

## United Therapeutics to build pig-to-human organ research center in southeast Minnesota

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This southeast Minnesota city could soon be at the forefront of efforts to use genetically modified pig organs for human transplants.



United Therapeutics Corp. said it will invest about \$100 million into a specialized research farm in Stewartville's Schumann Business Park.

The facility, set to begin operations in 2027, will be the second of its kind for United Therapeutics, the biotechnology company responsible for engineering organs for the first-ever pig-to-human heart and kidney transplants.

United plans to build the research site on 32 acres of land about 10 miles south of downtown Rochester. The Maryland-based company paid \$4.5 million for the property.

The 70,000-square-foot facility will model one already up and running in Virginia's Blue Ridge Mountains, said Dewey Steadman, head of investor relations at United. To prevent exposure to pathogens, all pigs will be born and harvested within the tightly controlled facility, which is equipped with biosecurity measures regulating every aspect of their lives.

"Every item that crosses the barrier into the pig area is filtered or sterilized to kill pathogens—this includes air, water, feed, bedding, tools and environmental enrichment toys," Steadman said.

The practice of animal-to-human transplants, known as xenotransplantation, has taken on new life in recent years thanks to advancements in gene-editing and immunosuppressive drugs.

While data outside of the lab remains limited, there is hope among scientists that xenotransplant organs could soon play a pivotal role in solving the shortage of organs available for transplant. In the U.S., there are now more than 100,000 people awaiting an organ, with about 90% of them in need of a kidney.



"There is a real expectation that this will have a role in how we treat patients," said Dr. Andrew Adams, chief of the Division of Transplantation at the University of Minnesota Medical School, who is not associated with United Therapeutics. "The question is timing and how much more development it needs before it's ready to be used in patients."

The idea of xenotransplantation has been around for decades, but attempts at it have proved mostly unsuccessful.

That began to change in the past five or six years, said Adams, with the emergence of better tools for cloning and gene editing—none more important than the CRISPR-Cas9 technology, a revolutionary development that earned two researchers the Nobel Prize in chemistry in 2020.

Using the CRIPSR-Cas9 "genetic scissors," scientists are now able to remove certain pig genes from the organ while adding human genes to improve the organ's functionality in the human body. The technology, coupled with new immunosuppressive drugs, has helped solve issues with early rejection after a xenotransplantation.

In 2022, the University of Maryland conducted the first successful xeno-heart transplantation using an organ from Revivicor, a company owned by United. The patient, on <u>life support</u> and ineligible for a human transplant, died six weeks later. Still, the experimental procedure was hailed as a milestone and provided evidence that a gene-edited pig heart can function in the human body. The first successful pig-to-human kidney transplant was performed earlier this year.

"The focus now is getting some consistency with good outcomes in the early post-transplant period, and then seeing if we can push the success rate for longer transplant survival for xenotransplants beyond what's



been observed so far," Adams said.

The announcement of the Minnesota facility comes as United seeks FDA clearance to begin clinical trials to prove the safety and effectiveness of pig-to-human organ transplants. Human studies would initially focus on modified kidneys.

In selecting the Stewartville site to support its ongoing research, Steadman said a number of factors stood out: the region's skilled health care, biotech and agricultural workforce; proximity to Rochester International Airport; and the presence of Mayo Clinic.

While Mayo is not directly tied to the project, United and Mayo have a history of collaboration. In 2019, the two organizations partnered to build a 75,000-square-foot discovery and innovation center on Mayo's Jacksonville, Fla., campus aimed at addressing the shortage of lungs available for transplant. In 2022, United CEO Dr. Martine Rothblatt was appointed to serve on Mayo's Board of Trustees.

Mayo also has ties to Miromatrix, a University of Minnesota startup acquired by United in 2023 for \$91 million. Miromatrix's work focuses on engineering organs for transplant by adding human cells to pig kidneys and livers. In 2021, researchers with Miromatrix and Mayo collaborated to successfully transplant bioengineered livers into pigs.

Mayo declined to comment, referring questions to United.

Once up and running, United plans to have up to 200 pigs on site and employ about 20 people. Staff will all be required to shower and be fully covered in sterilized clothes before entering the facility. They will be regularly screened for any pathogens that could be transmitted to the pigs, Steadman said.



United's hope is that <u>human studies</u> could begin as early as next year, with the Stewartville facility eventually playing a major role in supporting the research.

Adams, the U professor, said he sees the potential for xenotransplantation to become a more common practice in the next five to 10 years, providing options for patients who are running out of time as they await a human <u>transplant</u>.

Still, he cautioned, more research and data are needed to prove pig organs can be the answer to shortages in organ donations.

"There is a lot of excitement," Adams said. "But based on what we know today, there is still a little more work that needs to be done before this is a therapy that is ready for prime time."

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