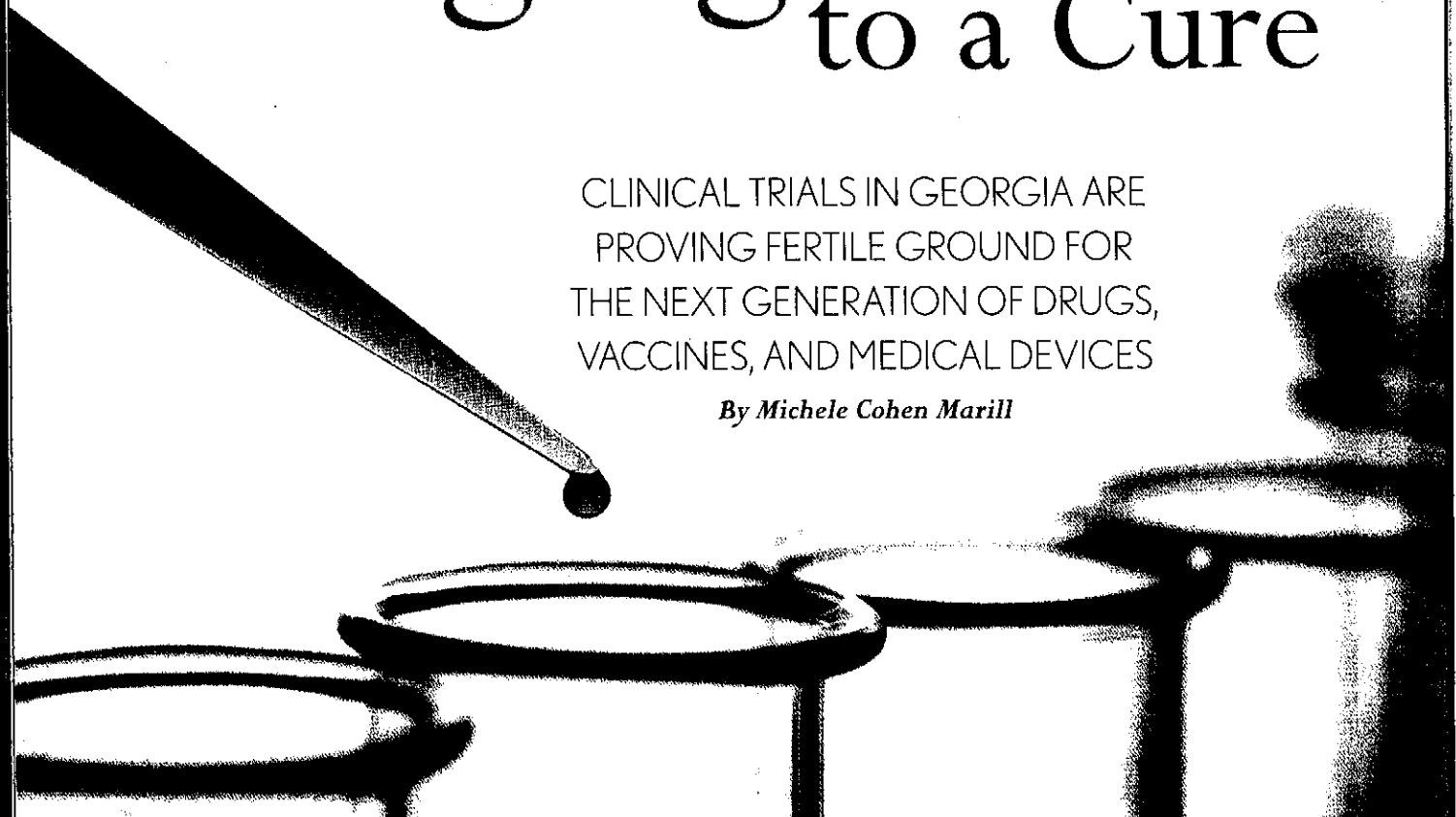


Forging a Trail to a Cure

CLINICAL TRIALS IN GEORGIA ARE
PROVING FERTILE GROUND FOR
THE NEXT GENERATION OF DRUGS,
VACCINES, AND MEDICAL DEVICES

By Michele Cohen Marill



A device that is no bigger than a small paper clip detects signs of heart failure. Two breakthrough drugs keep the HIV virus from replicating. A new transplant drug prevents rejection while preserving kidney function.

These advances were born of hope, ingenuity, and patients willing to step into the frontier of medical research. The path from a brilliant idea to the next great medical innovation is an arduous one, and it often requires hundreds or even thousands of people who are willing to try an unproven treatment. Georgia research centers have crafted a network that connects patients in search of a cure with clinical trials of the most promising drugs, vaccines, and medical devices.

In mid 2011, more than 6,000 clinical trials were underway in Georgia, including studies that seek to

extend the lives of women with advanced breast cancer, improve the treatment of diabetes, and stimulate function after spinal cord injury. There are more than 400 ongoing cancer clinical trials at more than fifty research sites throughout the state.

"This is what advances cancer care. It moves us forward clinically and scientifically," says Nancy Paris, M.S., F.A.C.H.E., president and CEO of the Georgia Center for Oncology Research and Education (Georgia CORE). "There's increasing awareness among cancer patients and consumers that this is a strong indicator of the quality of cancer care."

A discovery in a Georgia lab sometimes becomes the new paradigm. The nation's first coronary stent was implanted at Emory University in 1987. Now, more than half a million Americans receive coronary stents each

year. Two HIV/AIDS drugs developed at Emory are now used by 94 percent of Americans being treated for that disease. Seven drugs have been developed at Emory, the fourth-highest number of drug and vaccine discoveries by a U.S. public-sector research institution in the past forty years.

Just last fall, the first patient in the U.S. to receive an embryonic stem cell injection for a spinal cord injury occurred during a landmark FDA-approved clinical trial at the Shepherd Center. And in March, the first patient in the Southeast to receive a complete hand transplant (fourteen such procedures have been performed in the U.S.) took place at Emory University Hospital.

"Patients don't need to travel to Florida or Minnesota to be able to get leading edge care," says Jeff Kingsley, D.O., chief executive officer of SERRG Inc., a multi-specialty research organization based in Columbus that also has facilities in and near Savannah. "They can get access to the cutting edge of medicine right here in Georgia."

During the recession, many companies cut back on their research-and-development budgets, and resources remain a concern. But Georgia is well-positioned to gain as research funding ramps up again, says Kingsley. "There's more research being done here today than there was at any time in the past."

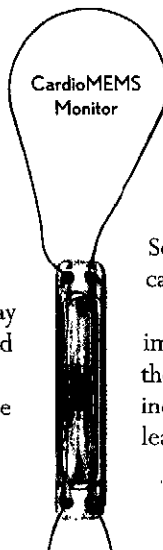
YOUR CARDIAC DEVICE IS ON EMAIL

Nirav Raval, M.D., a cardiovascular specialist at the Piedmont Heart Institute at Piedmont Hospital, was at a symposium recently, preparing to explain a new device for monitoring heart failure, when he got an alert on his Blackberry. It was, essentially, the device sending an email. A patient's pulmonary artery pressure was too high. Raval's team would respond by adjusting her medication.

With those taps on his Blackberry, he demonstrated the immediacy of the CardioMEMS approach. Implanted in the pulmonary artery, the tiny, wireless sensor is powered by radiofrequency and sends information to a monitoring unit in the patient's home. That unit then transmits the real-time results to the physician. It was created with micro-electromechanical (MEM) systems developed at the Georgia Institute of Technology.

A recently completed clinical trial found that the CardioMEMS monitor reduced hospitalizations by 38 percent and improved the quality of life of heart failure patients. The clinical trials were conducted at sixty-four prominent heart centers around the country, six of them in Georgia. The diversity of the patient population here provided a strong basis for the research, says Jay Yadav, M.D., founder and CEO of CardioMEMS and a cardiologist with the Piedmont Heart Institute.

"If the purpose of clinical research is to determine if a device or a drug is applicable to the general



Georgia's strength lies in integrating basic research, clinical research, and biotech incubation.



The Harbin Clinic in Rome, Georgia

population, then the research has to be conducted in institutions that mirror the general population," Yadav says.

That means engaging patients in rural communities and urban centers, of various ages and ethnicities, at physician offices and major medical centers. The Harbin Clinic, the state's largest privately owned multi-specialty physician group, has conducted more than 170 trials and enrolled more than 700 patients at its facility in Rome. As a member of the Atlanta Regional Cooperative Clinical Oncology Program, it literally brings national studies to the doorstep of people in north Georgia.

A plaque on the wall in the reception area of the Southeast Regional Research Group in Columbus lists the drugs that have come to market because of clinical trials conducted at the facility. They include an anticoagulant, antibiotics, treatments for COPD, treatments for diabetes, and a drug for patients in renal failure. While nationally, minorities have been underrepresented in clinical trials, about 40 percent of the patients enrolled in trials by the Southeast Regional Research Group are African American, matching the community demographics.

The Morehouse School of Medicine also works to improve access to clinical trials and build support in the minority community. A community advisory board includes clergy, teachers, nurses, and other community leaders, and a research-subject advocate acts as an

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PIONEERING A PROMISING SOLUTION FOR HAIR LOSS

Hair loss affects 80 million people in the U.S. alone. In an effort to solve this problem, Aderans Research Institute is pioneering an innovative cellular-based hair regeneration process. It is being tested in a clinical study across the country, and the biotechnology industry is taking note.

www.aderansresearch.com



The Winship Cancer Institute at Emory University

ombudsman for patients after they enroll. "We find that [opportunity for] feedback helps us get the trust of the participant," says Elizabeth Ofili, M.D., M.P.H., F.A.C.C., chief of cardiology, associate dean for clinical research, and director of the Clinical Research Center at Morehouse. "People want to know, 'Someone is looking out for me in this study.'"

Meanwhile, the Winship Cancer Institute at Emory University became a designated National Cancer Institute site in 2009, expanding access to clinical trials that originate around the country. Georgia CORE has extended its network throughout the state, with 371 oncologists at sixty-eight research sites. About 40 percent of their clinical trials take place outside of metro Atlanta. While it boosts cancer care, the Georgia CORE network also creates an opportunity for companies looking for a proving ground for their promising new treatments. "There's capacity to take on new clinical trials in the state," says Paris. "There's a mechanism for doing research that is efficient and effective."

TEAMWORK BREAKS THROUGH BARRIERS

Imagine the future of medicine if some of today's clinical trials prove

effective:

- A drug developed at Emory may spur the bone marrow to regenerate blood vessels to replace those that are blocked.
- Transplanting pancreatic islets may allow diabetics to live without insulin injections.
- Gene therapy may provide a nerve growth factor to the brain to sustain brain cells and halt the degeneration that occurs with Alzheimer's disease.
- "Pharmacogenetics," under study in a Morehouse-led trial, may use genetic markers to determine the optimal dose of warfarin, an anticoagulant.

Some clinical research opens the door to entirely new ways of treating disease. Some may cure conditions that were previously incurable or bring new hope where progress has been difficult. While the therapies vary, there is a common thread. Collaboration across disciplines and academic institutions creates new possibilities.

Interventional cardiologists and cardiac surgeons—once at odds because of their different approaches to cardiac disease—have worked together to create a bioprosthetic valve that can be placed over an existing valve through a catheter. Instead of spending weeks in the hospital, a

patient might be able to return home within a few days.

"Team science is so important now. That's the changing face of science," says W. Robert Taylor, M.D., Ph.D., director of the division of cardiology at the Emory University School of Medicine. Taylor has a joint appointment as a professor of medicine and biomedical engineering, a joint department between Emory and the Georgia Institute for Technology.

The Atlanta Clinical and Translational Science Institute, created four years ago, brings together researchers from Emory, the Morehouse School of Medicine, Georgia Tech, Children's Hospital of Atlanta, and Kaiser Permanente of Georgia. "We've lowered the administrative barriers to working within the [institute]," says Jeff Sands, M.D., senior co-principal investigator at ACTSI and professor of medicine, renal division director, and executive vice chair of medicine of the Department of Medicine in the Emory

A discovery in a Georgia lab will sometimes become the new paradigm.

School of Medicine.

DOING MORE, EXPECTING LESS

For all of the progress, there are still significant barriers. State funds support the Georgia Cancer Coalition, which promotes research and other cancer organizations such as Georgia CORE. In 2010, Georgia institutions received \$417 million from the National Institutes of Health (NIH). Georgia ranks sixteenth in NIH funding, although the state is the

nation's ninth most populous.

Researchers have been told to expect less from the NIH in upcoming budget cycles. The state's finances are strained. It's harder to attract investment for biotech startup companies during an economic downturn. And yet the great ideas—and the great medical needs—have not abated.

"With the current fiscal climate, the federal government is going to be contracting its research infrastructure in a greater way than ever before. Because of that, our partnerships



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Learn more at StrokeAssociation.org or 1-888-4-STROKE.

with industry and venture capital and philanthropy are going to be more important than ever before to keep the momentum going," says Allan Kirk, M.D., Ph.D., scientific director of the Emory Transplant Center and vice chair for research in the Department of Surgery at the Emory University School of Medicine.

Georgia's strength lies in its ability to integrate basic research, clinical research, and biotech incubation, thanks to entities such as the state-supported Georgia Research Alliance. It provides a platform "where everyone is talking to each other and you can maximize the progress you're trying to make," says David Munn, MD, professor of pediatric oncology at the Georgia Health Sciences University in Augusta.

Munn and his colleague, Andrew Mellor, MD, a professor of medicine, identified an enzyme that blocks the immune system, opening up the potential to improve cancer immunotherapy, reduce the rejection risk of transplanted organs, and treat autoimmune disorders. D-1MT, an anti-tumor pill based on their research, has been licensed by a biotech company in Ames, Iowa, and is in early clinical trials as an adjuvant, or added boost, of a cancer vaccine.

What about biotech firms in Georgia? Top researchers and facilities here are building an "intellectual capital" that will attract more biotech companies, says Mellor. "We are growing the best science here, and this will crystallize life sciences commercialization in the future," he says.

Add that to the state's already rich mix of pharmaceutical, biotechnology and medical device companies, ranging from small R&D firms to established multi-national corporations, says Georgia Bio President Charles Craig, and you'll see that "they are essential drivers of medical innovation."

But Georgia needs to maintain its investment in both basic and clinical research, says Kirk. "We have built something special in Georgia," he says. "It's making real differences in real patients."