The CenterWatch Monthly

2018 Top Innovators
changing the face of the clinical trials industry

25th Anniversary Special Edition
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/InVeniHealth 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.

To all clinical research volunteers, thank you.

A sincere thank you to all of the men and women who take part in clinical research studies each year. By volunteering today, you become a medical hero forever. For more information about clinical research, please visit CISCRP.org.
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 women 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.”

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.

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.

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.