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For UCHealth, Campus Partners, New Center Is Both Business and Personal

By Tyler Smith

University of Colorado Health and its partners on the Anschutz Medical Campus embarked this month on an ambitious effort to blaze new trails in research, innovation, and clinical care.



David Schwartz, MD, chair of the Department of Medicine at the University of Colorado's School Medicine, says the Center for Personalized Medicine and Biomedical Informatics promises to change patient care, but cautions that it will develop over a period of years, not months.

The Center for Personalized Medicine and Biomedical Informatics, formally announced April 20, is a five-year, \$63 million investment and collaboration between UCHealth, the CU School of Medicine and its Department of Medicine, University Physicians, Inc., and the University of Colorado. One aim is to expand the DNA testing necessary to develop new therapies that target specific genetic mutations in patients with cancers and other diseases. The work, broadly characterized as "personalized" or "precision" medicine, has yielded a crop of new targeted medications in the past decade

and improved clinicians' ability to predict how well – if at all – patients will respond to a particular therapy.

"This program will fundamentally change the way we offer care for patients by moving from a reactive system where we treat patients with established disease to a proactive system where we predict who will develop disease and identify disease in its very earliest stages," David Schwartz, MD, chair of the Department of Medicine at the CU School of Medicine, said in a press release.

It's an idea whose time has come, said <u>Matthew Taylor</u>, MD, PhD, director of the Adult Genetics Clinic at University of Colorado Hospital.

"Personalized or precision medicine is the way science is heading," Taylor said. "Sequencing genes is now commonplace; it's no longer confined to a small group of scientists."

Growing cadres of researchers and clinicians, Taylor said, have set their sights on large-scale data mining to unlock the secrets of cancer and diabetes, as well as varieties of lung, kidney, heart and other disease heavyweights that burden patients and the health care system.

The benefits of personalized medicine have been particularly noteworthy in cancer, said <u>Dan Theodorescu</u>, MD, PhD, director of the University of Colorado Cancer Center, and the center promises to extend them to other diseases.

"Molecular tests and targeted therapies are already here, and they're a contributing reason why our patients' survival rates for certain types of cancer are significantly better than national

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outcomes," Theodorescu said in the press release. "This Center will bring those kinds of outcomes and life-saving therapies to all diseases in a similar way while providing more laboratory and computational power to evaluate cancer DNA."



Leaders of Health Data Compass, a data warehouse that will be an essential component of the new center. Left to right: Interim Director Michael Kahn, Director of Finance and Administration Donna Brown, and Associate Director Michael Ames.

In the bank. A key building block of the center will be a DNA bank that will provide the molecular grist for research and discovery. But that bank will be part of a much larger data warehouse, dubbed Health Data Compass, that will house and integrate vast stores of clinical and financial information pulled from the Epic electronic health record and other sources.

At present, genetic information is available in labs and biobanks scattered around campus — most notably the Cancer Center's Tissue Banking and Processing Shared Resource — and clinical information is housed in Epic and other medical records databases. But a researcher interested in linking DNA samples to the medical records of disease-specific cohorts of patients — to understand the characteristics they share with others in the group or how they differ from others who do not have the disease, for example — has no practical way of doing so.

"We do not have an integrated research engine today," said Steve Hess, chief information officer for UCHealth. Health Data Compass, he said, will be the repository where previously disparate streams of information will merge.

A crucial link to the DNA bank will be the Department of Pathology's Colorado Molecular Correlates Laboratory (CMOCO), which today uses so-called next generation gene sequencing to crunch massive

amounts of genetic data in search of cancer-associated genes known to respond to targeted therapies.

<u>Dara Aisner</u>, MD, PhD, co-director of CMOCO and assistant professor of pathology at CU, said she stores DNA and with proper consent is willing to send samples to clinical trial sites that request it. It's an ad-hoc approach that helps individual researchers and patients get to an end point, she said.

"But I don't link my lab's DNA to patients' medical records," she said. "A DNA bank would let us get to a different level of research and integration with clinical care."

Bench to bedside and back. Aisner envisions a loop of innovation running from collection of a DNA sample to gene sequencing in CMOCO or another lab to research through Health Data Compass to clinical discoveries that create new standards of patient care. In turn, hospitals and other providers seeking more sophisticated and effective ways to manage patients' health would drive demand for additional testing, research, and discovery.

"As research and clinical care integrate in tighter circles, population health management may help to drive personalized medicine,"

Aisner said

Health Data Compass won't include entire genomes of patients, but rather files that are maps of mutations across chromosomes — towering mountains of information "boiled down to a useful level," in the words of Michael Ames, MBI, associate director of Health Data Compass. Researchers could link the genetic data in these files to clinical and financial information that might help drive operational decisions, Ames said.

For example, the data warehouse might help researchers develop risk models based on discovery of biomarkers that predict positive or negative outcomes in patients who receive particular drug therapies, said Health Data Compass Interim Director Michael Kahn, MD, PhD. That information, in turn, might be translated into best practice advisories in Epic that guide providers' clinical decisions.

"That contributes to the efficiency of health care because it takes off the table costly treatments that don't benefit patients and allows us to redeploy resources," Kahn said.



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It's a predictive approach that represents a radical departure from the way much of medicine is conducted today — essentially try a treatment and see what happens, Taylor said.

"Our approach often has been to treat first and ask questions later," he said. "By gathering together genetic, social, and exposure data, we're trying to do a better job of thinking first, then treating and evaluating the outcomes."

Many questions. The formation of the center generated interest outside the world of the campus and UCHealth, including a lengthy Denver Post article. But it is very much a work in progress with many questions to answer. Schwartz, for example, said in an email that he anticipates the DNA bank will ultimately store several hundred thousand samples, but will take three to five years to develop. How to ensure the privacy of patients who contribute DNA samples to the bank is another thorny question, he said.

"We will need to carefully plan this component of the Center and engage the medical community, the institutional review board, lawyers, ethicists, the community, and clergy in figuring out how we're going to request specimens, how we obtain consent, and how we store specimens," Schwartz wrote. "This planning process may take more than a year."

Meanwhile, Health Data Compass is close to selecting a vendor to build the data warehouse infrastructure and could begin implementing the technology late this summer, Kahn said. Agreements are being developed to draw data from UCHealth, Children's Colorado, and UPI once a vendor is in place and contracts have been approved, he added.

"Our mission is to have a basic set of data and bring it up in 18 months," Kahn said.

Put to the test. But he emphasized that Health Data Compass will have to prove its worth to the small army of people already doing research on the Anschutz Medical Campus.

"If I have a lab and I have all the data to do my project, what is my incentive to use Health Data Compass?" Kahn asked. "We will have to demonstrate that we have a repository of data that is broader than what is available to an individual investigator, and that it will help make new connections in their research."

Kahn also stressed that Health Data Compass is not designed to take over the roles of those working in other databases. Its

value, he said, will be in gathering and integrating data from other systems, not in subsuming them.

"We're not replacing anything," he said. "The tools that are already in place will remain useful to those requiring a single institution's view of data; Health Data Compass is for those people who need an integrated view of disparate data."



CMOCO Co-Director Dara Aisner, MD, PhD, with Ellen Smith, a six-year survivor of stage IV lung cancer who was helped by targeted therapy at the University of Colorado Cancer Center.

Nor will Health Data Compass staff do the heavy lifting of research, Ames added. He envisions the warehouse's core team working closely with interested staff embedded in departments and programs around campus.

"The data is useless if it goes in and doesn't come out," Ames said. "We want to put power closer to the users."

Over time, as Health Data Compass grows, he said, demand will increase for innovative people with expertise in data science and advanced analytics. That's what's happened at Vanderbilt University Medical Center and Columbia University Medical Center and other academic trailblazers.

"With the support of two hospitals, UPI and the CU research enterprise, we're set up to create a distinctive resource that could compete nationally in breadth and quality," Ames said.

Forging new paths. Hess, who acknowledged that the benefits of personalized medicine may take several years to emerge, said Health Data Compass could nonetheless help to drive clinical and operational efficiencies much more quickly. For example, integrated clinical outcomes and financial data might help UCHealth hospitals



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develop new protocols and algorithms for treating patients with heart failure, diabetes, COPD and other conditions — the core of population health management.

"If we do it well, we can provide decision support to clinicians rather than rely on the heroic efforts of individuals in treating disease," Hess said. Proven successes in population management he added, will make it easier for researchers to submit and gain approval for grant proposals.



Natalie Thomas of CMOCO prepares tumor tissue for molecular studies by cutting the tissue into thin sections, which can subsequently be used to isolate the tumor cells for testing.

There is also the matter of who ultimately will lead the Center for Personalized Medicine and Biomedical Informatics. Taylor, who is on the search committee charged with selecting a chief, said the ideal leader would combine knowledge of genomics, medical records databases, and precision medicine — or at least be able to speak the language of all three. He or she will also need to balance competing demands among its partners about what the center should be.

"The individual will need a clear vision of the center's long- and short-term goals and a vision and plan for how to get there," Taylor said. That leader, he added, will need to decide quickly which projects need to be deployed immediately, understand how to characterize the center's successes to the public, and choose the next areas of discovery.

For Kahn, forging new clinical and research paths is at the core of the new direction in medicine that the Center for Personalized Medicine and Biomedical Informatics represents.

"The mission for Health Data Compass is to support discovery," he said. "If you just have data without people leveraging and exploring the data in strange and unusual ways, all you have is data."