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Right, on Time

Precision medicine pioneer Tempus leverages AI to provide personalized care programs to patients and now seeks to bring clinical trials to the community setting with its TIME program

By Chris Anderson, Editor in Chief

Six-and-a-half years ago, serial technology entrepreneur Eric Lefkofsky was perplexed. His wife had recently been diagnosed with breast cancer and, as an executive who had spent the better part of 20 years building companies that leaned heavily on data, he witnessed first-hand how little cancer care leveraged data and technology to chart the course of her treatments.

“I began thinking this has got to change,” says Lefkofsky. “As I dug deeper into the problem, it became apparent to me that the underlying conditions had now evolved to a point where you could bring technology to healthcare—that all these backdrop technologies that historically made it very hard to bring technology to healthcare had now been resolved.”

What could be brought to bear were: cloud computing, innovative imaging technologies, artificial intelligence, low-cost sequencing that provided new insights, and—most importantly—data that could be leveraged to improve cancer care.

With the problem defined and the technology at hand to potentially solve it, Lefkofsky launched and became CEO of precision health company Tempus in 2015, whose original mission was to improve cancer care via a data-driven approach using the above information sources, as well as the data contained in a patient’s electronic medical record.

“For the first time ever, you could build high-quality, low-cost data sets to allow clinicians to access vast amounts of data and technology for making clinical decisions,” Lefkofsky adds. “That is what got me fixated on the problem and starting the company.”

Fast forward to today, and Tempus has become entrenched in the delivery of cancer care. According to the company, its services are used at more than 80% of the country’s academic medical centers and community hospitals, and in one form or another affects the care of roughly one-third of all cancer patients in the U.S.

What’s more, Tempus contends it holds the world’s largest library of clinical and molecular data, which is allowing the company to move beyond its original mission to include collaborating with pharma companies in drug development and research, working to expand access to cancer clinical trials, and expand the same AI-driven approach it has used successfully in cancer to include other health conditions.

Accelerated clinical trial matching

A tenet of Tempus is to identify a problem and then build the solution. It is no secret that oncology clinical trials represent the very cutting edge of cancer care a patient can receive. Yet, when it comes to the percentage of eligible patients who qualify for a trial that actually enroll, the total is in the single digits.

“When you look at it from a purely business standpoint, there is one very obvious reason these patients aren’t enrolling,” says Amy Franzen, vice president of operations and program lead at Tempus. “It’s because the trial sites are

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—Amy Franzen, Tempus

located 500 or 5,000 miles away from the patient. So, you are dangling an opportunity in front of a patient and a physician, but then you are asking them to go travel long distances at time when the patient is often very sick.” In the end, faced with failing health and the prospect of multiple long-distance trips to an academic medical center that is running the trial, the vast majority of patients decide it is simply too cumbersome.

As Sibel Blau, M.D., a medical oncologist from Northwest Medical Specialists in Tacoma, Wash., sees it: “Bringing the research to our community, to our patients, is what we need to be doing and be focused on. It’s what the patients want.”

It was this understanding that led the company to launch



its Tempus Integrated Molecular Evaluation (TIME) Trial Program. Its mission: to rapidly match patients, largely in the community setting, to targeted clinical trials that can be conducted where the patient lives.

To pull this off, the team at Tempus knew they would need to create a new model for how clinical trials are delivered and also find a way to hasten a community hospitals or oncology practices to identifying patients that match an active trial in order to act quickly.

As Franzen explains it, it takes an average of eight or nine months to activate a site to conduct a clinical trial. For patients in the community setting, such a long wait when they have often already failed multiple previous lines of treatment and are very ill is not practical.

The staff at Tempus knew that once a patient has qualified for a clinical trial, his or her wait to receive their first treatment should be days, not months. So, they created a new model that could allow a community hospital to open a new trial for their patients quickly.

Employing standards

Features of the TIME program that enable this speed include executing a standard contract between the site and sponsor, a standard rate card for services, and a central IRB. In short, Tempus does the legwork up front for its participating providers in the TIME network with sites able to open a clinical trial within 10 days of a matched patient agreeing to participate.

Practices that become a part of the TIME program are committing to no more than having the capability to open a trial should one of their patients match selection criteria. Sponsors, on the other hand, are assured that Tempus has done the up front work to vet any medical centers or oncology practices that want to join. Onboarding for the program is also standardized and includes a full feasibility

questionnaire (maintained annually), medical licenses, GCP certifications, and clinician CVs. All of this information can be shared quickly with any sponsor if there is a patient match.

According to Blau, an attractive feature of the TIME program is that a practice doesn't need to have an eligible patient in order to take part, only a willingness to provide these opportunities to their patients. "With the just-in-time trial, the studies are all available to you, but you don't need to do anything," she says. "But if you have a patient (match), you can open your site to the trial and you are the



Eric Lefkowsky, founder and CEO, Tempus

PI because you are the doctor of that patient." Blau adds that her practice is part of the Quality Cancer Care Alliance (QCCA), a group of community oncology practices across the country, and their average time for patient enrollment via the TIME program was only two-and-a-half days, much shorter than the average time Tempus touts.

Franzen notes that while TIME is providing greater access to patients, it currently serves as a supplemental site strategy for pharma sponsors. Nevertheless, she thinks the model could be transformative.

"Pharma companies are in this transition right now. They need to live with their old infrastructure, but times are changing," she says. "They know that their drug only works in a specific sub-population, so they shouldn't test in a broad base. I think that having a model like this available will change how clinical development designs trials and will change how trials go to market." 