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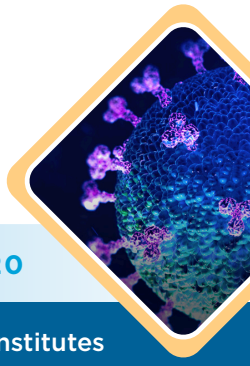

AN UNPRECEDENTED IMPACT

A SERIES OF FACT SHEETS ON COVID-19 AND BIOMEDICAL RESEARCH

JULY **2020**

We must maintain and strengthen our nation's investment in medical research through the National Institutes of Health. This is an urgent priority for Congress, as our nation works to restart stalled research, keep up with pressing public health challenges, continue to fight COVID-19 and prepare for the next potential pandemic.

PART 3 | PROGRESS ON HOLD | Researcher Profiles

While research on the disease caused by the novel coronavirus has been on a fast track the past several months, most other medical research ground to a halt in March and has yet to resume at anything near its pre-COVID pace. It is impossible to know the full implications of suspended work, lost experiments and delayed clinical trials, but for those waiting for a cure, time matters.

Steven Soper, PhD
Foundation Distinguished Professor | Chemistry and Mechanical Engineering | University of Kansas

KU THE UNIVERSITY OF KANSAS

DR. STEVEN SOPER and his lab at the University of Kansas (KU) had an important goal in sight when mandatory closures due to the COVID-19 pandemic were put in place in mid-March. The team was on a tight timeline to collect critical "proof-of-concept" data for a new technology that he expects will revolutionize disease testing and management by enabling the sequencing of RNA and DNA from a liquid biopsy marker easily and inexpensively outside of major medical centers.

> "Our data collection came to a screeching halt. Unfortunately, you can't just turn on a light switch and get back to where you were.

One of the applications they are developing the technology for is to guide treatment decisions for pancreatic cancer patients and help in the discovery of new therapies for these patients. There are few treatment options for pancreatic cancer patients due to the fact that the disease is typically diagnosed at an untreatable stage. This is the disease that recently claimed the life of Congressman John Lewis.

What makes his technology, the X-TOF nanosensor, unique is that it combines a relative low cost and small package with full automation to enable detection of illnesses from a very small amount of DNA from a blood sample. While most sequencing technologies require nanograms of DNA, Soper's technology can detect cancer from picograms (1000x smaller). This high sensitivity, combined with the fact the test can be done in a doctor's office, opens the door to detecting cancer at its earliest stages when it is most treatable — potentially saving more lives. This is particularly important in the case of pancreatic cancer, where it is often not found until later stages when the cancer can no longer be removed with surgery and has spread from the pancreas to other parts of the body.

The technology also facilitates local disease management and monitoring, reducing patient travel and providing what Soper calls "distributive

PANCREATIC CANCER

57,600 U.S. adults will be diagnosed with pancreatic cancer this year

Currently, **no specific, cost-effective screening tests exist** to easily and reliably find early-stage pancreatic cancer in people with no symptoms

For the 53% of people who are diagnosed after the cancer has spread from the pancreas to a distant part of the body, **the 5-year survival rate is 3%**

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UNPRECEDENTED IMPACT, *cont.*

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medicine," or getting medical services into the communities where they are needed. Presently, there is only one technology that provides distributive sequencing, but it requires micrograms of DNA — six orders of magnitude more than the X-TOF nanosensor.

The proof-of-concept data are essential to meeting key technical milestones for Sunflower Genomics, Inc., a new startup company in Kansas that is licensing the technology from KU. Meeting the milestones and continuing to demonstrate the unique potential of the technology are essential to convincing investors to support the company and moving the technology from the lab to the marketplace where it can benefit patients and improve the provision of healthcare.

Additionally, securing this data would support grant proposals to the National Institutes of Health (NIH) to continue his lab's academic research in this area.

As of mid-July, Soper estimated that the lab closure from mid-March to the end of May put them six months behind schedule. **"Our data collection came to a screeching halt," he said. "Unfortunately, you can't just turn on a light switch and get back to where you were."** Research facilities at KU are operating at about 50–75 percent occupancy due to social distancing requirements and he is concerned about another potential shutdown due to rising COVID-19 infections.

Right now, he's trying to speed things up the best he can and generate some helpful preliminary data, but he doesn't expect to have what he really needs until year-end. His grant proposal was due to NIH in late May and was submitted without the key proof-of-concept data so he doesn't know how it will be judged by the review panel and whether the hoped-for grant will be forthcoming. He also won't hit the upcoming August milestone for the startup's licensing agreement.

Soper's technology is applicable to other diseases, including the one caused by SARS-CoV-2. As a vaccine becomes available, monitoring for variations of the virus' genome will require rapid RNA sequencing. **"Our technology will provide rapid sequencing results in any laboratory to make sure the proper vaccine is administered to the patient,"** he explained. However, along with the other work, retrofitting the technology for use in the current pandemic also will be delayed.

EXONUCLEASE TIME-OF-FLIGHT (X-TOF) NANOSENSOR

- ✓ **Small and relatively low-cost:** A shoebox-sized instrument; the plastic chip at its core is easy to mass produce using production lines similar to those used for CDs, DVDs, and Blue-Ray Discs.
- ✓ **A variety of applications:** Can sequence both DNA and RNA, making it useful in a number of other diseases. For example, it can be used to monitor bacterial infections as well as determine the specific type of breast cancer a patient has to enable better treatment decisions.