

# HOW PERSONALIZED MEDICINE IS CHANGING BIOSCIENCE AND MEDICINE

BY DOUG MCPHERSON

**T**he way Jack Wheeler sees it, personalized medicine is where we're all headed.

But like a long family vacation, shouts from the back seat of "Are we there yet?" can still prove annoying.

The answer, of course, is not yet. But some say Colorado is doing its part to ensure a timely arrival at what promises to be a game-changing destination.

"It's true that the whole industry is slow right now," says Wheeler, founder and vice president of business development of MicroPhage Inc., a Longmont company that develops rapid diagnostics

products. "There's a lot of talk, but when we talk about a particular diagnosis related to a prescription, we're not there yet. It's where everyone wants to go but it's not often seen."

Nevertheless, Wheeler and others say personalized medicine in Colorado is passing mileage markers. "There's a huge opportunity going forward in the industry," he says.

In early 2009 MicroPhage announced that its new bacterial identification test, which quickly shows if blood is infected with common hospital bacteria, completed its first multi-center clinical trial, moving the product moved closer to market.

## MILE MARKERS ALONG THE WAY

In the first quarter of 2009, Accera Inc., a Broomfield biotech that focuses on therapies for central nervous system diseases, launched a new product called Axona, which manages mild-to-moderate Alzheimer's disease.

ARCA biopharma Inc., a biopharmaceutical company, also in Broomfield, that develops genetically targeted therapies for cardiovascular diseases, is working on bucindolol, which treats chronic heart failure.

Denver-based National Jewish Health has created centers on bioinformatics, genetics, therapeutics and advanced diagnostics.

"Although National Jewish focuses on respiratory diseases, I believe the model will be carried to many other treatment providers in the Rocky Mountain region including the University of Colorado Hospital," says Boris Tabakoff, a professor at the University of Colorado at Denver School of Medicine.

At Tabakoff's company, Lohocla Research Corp., researchers are examining genetic and proteomic diagno-

ses of psychiatric and addictive disorders. Tabakoff says Lohocla has identified markers that characterize certain types of depressive disorders and the predisposition to alcohol and drug abuse.

In the academic setting, the University of Colorado Cancer Center has had success using gene expression array technology to characterize certain cancers, which as led to what Tabakoff calls "optimal patient responses" to medication.

What's more, the Colorado Clinical and Translational Sciences Institute (CCTSI) at CU-Denver is "transforming professional medical education" in a way that will "drive the next generation of clinicians to adopt and use the latest fundamental research and molecular tools in patient care," says Rick Silva, director of CU-Denver's technology transfer office.

CCTSI has also landed a \$76 million grant to be used over the next five years to discover and adopt tools that "will make personalized medicine a reality," Silva adds.

Slow traffic ahead despite the gains in personalized medicine, insiders say there are roadblocks to a faster trip.

According to Larry Gold, founder, president and CEO of Boulder-based SomaLogic Inc., the first hurdle is, of all things, science.

Both genetics and the study of proteins for personalized medicine are still in their early stages, he says. "Even with strong science, the information technology infrastructure needed doesn't exist."

The entire system, with multiple payers, will be difficult to move, he adds. As for how to jump the hurdle, Gold says he'll leave that to President Barack Obama's administration. "Let's hope Harold Varmus and Eric Lander (co-chairs of the President's Council of Advisors on Science and Technology), two very smart people

in the Obama administration, can help make this happen.”

Another wrench in the cog is an outdated reimbursement structure of the diagnostics business, Silva says. “This structure basically reflects the technologies and practices of the 1970s and 1980s. Diagnostics back then were generally simple, nonproprietary, and didn’t need expensive clinical trials to validate.”

But the powerful diagnostic tools of today that predict drug response and measure multiple markers require “substantial investment” in clinical trials and approval from the Food and Drug Administration, Silva says. That generally doesn’t happen because the reimbursement structure will not allow recovery of those investments.

“The blockbuster drug development model is broken. Spending \$800 million to get a one-size-fits-all, mass-market drug approved to compensate for the high percentage that fail simply isn’t viable in the long term,” Silva says. “The evolving drug development business model will require companies to minimize their investment, hedge their risks, and build options (or) checkpoints into their clinical development plans so they can fail early and fail cheap.”

Driving personalized medicine home

Regardless of the problems, progress in personalized medicine is inevitable. One catalyst for that progress, according to Tabakoff, is lessening the high expectations that “one test should identify, perfectly, success or failure” of a treatment.

“Personalized medicine should be thought of as another important set of tools that allows for better diagnosis of disease variants and the better targeting of drugs for these variants,” he says. “Think of it as another component of risk assessment, which together with a number of diagnostic modalities, brings the best qualities of life to an individual.”

Tabakoff predicts personalized medicine will be the paradigm by which diagnosis and treatment will be pursued in the not-too-distant future. “Individual differences in disease progression and response to medications are an accepted fact. We’re basically at the point of now trying to determine what to do about it.”

According to Tabakoff there are two opposing philosophies:

We need to know everything about the genetics and environment of an individual to provide a truly personalized approach to their health status for both the prevention and treatment of disease.

An all or nothing approach is too expensive, too invasive of an individual’s privacy, and does not add much to success in treatment.

The second viewpoint is espoused primarily by “those who have a vested interest in the current medication marketing procedures,” Tabakoff says, and the position is “slowly but surely being debunked.

“I believe the optimum situation lies somewhere between the two. We need better diagnostic tools and better approaches for matching patient to treatment, but it’s not necessary for the physician or anyone else to know the full genetic and environmental program that constitutes the generation of an individual.”

In Tabakoff’s eyes, the major contribution the bioscience industry in Colorado can make today is to meet the demand for diagnostic tests that target groups of individuals who may be better responders or worse responders to particular therapies. This will prove more useful than generating faster and cheaper means to know everything we can about an individual’s genome.

## PERSONALIZED MEDICINE DEFINED

Personalized medicine is the concept that managing a patient’s health should be based on the individual patient’s specific characteristics, including age, gender, height, weight, diet, environment, etc. Recent developments in genetic testing allow scientists to develop “genomic personalized medicine.”

Source: *en.wikipedia.org*

For Wheeler, another accelerant is better communication between the organizations in the biotech industry.

“There’s a very large number of companies that are leaders in the field, and if we can improve the way we learn what each one is doing—if we can increase the knowledge—we can get more predictive in what drugs should be used,” Wheeler says. “It’s a matter of putting foot to the pedal and getting the drugs out there.”



# NeoTRES™

Advancing Cancer Research

## Colorado State University’s Internationally Recognized Animal Cancer Center

### > Clinical Trials for Veterinary and Human Proof-of-Concept Product Development

- Therapeutics (oncology & analgesia)
- Devices (bioengineering & drug delivery)
- Diagnostic & Biomarker Discovery/Validation
- Pharmacokinetics
- Advanced Imaging & Radiation Technologies
- GLP Compliant Laboratories



A division of CSU Ventures, Inc., an affiliate of

Colorado  
State  
University

300 West Drake Road • Animal Cancer Center  
Fort Collins, CO 80523 • 970.297.5100  
www.NeoTRES.org • info@neotrex.org