporary Clinical Trials under the title “Clinical trial participation assessed by age, sex, race, ethnicity, and socioeconomic status.”

Helping families of critically ill children

Advocate Aurora Research Institute pediatric researchers completed the final phase of a research project aimed at better understanding the communication needs of families with children admitted to pediatric intensive care units (PICU).

“Previous research proved that family care conferences (FCCs) provide high-quality communication between ICU medical teams and families of adult patients and also contribute to the family’s understanding of their loved one’s hospital course,” said Rani Ganesan, MD, pediatric critical care medicine and palliative care specialist. “But more research is needed for families of children cared for in the PICU. If we can identify families who would most benefit from FCCs, then we can make certain FCCs are offered to them.”

Dr. Ganesan served as the study’s principal investigator at Advocate Children’s Hospital in Park Ridge, Illinois.

Researchers worked closely with PICU health care teams and gathered evidence from both electronic health record data and parent feedback about FCCs. As a result of the study, a set of criteria was developed that proved reliable in evaluating a family’s need for the high-quality communication FCCs provide. The FCC criteria are a series of items measuring a pediatric patient’s illness severity, potential risk for increased severity, goals of PICU care, and discharge planning needs.

The project was a collaboration with Lurie Children’s Hospital of Chicago, with funding support from the National Palliative Care Research Center.

At Advocate Aurora Research Institute, our academic research programs are led by independent research scientists who dedicate their scientific expertise to both Advocate Aurora Health investigator-initiated studies and collaborative projects developed and conducted in partnership with academic or industry partners.

Each of our three leading research scientists have established a robust program of research and successful record of peer-reviewed publications that have brought new scientific evidence to the international health care community.

Veronica Fitzpatrick, DrPH, possesses a strong background in community health, which informs and propels her program of maternal and prenatal health research focused on improving outcomes, advancing care delivery and ensuring health equity.

Rasha Khatib, PhD, MHS, brings extensive experience in epidemiology and implementation science to her research aimed at identifying and developing interventions to reduce racial and ethnic health inequities, particularly related to cardiovascular health.

Michelle Simpson, PhD, RN, uses her expertise in the development of innovative models for geriatric care and aging populations to expand her research focused on improving care for older adults across the health care continuum.
Study finds colorectal cancer rates are quickly rising in younger populations

Researchers recommend colorectal cancer screening for younger or symptomatic patients

Recent rates of colorectal cancer have risen sharply in younger populations even while colorectal cancer rates decline in older populations, according to a 2021 study from Advocate Aurora Health researchers. The researchers found that if colorectal cancer screenings in young people are limited only to those with a family history of colorectal cancer, then a majority of cases in young people will go undetected.

The study findings, published in the journal Gastrointestinal Endoscopy under the title “Colorectal cancer in 18- to 49-year-olds: rising rates, presentation, and outcome in a large integrated health system,” led the authors to echo recent clinical recommendations that colorectal cancer screening begin even earlier in life. Furthermore, the researchers suggest patients with rectal and anal symptoms should promptly seek evaluation from a gastroenterologist.

The study, coauthored by gastroenterologist Nimish Vakil, MD, aimed to evaluate colorectal cancer detection rates at Aurora Health Care, now part of Advocate Aurora, by analyzing confirmed cases using a 32-year cancer database spanning from 1985 to 2017.

The researchers found that a colorectal cancer detection strategy that limits colon cancer screenings to individuals under age 50 with a family history of colon cancer would have found only 49% of cancer cases in the people ages 18 to 44 and only 37% of cases in people ages 45 to 49.

Can a common hypertension drug help veterans with PTSD?

Researchers publish results of study analyzing clonidine as a treatment for PTSD

Veterans with post-traumatic stress disorder (PTSD) treated with clonidine, a drug traditionally used to treat high blood pressure and sometimes attention deficit hyperactivity disorder, had reduced severity of PTSD symptoms, according to a 2021 study from Advocate Aurora Health researchers.

The retrospective study of data from a midwestern Veteran Affairs hospital was published in the Journal of Psychiatric Research under the title “Low-dose clonidine in veterans with Posttraumatic stress disorder.” The researchers found that 72% of patients who were treated with low-dose clonidine experienced improvement in the severity of their PTSD symptoms, and 49% scored “much improved” or “very much improved.”

“Colorectal cancer in 18- to 49-year-olds: rising rates, presentation, and outcome in a large integrated health system,” led the authors to echo recent clinical recommendations that colorectal cancer screening begin even earlier in life. Furthermore, the researchers suggest patients with rectal and anal symptoms should promptly seek evaluation from a gastroenterologist.

The study, coauthored by Gregory Burek, MD, an Advocate Aurora psychiatrist in the Veterans Retraining Program, and Mindy Waite, PhD, senior staff scientist with Advocate Aurora Research Institute and Aurora Behavioral Health Services.

Treatments for PTSD typically include medications and psychotherapy, but research indicates that there is significant variability in treatment response. Because of its ability to regulate norepinephrine levels, clonidine has been suggested as a potential treatment for PTSD. Until now, however, studies evaluating clonidine as a PTSD treatment have been limited.

Compared to other medications used to treat PTSD, such as selective serotonin reuptake inhibitors, or SSRIs, clonidine has a shorter response time and fewer side effects. Previous research suggests clonidine may be particularly effective in treating nighttime symptoms of PTSD, such as sleep disturbances.

The study was coauthored by Gregory Burek, MD, an Advocate Aurora psychiatrist in the Veterans Retraining Program, and Mindy Waite, PhD, senior staff scientist with Advocate Aurora Research Institute and Aurora Behavioral Health Services.
Thank you

Our Advocate Aurora Research Institute annual report would not be complete without recognizing the generosity of our benefactors.

This past year alone, charitable gifts significantly contributed to research grant programs and sponsorship of on-site resources that provided the key personnel and infrastructure necessary for our clinician investigators and research scientists to conduct innovative clinical trials and academic research aimed at helping people live well.

Many research opportunities made possible through philanthropic contributions have resulted in improved health and quality of life, reduced hospitalizations, and decreased health care costs.

We are grateful for the partnership of our many generous donors.

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Every dollar you donate goes toward research that will benefit people in our communities and beyond. Whether exploring new technologies in the lab or transforming best practices at the bedside, your gift will be dedicated to medical discovery and innovation that ultimately contributes to better care, enhanced safety and improved health outcomes.

Let’s continue to advance care through research, together.

*If you wish to donate to research, please contact Advocate Aurora Health Foundations at 877-460-8730 or donate online to Advocate Aurora Research Institute at advocategiving.org/aahresearch.*