The CenterWatch Monthly

2018 Top Innovators

changing the face of the clinical trials industry

25th Anniversary Special Edition

As *The CenterWatch Monthly* marks its 25th year, the clinical research enterprise is on the edge of dramatic change. The power of data and analytics, patient centricity, new technologies, a rapid move toward more targeted therapies and personalized treatments, along with the need for a lower cost R&D model, are among the forces driving transformation in how the research environment will operate in the future.

The industry is comprised of smart and talented people who understand that this rapidly changing landscape offers new opportunities for innovative ideas, products and services that will drive better drug development in the next decade.

To celebrate the 25th anniversary of *The CenterWatch Monthly*, we've chosen 20 Top Innovators, selected from nominations sent by readers, to honor for their novel ideas and their ability to implement them.

Many of the new approaches involve technology that can make processes more efficient, such as Forte's Protocol Exchange Calendar, which centrally builds protocol calendars for multiple sites on the same trial, or Microsystem's DocXtools for Life Sciences, which can reduce the time needed to review regulatory documents for submission. Innovative companies also are exploring how emerging technologies can improve clinical trial recruitment and retention rates. ERT has begun a proof-of-concept study to look at using voice assistant technology to collect patient data in studies while two junior regulatory specialists at INC Research/inVentiv Health have come up with a concept to use interactive, digital posters to raise awareness about clinical research.

Other initiatives promote data sharing to advance medical science. Vivli Executive Director Rebecca Li, Ph.D., has begun an effort to build a first-of-its kind global data sharing and analysis platform for clinical research while Pfizer's Craig Lipset and his colleagues are building tools to allow patients to share their health data with researchers.

Nearly half of the submissions centered around patient engagement activities, suggesting the growing importance of patient-centric initiatives in clinical research. Kristin Kinlaw, associate director of communications at PMG Research, developed and implemented a formal program that allows patients to share their thoughts and ideas with study sponsors and CROs. Meanwhile, The S.T.A.R. Initiative's Regina Greer-Smith has led development of a mobile app that aims to increase minority participation in research.

We believe these innovations all share a common theme: They can help drive the industry's success in delivering new medicines to patients more quickly, safely and efficiently during the next decade and beyond.

Kristin Kinlaw

PMG Research

The Patient Voice

More and more, the movement toward patient-centered clinical research is gathering momentum within the drug development industry. One example: Sponsors and CROs increasingly want patient feedback about the impact a protocol design might have on patient willingness to join the study. Yet the challenge many organizations meet in turning the concept of patient-centricity into an actionable process is connecting with patients.

Kristin Kinlaw, associate director of communications at PMG Research, led the development and implementation of a program, called The Patient Voice, to make that kind of connection possible.

Nearly 400 patients, many of whom have participated in clinical trials, have enrolled in The Patient Voice to provide their perspective on a wide range of topics regarding clinical research. Participants who have opted into the program's database provide feedback through online surveys, interviews, focus groups, patient panels and other forms. Since the it began in 2016, the Patient Voice community has provided input on 15 projects. In one case, a sponsor adjusted a recruitment strategy prior to launch based on patient comments about the protocol design. The PMG Research Feasibility Team has queried patients in advance of proposal or feasibility submissions to determine the level of patient interest in challenging studies and to provide more accurate enrollment projections. Similarly, a patient panel convened through the program provided a CRO with insights specific to clinical research participation motivators and challenges.

Kinlaw, who has worked in the industry for the past decade, found that patients are eager to share their viewpoints on how to make the research experience more patient-friendly, but feel like they don't always have a voice with the right audience. Having a formal process to share feedback prior to study start and impact protocol development, she said, has been meaningful for program participants.

"You often hear how challenging or expensive it can be for sponsors or CROs to engage directly with patients. It doesn't have to be. Our patients love the opportunity to share their experiences and ideas, whether through a quick online survey or an in-person panel. And we love the idea of giving them a way to share their voice," Kinlaw said.

Luke Kramer, Brian Craig, Kerri Weingard and Adam Simmons

The STARR Coalition

Project RockSTARR

Luke Kramer, executive director of The STARR Coalition, and the coalition's members wanted to honor clinical trial volunteers while at the same time connect them with advocates who view research as a critical part of discovering new therapies. Their idea: Project RockSTARR. For each volunteer who enrolls in a trial, participating sponsors will donate up to $200 to a local advocacy group of the participant's choice.

The STARR (Stakeholders in Treatment, Advocacy, Research and Recovery) Coalition, a nonprofit born out of conversations between clinical research leaders and advocates about ways to promote medical research while ensuring participants receive the care and services they need, began Project RockSTARR to forge relationships between clinical research sites and advocacy groups at the community level. As part of the endeavor, when clinical trial volunteers complete the screening process, they will be given information about advocacy groups within their area and choose which group will receive a donation from the sponsor on their behalf. Alkermes, a biopharmaceutical company focused on treatments for central nervous system (CNS) diseases, agreed to launch the program with a 500-patient conducted at sites in Miami, Florida; Dallas, Texas; and Little Rock, Arkansas. In addition, Verified Clinical Trials (VCT), a database registry created to improve patient safety and preserve data integrity in clinical research trials, has partnered with the group to create a database for disseminating information about clinical research at the community level and track project transactions. Coalition members instrumental in piloting the program included Brian Craig, chief executive officer of Pillar Clinical Research; Kerri Weingard, chief operating officer of VCT; and Adam Simmons, clinical program manager of Alkermes.

Kramer hopes the concept becomes an industry standard and creates more awareness of research opportunities in local communities while also providing financial support for advocacy groups, which often become a lifeline for patients struggling with a particular disease.

"Research is happening in our communities, yet many times research is invisible or shunned," he said. "This is a great way for potential volunteers to feel invested in this process. They are already giving their time, body and mind to research. Now they have the chance to help their community. It is just one opportunity, of what we see as many opportunities, to elevate and place the volunteer at the center of the research paradigm."

Kevin Bishop

Bioclinica

Reducing risk to supply chain through advanced optimization techniques

Managing clinical trial supply logistics has become more challenging and unpredictable for many reasons, including the globalization of clinical trials and more complex protocols, which have made it harder to accurately predict drug supply requirements at investigative sites. Sponsors want to minimize study drug waste, which costs millions of dollars each year, while mitigating the possibility of losing patients due to insufficient drug supply.

To address these issues, Kevin Bishop, global vice president and general manager, Randomization and Trial Supply Management (RTSM) at Bioclinica, leads a team that developed an RTSM software platform that allows sponsors to create an initial forecast for drug supply based on the proposed study design and then adjust those projections with actual patient accrual rates and drug supply needs as the study evolves. Whereas most RTMS systems trigger drug supply to investigative sites based on the current-day status of a study, Bioclinica's optimization model allows clinical operations personnel and clinical supply managers to proactively see into the future and predict demand months in advance, which can help detect and prevent potential supply issues.

Bioclinica first started to develop the RTSM solution through a collaboration with a large pharmaceutical company that wanted to integrate their randomization system with other clinical supply chain technologies. Today, the platform includes an interactive response system that interoperates with sophisticated clinical supply forecasting and management software and serves the full lifecycle of clinical

logistics from depot, through sites and ultimately, to patients.

Bishop, who has spent the past 20 years in the eClinical technology space largely focused on RTSM, sees additional opportunities for boosting the value of RTSM solutions as the use of predictive data analytics evolves. Real-life performance data on sites, patients and supply chains, for example, could inform the design and implementation of future clinical development programs. "This is an area the industry is significantly investing in right now and we expect to see an acceleration of capability targeted in clinical logistics," he said.

Jim Murphy

Greenphire

Hope for Houston

Jim Murphy, chief executive officer of Greenphire, believes innovative thinking and breakthroughs often come to life at time of need, when the reward outweighs the risk. One example: the company's Hope for Houston initiative.

Greenphire had been in talks with rideshare companies to explore how this service could best be used in the clinical trial space. But Murphy was wary about how sites and patients would respond. Is it secure? How can we be sure this will work? Would sponsors be willing to pilot this service knowing it's uncharted territory?

Yet when Hurricane Harvey hit Houston, Texas, the Greenphire team stepped up to the crisis and immediately established a portal that investigative sites could use to schedule free rides for patients and staff affected by the storm. Diana Perea, clinical research manager at Houston-based Endocrine IPS, burst into tears when Greenphire contacted her to offer the transportation assistance. When the site reopened, after being closed for a week, Perea learned that its patients had all been taken to shelters. Many of those patients had forgotten to pack insulin and other medications as they left their homes or had run out while displaced in the shelter. Some patients had lost their vehicles and homes and had very limited healthcare options available to them.

By providing convenient and free rides in the aftermath of the storm, Greenphire helped continue the research practice and potentially saved the lives of the patients in the study. Through the experience, it become clear to the Greenphire team that providing transportation services for clinical research, whether the community was facing devastation or not, is a critical component of the patient experience. Plans are now underway to expand the company's travel services to eliminate financial or logistical hurdles that may impact patient retention.

"This is an ongoing initiative, but to date, we have facilitated rides for dozens of patients and site staff who lost their vehicles," said Murphy. "This idea, while at a very small scale, has brought hope to a community facing devastation and risking their health and well-being because they could not access a healthcare facility."

Willie Muehlhausen

Icon

IGNITE crowdsourcing platform

As sponsors increasingly rely on CRO partners to manage clinical trial operations, a critical challenge has emerged: How can they retain their institutional knowledge if most staff in their clinical programs is outsourced?

To overcome this problem, Willie Muehlhausen, vice president and head of Innovation at Icon, and his team developed a unique crowdsourcing platform called IGNITE, which gives their sponsor partners access to the institutional knowledge and experience of some 13,000 Icon clinical research professionals. Launched in 2017, the platform allows sponsors to bring up a specific topic and collaborate with Icon employees to contribute ideas and solve the problem. The IGNITE challenges are open to sponsor employees, as well, which provides opportunities for greater collaboration between the organizations. While crowdsourcing can be used in almost any aspect of the R&D process, so far, the challenges have been focused on operational aspects of conducting clinical trials.

More recently, Icon has begun to prepare the external crowdsourcing platform to get direct feedback from site staff and patients. Patients have shown strong interest in reviewing protocols and procedures to help sponsors and CROs minimize patient burden in clinical trial participation. Icon's innovation team also anticipates including site staff in virtual "design thinking" workshops for their viewpoints on the CRO's technology and processes.

IGNITE builds on the success of Icon's internal SPARK Idea & Challenge Management platform, launched in 2015, which allows Icon employees to submit ideas, contribute to internal innovation challenges and collaborate with colleagues across Icon's global sites. Employee feedback has allowed the CRO to reduce time for internal software development and improve the overall performance of clinical teams.

Muehlhausen, whose has overseen a variety of new and innovative developments throughout his career and was recognized as a PharmaVoice 100 Global Innovation Leader, said the collaboration platform and system supports and strengthens the culture of innovation at the company and will change how the CRO collaborates with sponsors, sites and patients moving forward.

"Our industry is notoriously slow on the uptake of new technologies and processes. This may not be any different for this project. However, other industries have successfully used crowdsourcing for many years. We have to catch up in our clinical research industry and I believe crowdsourcing will be successful here too," he said.

Julia McCann and Daniella Frisoli

INC Research/inVentiv Health

Flex-e-Trial

Daniella Frisoli and Julia McCann, who are both study start-up and regulatory specialists in the SSU Academy at INC Research/inVentiv Health, have invented Flex-e-Trial, an innovative idea to use interactive, digital posters to help potential participants find out about clinical trials and sign up to receive more information.

The posters, created with cutting-edge flexible screen technology, would be featured in public places, such as hospitals and medical centers, and display an interactive clinical trials quiz designed to attract attention and de-bunk myths about research. Those who sign up for more information through the digital poster would be sent an email from Flex-e-Trial inviting them to download an app or visit the website to create a personalized profile. Users could then search for trials currently recruiting in their area through the app/website and be notified about opportunities for future trials. If they were interested in joining a specific trial, users could request more information through the app/website.

Frisoli and McCann also envision physicians using the Flex-e-Trial website during consultations if a patient expresses an interest in joining a clinical trial.

Frisoli and McCann both joined INC Research/inVentiv Health in May 2016 as part of the organization's SSU Academy, a development program that allowed them to experience different roles within SSU over a two-year period and give them a broader understanding of how study start-up in a CRO works. Frisoli and McCann came up with the idea for Flex-e-Trial within the first three months of joining the industry when they discovered that many patients had difficulty accessing information about relevant clinical trials and, in a majority of cases, would simply give up searching.

"Our 'inexperience' in this field enabled us to see clinical trials from the patient perspective and allowed us to see some of the challenges they face," said Frisoli.

The concept was a finalist in the 2016 "Inspiring Hope" Ideathon in Boston and has received widespread interest for its potential to increase clinical trial awareness. Frisoli and McCann, however, have put development plans on hold until they have the available time and funding to move the concept forward.

Matt Miller

Microsystems

DocXtools for Life Sciences

Each year, thousands of hours are spent reviewing electronic technical documents (eCTDs) in preparation for regulatory submissions and fixing problems related to incorrect usage of abbreviations, symbols, formats and phrases. It's a tedious, manually intensive process and many times occurs at the final publishing step when formatting, structure and function issues can slow document completion or negatively affect work quality.

That's where DocXtools for Life Sciences, from Microsystems, comes in. The specialized software integrates into Microsoft Word and is designed to find deviations from document standards quickly and correct them with a click of a button. Using artificial document intelligence (ADI), the technology also finds and fixes cross-references and improper phrases that should be avoided.

A global pharmaceutical company recently bought the application to reduce time spent validating the list of abbreviations in their documents. The organization saw its review times associated with quality checks drop from hours to minutes across lengthy and complex documents. Another sponsor company reported a 50% reduction in time spent analyzing documents for submission compliance after using the software for six months.

Matt Miller, the senior product manager overseeing the software's tactical and strategic initiatives, who has 10 years' experience in the life sciences field, worked hand-in-hand with the team developing the software, ensuring customer feedback from a market test program was taken into consideration during product development. Surveys found the most sought-after feature businesses look for in their document software is automated quality control (QC) review; more than 80% of the users surveyed believe that they could speed up submissions by using smart technology.

DocXtools for Life Sciences was recently rebranded and released with new features. There are some 27 customers and close to 4,000 users of the application.

"We know in speaking to our clients and the market in general that an inordinate amount of time is spent on format-related issues. We wanted to remove or drastically reduce the time spent in this area," said Miller. "We want to help users focus on what matters and bring greater efficiency to the process. Our tagline is Patients Are Waiting, and if we can help our clients get work done hours or days faster, there is a significant impact there."

Rebecca Li, Ph.D.

Vivli

Vivli Platform

Rebecca Li, Ph.D., executive director of Vivli, leads an effort to build a first-of-its-kind global data sharing and analysis platform for clinical trial research that aims to transform how clinical trial data is aggregated to accelerate scientific discovery and improve public health.

Currently, clinical research data largely remains siloed according to sponsor, funder or disease consortium and most organizations lack formal mechanisms or easily accessed platforms for sharing and analyzing data. Established clinical trial registries, such as ClinicalTrials.gov, include only protocol and result summaries.

Vivli, an independent nonprofit that was created from a project run by the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard University (MRCT Center) and key stakeholders, is working with institutional and industry partners to design a platform that will include a data repository, analysis tools and an easy-to-use search engine through which anonymized individual patient data and metadata from clinical studies worldwide can be accessed by researchers and sponsors. The data sharing platform will make it easier for researchers to search across multiple sources and find what clinical trials exist, request access to those trials and analyze data sets. The platform will be launched this year.

Others instrumental in developing the platform include Vivli technical lead Ida Sim, M.D., Ph.D; and Barbara Bierer, M.D., and Mark Barnes, J.D., who both serve on the Vivli Board of Directors.

While the primary purpose of the Vivli Platform will be to drive scientific discovery, Li, the former executive director of the MRCT Center who has more than 20 years' experience in the drug development industry, said sharing clinical trials data is also critical to inform clinical and regulatory decision making and to honor trial participants who put themselves at risk to advance science.

"Utilizing data at the anonymized individual patient data level may allow us to drive new research insights and ultimately improve public health. We have an obligation to clinical trial participants to recognize and value the contribution they have made and there is no better way to do that than to share the data from the trial within which they took part," she said.

Bill Smith

Lash Group,
an AmerisourceBergen company

Fusion

Bill Smith, senior vice president, Business Transformation at Lash Group, an AmerisourceBergen company, was a leading force behind the launch of Fusion, a new technology platform developed to better support patient services programs for drug manufacturers, ultimately improving patient access to new therapies and advancing healthcare.

Fusion, which will primarily be used internally by Lash Group associates, combines operational and analytics technologies to help patients access medications faster, improve patient and provider engagement and generate actionable insights. Fusion differentiates itself from other platforms by combining best-in-class technologies with workflows that are customized for patient support services, creating a comprehensive end-to-end solution, and providing more functionality than customer relationship management (CRM) platforms used in the industry today.

Among its novel features, the platform provides smart automation, leveraging artificial intelligence technology to predict outcomes for benefit verification. Smith said Fusion technologies, such as computer-telephony integration (CTI), along with a variety of communication channels, which include live chat and email, create a simpler, more intuitive set of interactions, allowing patients and providers to access the right information quickly and receive a more personalized experience. In addition, data interoperability means the platform can integrate third-party data sources to produce insights about the patient experience.

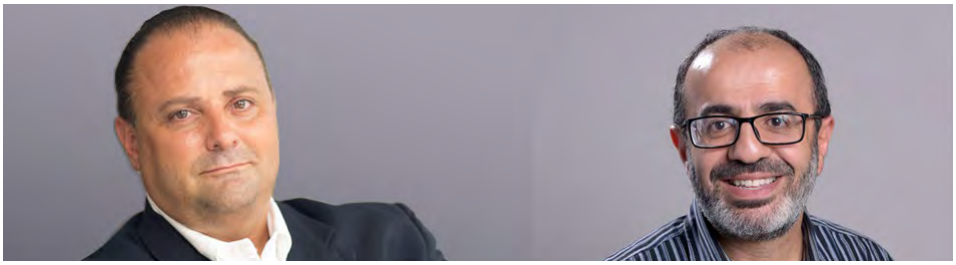
Fusion was designed to address many of the challenges pharmaceutical manufacturers face in the marketplace. Intense competition, rising commercialization costs, disaggregated data and a shift to value-based healthcare have all complicated the commercialization process for a new therapy. Manufacturers also face increasing pressure to clearly articulate the business and economic value of patient support programs to internal and external stakeholders.

Smith's career in healthcare spans nearly 20 years, from medical billing and health insurance to his current role developing solutions to solve some of the industry's most pressing challenges.

"I'm proud to be a part of the evolution of healthcare and work for a company that is always innovating to better support the delivery of patient care," Smith said. "Throughout my career, I've looked for opportunities to positively impact patient care and help create healthier futures."

Paulo Moreira and Munther Baara

TransCelerate BioPharma



Clinical Trial Registry of the Future Concept and Wireframe

TransCelerate BioPharma has some of the greatest minds in pharmaceutical R&D dedicated toward a common goal of identifying common issues and model solutions that will drive efficiencies into the R&D process.

In one of its latest projects, Munther Baara, senior director, Development Business Technology, New Clinical Paradigm, Pfizer; and Paulo Moreira, vice president, Global Clinical Operations—External Innovation, EMD Serono, have been instrumental in designing the consortium's Clinical Trial Registry of the Future Concept and Wireframe.

The Clinical Trial Registry of the Future Concept and Wireframe was created to provide a tangible example of improvements that can be made to publicly-owned, government-mandated clinical trials registries. Patients and their caregivers are the single largest user group for registries, yet the online resources are difficult to navigate and don't provide the information patients want before considering clinical trial participation. TransCelerate hopes the concept and wireframe proposal can help start a conversation about building registries that provide a better user experience for patients and caregivers who want to search for information about clinical trials.

TransCelerate designed the Clinical Trial Registry of the Future Concept and Wireframe through collaborations with the Center for the Information & Study on Clinical Research Participation (CISCRP) and a patient advisory board. Through a series of iterative user experience and design workshops, TransCelerate learned about the types of information and features patients want from a clinical trial registry. The insight helped TransCelerate provide concrete examples of how government-sponsored clinical trial registries could be made more accessible and useful to the patient community. Additionally, TransCelerate's proposal outlines steps that various stakeholder groups would need to take in order to enable this future vision.

Moreira and Baara each have more than 20 years of experience in the pharmaceutical industry and have led numerous initiatives driving innovation at their respective companies. Moreira is responsible for clinical innovation as well as for patient centricity in clinical development and operations at EMD Serono. At Pfizer, Baara is spearheading initiatives driving innovation in development operations to align with the paradigm shift in the clinical trials execution model and emerging technologies.

"In this sector, we contribute to the cutting-edge of science and innovation," said Baara. "Right now, I feel that there is no better industry to work in, especially because of recent advancements in technology enabling the creation of transformative business models within biopharma R&D."

Mark Heinold

TrialScope

Trial Results Summaries Portal

Mark Heinold, chief executive officer of TrialScope, and his team, in partnership with AstraZeneca, have developed the Trial Results Summaries Portal, which aims to improve the experience of clinical trial participants by allowing access to available clinical trial results summaries through a publicly accessible website.

Through the portal, study participants can search for trial results from participating sponsors and subscribe to be notified by email when a results summary is available. The summaries, which are written in lay language, include information about the purpose and outcomes of the clinical trial. For sponsors, the portal provides a secure, central location to communicate trial summaries in a non-promotional context.

A growing number of sponsors provide lay language summaries of clinical trial results to research participants as part of patient engagement and transparency initiatives. Studies have shown that providing lay language summaries, which translate technical trial results into everyday language, can improve the overall satisfaction of clinical trial volunteers and increase their likelihood of participating in a future study. Providing plain language results will soon become mandatory for studies conducted in the European Union. A recent survey conducted by TrialScope found that almost 90% of sponsors plan to provide trial result summaries and more than a third have already updated polices and processes to support this commitment.

"Sponsors are realizing that in order to recruit patients, increase study completion and have them participate in future trials, the industry must make a more concentrated effort to provide a satisfying experience to the patients," said Heinold. "A source for dissatisfaction is that most times, patients never receive the results of the trial, often making their experience unfulfilled."

Heinold said the TrialScope portal offers a single location for study participants to access trial results summaries from participating sponsors and represents a significant process upgrade for organizations that distribute trial results through paper-based processes. The portal, which was originally launched in February 2017 with results available in English, has since added seven additional languages: Chinese, French, German, Japanese, Polish, Russian and Spanish. The company's long-term goals include adding more languages and working with additional sponsors.

Georgia Mitsi, Ph.D.

Apptomics, Inc.

iMotor: Objective Movement Monitoring Movement in Neurological Studies

Georgia Mitsi, Ph.D., founder and chief executive officer of Apptomics, which provides digital health solutions for patients living with chronic neurological conditions, has led efforts to develop iMotor, an innovative mobile application that can quantify changes in motor function for patients with Parkinson's disease (PD) remotely and report health data to physicians in real time.

The scientifically validated iMotor system gives physicians more accurate insights into a patient's disease progression, which allows for faster optimization of treatment and, ultimately, can lower overall healthcare costs. The application is also designed for use in clinical trials to help advance the development of therapies and improve patient outcomes for neurological conditions.

Apptomics has partnered with BBK Worldwide, which brings extensive experience in clinical research and patient engagement, and the U.K.-based digital health technology provider Biotaware, to develop a suite of remote healthcare monitoring applications for use by patients, caregivers, physicians and payers. The first iMotor application was for PD and essential tremor, which became available in November. Other applications for related neurological conditions are planned for release in 2019.

Treatment of PD and other neurological conditions has been limited by the inability to collect and analyze objective data about changes in patient symptoms between visits to the clinic. iMotor shifts this paradigm by providing physicians objective and patient-reported data, collected both during and between office visits. The system captures a range of data through validated tests, activities and proprietary algorithms and can provide longitudinal reporting, all within a global regulatory-compliant environment.

In December, the iMotor application for PD was deployed in its first interventional study. iMotor has been validated through two other studies and the study results have been published in academic journals. Many features of the iMotor application have been designed for use within clinical trial settings, such as the ability to incorporate or link with other ePRO/eCOA tools and deliver patient education materials to patient advocacy organizations and support groups. As the system integrates into clinical research, Mitsi said the hope and expectation is that the mobile app will provide a "greater sensitivity" to help evaluate the effectiveness of current and new medications.

"We expect the benefits to be immeasurable, ranging from improving the overall experience to positively affecting the economics of the trial," she said.

Craig Lipset

Pfizer

Enabling Patient Data Donation for Research

As head of Clinical Innovation in the Global Product Development organization at Pfizer, Craig Lipset is carrying on a mission that has long been a passion: transforming the role of patients in clinical research by allowing them to share health data and become true collaborators in uncovering new medical breakthroughs.

Patients today have unprecedented access to their diverse health data, thanks to enabling technologies as well as government policy, and many studies have shown that nine out of ten patients are willing to share this data to support medical research so long as their privacy wishes are maintained. Researchers are voracious for data, which fuels their work, but patients lack easy-to-use, trusted tools to share access to their health data for various researchers.

Lipset, who has talked about enabling patient data donation for several years and outlined his vision in a TEDx event, collaborated with his colleague Munther Baara, senior director, Development Business Technology, New Clinical Paradigm, Pfizer, to prototype a data donation app that aggregates and shares patient health data for a range of research opportunities. The Pfizer team has already begun to work on a next-generation data donation app that leverages blockchain technology, addressing permissions for patient data sharing, and is testing the app concept with patients for feedback and input. Ultimately, the app may be tested as a tool to accelerate screening visits and help capture electronic patient data in clinical trials.

Since Lipset joined Pfizer about a decade ago, pushing the boundaries of innovation and patient engagement has been a top priority. Among other things, at Pfizer he pioneered the notion of returning data to patients by making lay-language summaries of study results available to participants as well as experimenting with returning individual patient data to clinical trial volunters. He also is working with the White House Office of Science and Technology Policy to pave the way for initiatives to enable sharing of electronic health data between patients and researchers.

"Data donation will transform the role of patients as participants in research by putting them truly at the center of data exchange and sharing," said Lipset. "I define innovation as an idea from which you derive value. For much of the last decade, data donation has been an idea. Today, we have turned the idea into execution, creating the opportunity to realize value, and earn the opportunity of calling the work innovation."

Regina Greer-Smith

Healthcare Research Associates

The S.T.A.R. Initiative E³ Mobile Engagement App

Regina Greer-Smith, president and owner of Healthcare Research Associates, is the creator of The S.T.A.R. Initiative and a bit of a dynamo: an advocate and visionary on a mission to increase minority participation in patient-centered outcomes research and clinical trials.

Her latest project, The S.T.A.R. Initiative E3 Mobile Engagement App aims to engage African-American women in breast cancer clinical trials by use of a smartphone app. The E3 symbol stands for engagement, education and empowerment. The mobile app will use educational programs, video and chats to connect with potential study volunteers and provide the necessary information and resources for patients to make an informed decision about clinical trial participation.

A prototype of the app was designed by a team of patient advocates, technology experts and researchers. Plans include testing and launching the mobile app within the next six months. While the initial project focuses on engaging African-American woman an in research, the app can scale to include all minorities and underserved people.

Greer-Smith founded The S.T.A.R. (Strategically Targeting Appropriate Researchers) Initiative in 2013 to match patients with researchers who are sensitive to the needs of minority communities. Her work involves creating innovative methods to engage patients and stakeholders in patient-centered outcomes research. Among her many activities, Greer-Smith serves as a Patient-Centered Outcomes Research Institute (PCORI) ambassador, was recently named a patient governor for Arthritis Power Patient-Powered Research Network (PPRN) and is a Patient Safety Champion of the Americas for the World Health Organization (WHO).

Through her involvement in various initiatives, Greer-Smith remains committed to ensuring that minority and underserved communities not only engage in research, but also understand that engagement is critical to improving their healthcare and quality of life.

"The low participation rate of minorities in clinical trials prevents this sector of the American public from benefiting from drug innovations," said Greer-Smith. "It is a huge responsibility to provide innovations that lead to higher diversity and inclusion in clinical trials and drug development. We are grateful that our work may play a part in this important work and inspire others to do the same."

Kelly Johnston McKee

Eli Lilly and Company

Popup Star

As a leader in the Clinical Innovation group at Eli Lilly and Company, where she focuses on novel patient recruitment and engagement strategies, Kelly Johnston McKee thinks about fundamental questions: What if every stakeholder in healthcare could participate in creating awareness for clinical research as a care option? What methods could help engage the community?

To find out, Lilly became the flagship sponsor behind an international clinical trial awareness contest called Popup Star, which was designed to inspire grassroots clinical trial awareness campaigns and generate ideas that study teams and sponsor companies could replicate to engage local communities in research participation. Teams from around the globe, which began forming at the end of 2017, will compete to design and implement innovative awareness-raising events that bring together patients, physicians, researchers, advocacy organizations, academic institutions and healthcare payers in the community. Participating teams will submit videos of their projects that will be edited into reality TV-style web episodes and featured during a 10-day clinical trials community awareness event in April. Three finalists will participate in a live broadcast finale in New York City this summer.

The idea originated from the combined efforts of McKee; Angela Radcliffe, managing director and executive vice president of FCBVIO; and Jennifer Byrne, founder and president of The Greater Gift Initiative. These patient engagement experts and contest co-sponsors share the vision of involving everyone, not just those in the clinical trials industry, in raising awareness about the importance of clinical research in local communities. In the competition, teams will need to answer the following types of questions: What will it take to get the biggest audience? Will people respond better to an event focused on research participation in one disease or all conditions? What will motivate people to attend this event? What is the health literacy of our community and how can we improve it?

"As an industry, we don't have all the answers. We need the help of local communities to raise awareness of clinical research," said McKee. "Clinical trial awareness is needed on all levels and we need to engage individuals in an everlasting way, not just in temporary, transactional and isolated ways."

Michael Keens

Firma Clinical Research

Remote Visit Services (RVS)

The basic idea of allowing clinical trial volunteers to participate in studies from their homes or other non-traditional locations, which can help minimize the burden of study visits and improve patient retention, has been around for a few years in the drug development industry. Now, Michael Keens, chief operating officer, Firma Clinical Research, wants to move the concept to the next level.

Despite his top executive position, Keens works daily with project teams to innovate and improve its Remote Visit Services (RVS) offering. Most recently, he has worked with team members and clients to improve sponsor and site transparency into visit information, which is provided through a client service portal, as a result of organizations sharing their frustration with the industry about the lack of sufficient information regarding when remote visits occur or the qualifications and training of staff.

Two key changes were made to address these concerns. First, before the conduct of any patient visit, Firma Clinical sends the assigned staff member's CV, licensure and training certificate to the investigative site for review and approval via the delegation of authority log, which allows the principal investigator and site staff time to interview the clinical service provider before remote visits begin and feel more comfortable with the service. In addition, Firma developed a proprietary Remote Visit Management System (RVMS) that will give sponsors the ability to review, in real-time, information related to patient visits and performance.

Keens earned a master's degree in public health and had been on a path toward becoming a physician. But rather than apply to medical school after his graduate program, he decided to explore scientific areas outside of medical school and joined the clinical operations group of a large CRO. He's worked in the industry ever since, taking a leadership role in supporting those undertaking drug development.

As the nature of clinical development support continues to evolve, Keens said he constantly evaluates areas where Firma Clinical's services can be improved to incorporate advances in technology, such as how the use of wearable technology can be integrated into clinical trials.

"This continues to be an exciting time to be involved in clinical drug development, with significant advances in drug treatments and now advancements in data collection, monitoring and patient support," he said.

Shree Kalluri

Forte

Forte Protocol Calendar Exchange

Shree Kalluri, founder, president, chief executive officer and chief customer officer of Forte, has led development of a technology platform that centrally builds protocol calendars for multiple sites on the same trial, rather than having each site duplicate the effort from scratch, to standardize interpretation of the protocol document across sites, increase efficiencies and streamline study activation activities.

Kalluri, who began the clinical trial software and services company in 2000, considers the protocol calendar, a schedule of treatments and tests a participant completes on a research study, the most important aspect of a clinical trial. Any deviations from the calendar can result in missed visits and inaccurate treatments, creating safety issues for patients along with regulatory and compliance concerns for sites and sponsors. Yet building protocol calendars can be subjective and any two study coordinators could interpret the same protocol calendar very differently, which can result in protocol compliance issues and deviations downstream.

To address these concerns, Forte launched the Protocol Calendar Exchange, a library of standardized schedule-of-events documents that can be downloaded by sites into clinical trial management systems. The company first assembled a team of clinical research coordinators in 2013 to build protocol calendars, in response to a customer request, and immediately saw an opportunity to increase efficiencies in multi-center trials by making these calendars sharable across institutions. More than 4,800 calendars have been built and are available through the exchange. As part of the initiative, Forte has collaborated with multiple institutions to establish community-wide guidelines and standards to promote greater consistency in protocol calendar interpretation.

Forte built the platform to build and distribute standardized protocol calendars as industry has increasingly adopted technology tools to improve clinical trial operations.

"It's odd to encounter an institution serious about clinical research that doesn't have its own technology to help manage operations," said Kalluri. "Technology increases efficiencies by decreasing cycle times. It can decrease protocol deviations by enabling consistent and streamlined processes. Technology also enables leadership to achieve greater visibility into their operations, enabling them to make better, more informed decisions and adjust their strategies accordingly."

Gregory A. Folz, CCRP

Research Institute of Deaconess Clinic

Kits4Life

Gregory A. Folz, administrative director, Research Institute of Deaconess Clinic in Evansville, Indiana, was the driving force behind creation of the unique technology platform Kits4Life, which will give research sites and sponsors the means to repurpose unused clinical trial lab kits for humanitarian aid.

Most sponsor companies require investigative site staff to destroy surplus lab kits upon study closeout. Deaconess research nurses repeatedly pointed out the wastefulness of the practice, particularly when many developing countries and charitable clinics in the U.S. experience a severe shortage of medical supplies. Folz came up with a solution based on the technology of the letgo app, a mobile marketplace for people to sell items they no longer want.

The nonprofit Kits4Life platform is supported by a mobile app that allows research sites to post and donate their unused lab kits to relief organizations. To ensure the donated supplies reach recipient aid organizations and are not diverted or sold, Kits4Life uses only accredited Medical Surplus Recovery Organizations (MSROs), which also certify that the donated supplies have been processed according to World Health Organization (WHO) guidelines and international laws.

Folz, a national consultant on the development of clinical research operations and the co-founder of MyIRE, a suite of integrated research tools built to ensure reproducible investigator-initiated trials, began raising seed funds and enlisting in-kind support to develop Kits4Life after the idea won the Society for Clinical Research Sites (SCRS) award for innovative technology concepts in 2016. Many industry leaders and stakeholders, including Kimberly Ray and Jessica Shephard of IQVIA, Christine Pierre of SCRS, Dirk De Naeyer at Janssen, Pablo Tachil of UST Global, Jackie Kent of Eli Lily and Company, Q2 Solutions, UPS and the MedSurplus Alliance, were instrumental in offering logistical know-how, leadership and technical resources to create a sustainable, nonprofit platform for international humanitarian aid. Folz said the goal is to launch the platform and begin distributing medical supplies by late in the first quarter of this year.

"The shared vision that immediately occurred was very humbling," said Folz. "I feel very fortunate to have witnessed first-hand what our industry can accomplish in just a few months for those in need. It was something bigger than each of us alone, but not bigger than all of us working together."

Karin Beckstrom

ERT

Voice Assistance Data Capture Solution

Could voice assistant technology, such as Amazon Alexa or Google Assistant, open up clinical trials to broader patient populations, including those with disabilities, and help lower participant dropout rates? Karin Beckstrom, senior product manager at ERT, believes so.

Beckstrom, who has more than 20 years' experience driving software product innovation in both the online employment and pharmaceutical industries and now focuses on bringing new technologies to clinical trials, launched a proof-of-concept project at ERT with healthcare software provider Orbita to look at how patients could benefit from using voice options instead of the traditional, manual methods to submit clinical trial data. The Voice Assistance Data Capture Solution developed through the collaboration aims to make data collection as easy as possible by giving study participants the ability to use voice technology to complete daily assessment surveys, report vital statistics measurements, ask questions, receive training and report health concerns. By simplifying and enhancing clinical trial participation, the solution can help keep patients engaged, enrolled and compliant with the study protocol. ERT thinks this capability has great potential for capturing important real-world data from clinical trial participants, as well as from patients participating in post-launch, late-phase programs.

Smartphone apps are commonly used today to collect patient-reported outcomes data and communicate with study participants. Yet Beckstrom found that some patient populations, particularly those with dexterity limitations from conditions such as Parkinson's disease or rheumatoid arthritis, find the apps difficult, if not impossible, to use. Relying on traditional paper systems as an alternative to apps does not offer a solution and could result in less efficient or inaccurate data capture and retention problems. Beckstrom said that providing a voice alternative for data capture and patient training maintains the advantages of electronic data capture without the physical burden to study participants. In addition, it could expand the potential patient pool for clinical trials by providing solutions that match the patient's capabilities.

"In clinical trials, it's critical to put patients first and really understand their lives and challenges. Only then can you match their needs against the potential of new technology for a winning combination that leads to better outcomes for pharmaceutical companies and patients," she said.

Brent Reed and Chris Clendening

PPD Laboratories

Preclarus investigator site portal and companion mobile application

PPD Laboratories has developed innovative technology that addresses decades-old issues concerning management of patient samples collected during clinical trials: Visibility gaps in the chain of custody from sites to laboratories and human errors made by investigative site staff recording data manually.

The Preclarus investigator site portal, a web-based platform accessible via a computer's standard web browser, was designed to streamline routine tasks associated with collecting samples from patients in a clinical trial, including subject registration, sample tracking and test-result reporting, and to improve interactions between sites and central labs. Launched in 2016, the portal's tools incorporated barcode scanning technology for patient samples that establishes a clear chain of custody, giving sponsors and labs real-time information about sample collection and shipping, and provides data quality checks and validation of subject information, allowing errors to be identified and corrected immediately.

Chris Clendening, executive director of Global Project Management and Design, and Brent Reed, associate director of IT, have designed the technology around site activities and included site feedback in the development and workflow design stages to increase the potential for quality and avoid developing a site portal that creates inefficiencies or adds to the technology burden at investigative sites. PPD Laboratories is continuing to expand the functionality offered within the investigator site portal to encompass more aspects of trial management. A mobile application for smartphones and tablets will be released in the second quarter of 2018, which will allow investigators, clinical trial managers and other site staff to view safety alerts, manage supplies and perform accessioning activities from any location.

"We've listened to the people at the sites who are managing trials and enrolling patients in addition to their primary responsibilities. Whether they're nurses, physicians or site managers, they're busy. We need to ensure their interactions with the technology we use are conducive to their workflows and results in a positive user experience," said Reed. "That's the fundamental premise behind the mobile app. We want sites to leverage a platform that can be accessed anywhere on a system they're familiar with."