

ATTACKING COVID-19

From the molecular level to drug development to clinical trials, Buffalo companies and research institutions collaborate with worldwide partners to test and treat coronavirus

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Drug development typically runs at a snail's pace, with timelines often extending for multiple years.

That formula has been tossed aside as researchers and pharmaceutical companies from around the world race to come up with treatments for COVID-19. Processes that once took months are now unfolding in days.

In Buffalo, that has led to expanded collaborations locally and internationally, with unprecedented sharing occurring.

"I can't even begin to describe the worldwide scientific effort that's involved in this," said Edward Snell, president and CEO of Hauptman-Woodward Medical Research Institute. "I don't think there's any competitive stuff going on out there. So many people have shared information before it's published. That's pretty rare.

"Typically, everyone's competing for funding, everyone's competing to be the first for something," he said. "And now, people are just throwing things out there."

HWI is contributing to the effort at the very early levels. Other research institutions and private companies are getting involved at other phases of the continuum. Here's a look at local efforts to make a difference in the battle against the coronavirus.

ZeptoMetrix

In mid-March, ZeptoMetrix received its first shipments of coronavirus samples, from which it will create inactivated specimens of SARS-CoV-2. Those will be used by diagnostic companies working to develop more accurate tests for the disease.

The Buffalo company develops natural and synthetic virus specimens for customers such as academic researchers, private firms and government labs.

Hauptman-Woodward

HWI works with many of those same types of customers, but at the structural-biology level. HWI's role in the process starts with identifying microscopic proteins in its crystallization center.

HWI is working on four COVID-19 related projects for client laboratories in Tennessee and Minnesota. HWI is growing the crystals that make up the jigsaw-puzzle pieces of the virus.

"What we literally do is make the invisible visible," Snell said. "We're trying to see what components of the virus look like. If we can see what they look like, we can stop it from reproducing."

HWI also has drug-discovery projects underway at its Chicago facility

supporting academic and pharmaceutical-company efforts for treatments. More projects are expected to come in over the next week.

HWI is working on computations with scientists around the world that could be applied to thousands of potential drug treatments now under exploration.

"It's a huge international effort. I've never seen anything like it," Snell said. "We have subject-specific boards online, and everyone is sharing information, sharing ideas. And everyone is engaged."

Circuit Clinical

Once a drug is identified as a possible candidate, clinical trials begin. That's where companies such as Circuit Clinical come in, helping physicians identify clinical trials for their patients, and giving pharmaceutical companies a place to share their research on novel therapies.

The Buffalo firm, founded by cardiologist Dr. Irfan Khan, has developed a COVID-19 working group with clinical trials and biotech expertise. He is also studying how best to use the company's decentralized network of research sites to help identify patients in multiple locations.

"We are at this really important window where we're going to need to collect the samples to let people do the basic science," Khan said.

Khan said it will still be a few weeks before Circuit Clinical can actually begin its work, because researchers want to do things right and thoughtfully. But companies working on both tests and treatments are already lining up, he said.

"There's huge demand. We're getting calls from pharma companies around the country saying, 'You guys are in a hot zone.'" he said. "Right now, there are 47 clinical trials across the country, but there are dozens more on the way. It would not surprise me if there were hundreds up and running by the end of the year."

Roswell Park Comprehensive Cancer Center and the University at Buffalo

Clinical trials kicked off this week at Roswell Park Comprehensive Cancer Center in tandem with the University at Buffalo to test the effectiveness of an anti-inflammatory drug commonly used to treat lupus and rheumatoid arthritis.

The trial is part of an international COVID-19 trial sponsored by Regeneron to assess the effectiveness of the antibody sarilumab (Kevzara). It's the first of several clinical trials for therapies expected to begin soon at Buffalo trial sites.

Dr. Igor Puzanov, director of the early-phase clinical-trials program and chief of melanoma at Roswell Park, said the criteria for inclusion required sites to be ready quickly.

"You had to promise to be active in 24 to 48 hours," he said. "Based on our prior experience and having the infrastructure here at Roswell, I said yes, absolutely.



A view of the Frontier Science Foundation on Maple Road.

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"Without that (infrastructure), we wouldn't be able to do it. You have to be ready for the opportunity. It's the same as anything else in life. Opportunity favors the prepared."

The trial will include eligible patients from Buffalo General Medical Center, Erie County Medical Center and Millard Fillmore Suburban Hospital.

Patient protocols for those patients will be overseen by Gene Morse, co-principal investigator of UB's School of Pharmacy and Pharmaceutical Sciences, who also leads the UB Center for Integrated Global Biomedical Sciences and serves as director and representative for the Global Virus Network.

Participating clinical-trial sites are expected to enroll 400 patients around the country, including the sickest patients with confirmed COVID-19 infections who require high levels of oxygen and intubation and whose organs are failing, Puzanov said.

The hope is this anti-inflammatory drug will help the lungs improve to the point where a ventilator isn't needed, he said.

Other trials are likely to come to test patients at different levels of the disease, he said, through several therapies still undergoing FDA review. That includes some where the science was developed at Roswell Park.

"A lot of the intellectual strengths we garner to fight cancer, we can repurpose to fight this virus," Puzanov said. "We're looking at what we've learned about the immune system through immuno-oncology. Now you see that being applied here in this situation."

Frontier Science Foundation

At the tail end of the continuum are companies such as Frontier Science Foundation, which provides computational analysis of all data from clinical trials to determine if the drugs are actually working.

Based in Amherst, the nonprofit spun off from UB in the 1970s and now crunches

numbers and helps researchers around the world to manage data and run statistics.

With millions of dollars in funding from the National Institutes of Health, Frontier Science has focused most of its work on cancer and HIV/AIDS for research consortiums that include Harvard University, Dana-Farber Cancer Institute, UCLA and institutions around the world.

CEO Suzanne Siminski said the network has now been repurposed to focus on COVID-19, and Frontier Science will be right in the thick of it.

Frontier has about 30 staffers working on this project to test the database and manage the data.

A typical study protocol would take about six months to develop through its network infrastructure, but this one has been pulled together in about six days, with enrollment in studies expected within the month.

"We've been doing similar work for the past 40 years, so we have the infrastructure," Siminski said. "We can leverage all the things we've done in HIV and the other infectious diseases and get up and running ASAP."

To help in that process, Frontier Science will pivot along with its partner networks, as it has done before to address H1N1 and other major international outbreaks, said Marlene Cooper, Frontier's principle investigator.

"We're able to be pretty agile when a new research need comes up, where we can very quickly develop a protocol and get that information into the field," she said.

Frontier Science is the liaison, adjusting the study design by using best practices and providing data collection that results in balanced, clean information.

"Then statisticians can do that analysis, so you can publish and get that data into the field quickly," Cooper said. "We're really the liaison between the clinical sites, who are the boots on the ground seeing the participants and collecting that data."