By Denise Myshko

The Clinical Trials *Technology Ecosystem*

Technology improvements are enhancing R&D efficiency, accelerating time to market, improving safety, and boosting data accuracy — all of which are increasing the success rates for pharmaceutical sponsors and their clinical trial partners.

Data are — and will continue to be — the linchpin for clinical trials. In the future, fewer data points will come from the traditional investigator-led EDC data entry process. Emerging technologies offer an incredible potential in transforming drug development. The ability to pool real-world data evidence information from payers, from insurance companies, EMR integration, and with analytics will become the new normal.

Making this transformation possible are cloud-based technologies, increasing computing power, and the sophistication of machine learning and algorithms. These advances are powering a move toward data integration and creating an anonymized, aggregated way to share data across trials.

Some experts say the industry remains somewhat slow to adapt to changing technology, but we've found that biopharmaceutical companies and their technology partners are making significant technological strides to impact R&D efficiency, accelerate time to market, improve safety, and boost data accuracy. In this special cover story, we explore a number of these collaborative technological and drug development successes.

Identifying Drug Targets

Newer technologies aim to increase access to and integrate more information — about targets, compounds, and diseases — to enable a more comprehensive approach to drug discovery. Specifically, advances in genomics are providing more opportunities for drug discovery than ever before.

Regeneron, for example, has teamed up with Geisinger Health System to create a genetics database. The Regeneron Genetics Center (RGC) has sequenced the exomes of more than 150,000 people. The project uses a platform created by DNAnexus, which provides a global network to share and manage genomic data and tools to accelerate genomics.

De-identified EMR data from Geisinger's patients participating in its MyCode Community Health Initiative are integrated with whole exome sequencing data from the same patients — an effort known as the DiscovEHR Project.

"The platform has allowed Regeneron to scale operations and collaborate with external partners and exchange data in a secure and compliant manner," says George Asimenos, Ph.D., chief technology officer, DNAnexus.

Once the data are uploaded, Regeneron is able to detect any genomic variant that patients have with respect to common human reference. In parallel, Regeneron receives the medical records, which contain rich phenotypic information. The company's researchers are then able to conduct statistical correlation to figure out what significant mutations, gene modifications, or pathway modifications may be enriched in any given phenotype.

"Regeneron's goal is to figure out the genes that are implicated in specific diseases," Dr. Asimenos says. "These data could then point to potential drug targets. So far, the company has sequenced more than 150,000 patients."

He says Regeneron has a planned project with UK Biobank, which has recruited 500,000 people between 40 and 69 years old, who have provided blood, urine, and saliva samples for future analysis.

Regeneron's effort with Geisinger has uncovered a possible drug target. The findings revealed a genetic variant that appears to result in reduced levels of triglycerides and a lower risk of coronary artery disease. Researchers used the genetic information from the integrated database to identify patients with a

We're changing our mindset at Lilly particularly in terms of clinical innovation; we have stopped designing things for patients and are moving toward designing things with them.

JOSEPH KIM
Lilly

suspicious mutation, and use the EHR data to evaluate a range of parameters, including lipid levels and coronary artery disease status. Regeneron has performed subsequent studies in several animal models.

"Regeneron has made a commitment to genomics," says Richard Daly, CEO of DNAnexus. "Rather than buy onsite computers and data storage, Regeneron is using our platform to do its processing directly in the cloud."

Mr. Daly says for a project like this to be successful there has to be a commitment to technology from the C-suite.

"Regeneron is pretty extraordinary because of its level of expertise and vision," he says. "There was a commitment from Dr. Leonard Schleifer, the company's founder, president, and who identified this initiative as strategic."

Engagement from the top-levels of a company is critical because a genomic initiative such as this is a three- to five-year program that involves understanding the need for multiple data sources.

"There needs to be an understanding that these data sets are large and complex and need to be informed by other data sets," Mr. Daly says. "Companies need a more complex computing infrastructure that operates on a global basis."

Dr. Asimenos says the cloud has transformed how the industry thinks about doing research.

Collaboration is also critical, Mr. Daly says. The next level of important research questions to be answered are going to require larger data sets, and to more therapy-specific data sets.

"It will no longer be sufficient to have a 10,000-sample population," he says. "Companies will need to be specific in terms of their investigative direction. For example, if

eClinical Integration

Systems integration is an increasing necessity for a successful clinical trial. Leveraging technology can help sponsor companies address time, cost, and quality of clinical trials. But this requires systems integration to ensure data are accurate and consistent. This is especially true with the movement toward eSource data, which is defined by the FDA as electronic source data initially recorded in electronic format.

Craig Lipset, head of clinical innovation, worldwide research and development, Pfizer, says this move toward eSource will lead to automation and collaboration. He says there are likely to be more opportunities for eSource use and data that are largely to be powered by EHRs and companies' ability to pull data from those EHRs.

"We've replaced paper case report forms with electronic data capture but the process itself is still disconnected and largely unchanged," he says. "The investigator is still redundantly entering data into both places, and we fly out monitors to do source data verification and employ data managers to issue queries and manage those data."

Mr. Lipset says EHR is definitely one way to improve the process, but electronic source data can also come from other places.

"eSource data might mean tablets that are being used in the clinical setting or diagnostic devices," he says. "Or, it might come from the patients themselves who are self-reporting data on a mobile device like an electronic diary or an ECOA. In all of these cases, the data are being captured electronically at the source and this creates an opportunity for us to use technology to move those data into a study database."

Pfizer is experimenting with the ability to use artificial intelligence and other technologies to automatically generate content whether it's patient narratives or clinical study reports in the future.

eSource itself brings some challenges as well, Mr. Lipset says.

"Many companies focus on the struggle of interoperability with health information technology," he says. "In truth, we don't need EHRs across institutions to be fully interoperable. This is a challenge that healthcare has to solve but it's not necessarily a barrier to use eSource for clinical trials today. We need data to flow in one direction to support eSource and we need to pull data out of different health systems to support eSource. But not all that data exist in a structured way, the way we may want it to, and it doesn't exist across the different EHRs in a structured way."

Pfizer, he says, is considering working with different partners that may have already put in place certain types of connections to pull data out of EHRs and different systems in the United States, mapping that data together in a structured and consistent way.

Joseph Kim, senior advisor in clinical development innovation, Lilly, says an obstacle of data integration is related to how data are structured and normalized.

"We did an analysis of ClinicalTrials.Gov, looking at the inclusion-exclusion criteria," he says. "There were about 700 different ways in which sponsors described pregnancy as an exclusion criteria. Because of this, it is hard to use technology to match patients to research. As an industry, we haven't standardized or normalized the way we present our research."

Mr. Kim says until there is standard terminology, no matter how innovative the technology is, there will still be hurdles to overcome.

"We have to wait for sophisticated, natural language processing and AI to decode the language," he says. "There is a bright spot. Industry consortiums are working to develop a common technical protocol, which will give us some standardization."

Clinical Research Tools

ARISGLOBAL INTRODUCES REGULATORY INFORMATION MANAGEMENT SYSTEM

ArisGlobal has released LifeSphere RIMS, a multi-tenant cloud-based Regulatory Information Management System (RIMS), a workflow-driven approach for handling all regulatory affairs business processes, using a fully IDMP-compliant data structure.

"LifeSphere RIMS comes with built-in industry standard practices based on our 20 years of regulatory experience and the active participation and feedback from a well-established users community to solve real-life problems," says Wim Cypers, senior VP, regulatory. "It's a uniquely rich and flexible solution that handles all regulatory affairs processes and their variations."

Additionally, ArisGlobal has released agClinical 3.3, the latest version of its clinical trial management software. This release further enables life-sciences organizations to confidently and efficiently meet new compliance and submission requirements, improve risk-based monitoring, and better manage the electronic trial master file so that compliance is assured and transparency is improved.

BIOCLINICAL RELEASES TRIAL SUPPLIES SYSTEM

Bioclinica eHealth Solutions division has released a purpose-built, end-to-end, configurable randomization and trial supply management (RTSM) software platform. Bioclinica Agile RTSM combines the latest release of Bioclinica's Trident Agile IRT and the advanced Optimizer clinical supply forecasting and management software.

The Bioclinica Agile RTSM platform provides real-time visibility and reforecasting capability based on study actuals.

"Traditional, siloed and heavily customized systems create significant efficiency gaps, with costly re-work and drawn-out timelines," says Bioclinica eHealth Solutions President Mukhtar Ahmed.

JEFF KINELL
CEO, Bracket

BRACKET TO DEVELOP ELECTRONIC RATING SCALES FOR PARKINSON'S ASSESSMENTS

Bracket has an agreement with the International Parkinson and Movement Disorder Society (MDS), to develop electronic versions of the MDS-Unified Parkinson's disease Rating Scale (MDS-UPDRS) and the Unified Dyskinesia Rating Scale (UDysRS). The migration of these complex scales to an electronic clinical outcome assessment (eCOA) format aims to improve trial conduct and data quality for Parkinson's disease (PD) studies.

"Clinical trials in Parkinson's disease and other

By looking at large amounts of data, indications for therapies can be identified that never would have been explored.

DR. RANDALL STEVENS
Centrexion

investigating a particular type of cancer, they will need to build a cohort of genetic and phenotypic data to conduct the research."

As a result, companies will need technology to assemble these more complex data sets.

"This also means that no one individual company or entity will be able to create these large data sets, and companies will need to figure out how to share and collaborate around data in a way that's compliant with all of the patient protection regulations," Mr. Daly says. "This is a fairly complicated problem that everybody is working on now."

Big Data in Early Development

Big data analytics have been used later in development to help with patient recruitment and clinical decision support. Now pharma sponsors are also applying data analytic tools to increase their understanding of potential therapies in early development and to better assess biological targets.

Centrexion, for example, is using a big data approach to help determine potential indications for compounds to treat chronic pain conditions. Centrexion has partnered with BioXcel, a big data analytics company, to identify the best indications to pursue based on extensive data collected, including genetics, proteomics, in vitro, in vivo, and clinical on the drug candidate and potential indications. The partnership allows Centrexion to efficiently mine the literature across many disciplines and make linkages to support the scientific rationale and development strategy for each of the pain drugs.

In March 2016, the company acquired three new analgesic candidates from Boehringer Ingelheim: selective cytokine CCR2 antagonist with a unique analgesic profile; the first of a new generation of potent and "super-selective" cannabinoid CB2 agonists; and first-in-class, potent and selective somatostatin SSTR4 agonist. These compounds are currently in Phase I development.

These products are the focus of the Centrexion's collaboration with BioXcel, which is using preclinical, clinical, basic science, chemical, and pharmacokinetic data that are interlinked to look for biologic relevance.

"We want to look at all of the indications BioXcel is able to determine to see if they fit with our strategy," says Randall Stevens, M.D., chief medical officer, Centrexion. "We will look at the set of indications and then decide which of those indications to bring to Phase IIa. Typically, companies will take a single indication forward. We want to do something different; we want to look at several indications in a single trial to see which patients and which conditions will have the biggest benefit. We will then expand the patient group if there is a signal that the analgesic is working."

So far the collaboration has identified between four and 10 indications for each of the three molecules. The company plans to continue the collaboration with BioXcel and once Centrexion has more clinical data, it will mesh that data with the intelligence from BioXcel.

"I've been working in the industry for 27 years and there is only so much literature that researchers and clinicians can scour to uncover indications or benefits for a potential therapy," Dr. Stevens says. "Researchers often focus on certain therapeutic areas and may miss opportunities in other therapeutic areas. By looking at large amounts of data, researchers can pick out indications for therapies that they never

FAST FACT

THE ECLINICAL SOLUTIONS MARKET IS EXPECTED TO GROW TO $7.61 BILLION BY 2022, AT A CAGR OF 12.4%.

Source: MarketandMarkets

Companies need to have the right clinical experts as part of the process because it is a marriage between the people, process, and technology that makes for a successful solution.

SUZANNE CARUSO
WIRB-Copernicus Group (WCG)

would have thought about or explored."

Site Selection Technologies

Use of reliable data analytics, timely site start up and patient recruitment, and managing the supply chain for trials in ever-evolving innovative therapeutic areas are just a few of the many challenges involved with drug research and development.

The use of digital in clinical trials in fresh and new ways will continue to change the landscape and create new opportunities to make a very meaningful impact going forward.

CRAIG LIPSET
Pfizer

Site selection is one of the more critical decisions sponsors make in preparing for a clinical trial. The selection of sites establishes the framework for whether sponsors will be able to meet their trial goals. Automating the process of selecting and validating sites can build consistency into the process, helping sponsors to enroll sites and patients faster and with less bias than more manual processes that do not have the transparency aspects that technology enables.

Merck is one of the companies that has taken steps to automate more of the site selection process using WCG's Site Feasibility Solution to help assess clinical sites. The solution helps Merck narrow the field of investigators for a specific trial based on therapeutic and enrollment trends. The solution also assists in determining the sites' and investigators' feasibility for the trial.

Merck used the feasibility solution for a non-small cell lung cancer trial in 2015 at a time when it was difficult to get teams out to sites to do on-site visits for site assessments. The feasibility tool helped to increase the investigator response rate to the feasibility questionnaire and allowed Merck to make better-informed site-selection decisions within a shorter time.

"Typically response rates to feasibility questionnaires average as low as 20% or 30%," says Suzanne Caruso, VP, clinical solutions at WIRB-Copernicus Group. "In leveraging our tool, Merck has more than doubled the response. This program is now used for all of Merck's studies."

Dawn Furey, executive director, head of global operations within global clinical trial operations at Merck, says the solution gave the global team the opportunity to use face time with sites in a more meaningful and more focused way.

"When manually conducting site feasibility, there's no transparency to the various stakeholders throughout the organization as to how the sites have actually responded," Ms. Furey says. "We found there were times when the site would provide an estimated number of patients they could contribute but by the time the decisions were made as to whether that site should participate or not, the numbers were pretty far off from the original estimate. We wanted to see if we were including more sites than we needed in order to execute our research and how we could tie those data points together."

In many cases, using the WCG system, Merck has been able to identify sites for participation within three days. Previously, this process sometimes took eight to 10 weeks. Merck has since rolled this solution out to all trials with more than 20 sites to be enrolled.

Ms. Furey says one of the important learn-

Clinical Research Tools

movement disorders are extremely complex and have a high failure rate," says Jeff Kinell, CEO of Bracket. "Fortunately, digitization in clinical trials is improving results, as the logic of eCOA streamlines scoring protocols and compliance."

DR. STEVE TOON
President and Managing Director, Simcyp

CERTARA LAUNCHES SIMCYP ACCESS TO EXPAND SIMULATOR AVAILABILITY

Certara has launched Simcyp Access. This new cloud-based licensing approach provides trained individuals at smaller pharmaceutical companies (fewer than 500 employees) with a method for using Certara's Simcyp population-based simulator in research projects.

"As the benefits of using Simcyp and physiologically based pharmacokinetic (PBPK) modeling have moved from being an academic nicety to a regulatory necessity, we recognized that we needed to expand the ways in which scientists can avail themselves of this technology," says Simcyp President and Managing Director Steve Toon, Ph.D.

Additionally, Certara has released D360 version 9.0 along with D360 Express, its data informatics platform for discovery scientists. D360 is a self-service data access, integration, and visualization solution used to query multiple cheminformatics and bioinformatics data sources and make informed go/no-go and next step research decisions.

Certara has also launched Quantitative Systems Pharmacology (QSP) Immunogenicity Consortium. The QSP Immunogenicity Consortium brings together leading biopharmaceutical companies in a pre-competitive environment to cooperatively develop an Immunogenicity Simulator that will predict immunogenicity of biologics and its impact on their pharmacokinetics, efficacy, and safety in diverse patient populations.

The company also has released version 16 of its Simcyp population-based simulator, its platform for determining first-in-human dose selection, designing more efficient and effective clinical studies, evaluating new drug formulations, and predicting drug-drug interactions (DDIs) and pharmacokinetic (PK) outcomes in clinical populations.

Certara's d3 Medicine has a new interdisciplinary pharmacometrics approach, called Pharmacology to Payer (P2P), which it applied to assess the value provided by specific deployment strategies of an antiviral drug under pandemic conditions. P2P provides a framework to optimize what dose to give and whom to give it to, taking into consideration the

Clinical Research Tools

varying infectivity and virulence of an emerging pandemic virus.

CLINERION INTRODUCES NEW SERVICES FOR MARKET ACCESS

Clinerion has begun offering new services for market access that give pharmaceutical companies insights into patient populations based on its health data analytics tools. Clinerion's Patient Recruitment System (PRS) patient finder tool has a wealth of health data that can now be harnessed to guide pharmaceutical companies in their R&D and commercial decision-making by providing information on the prevalence of target diseases and the distribution of patient populations.

"As we venture into healthcare data analytics, we see a growing demand from pharma companies," says Tigran Arzumanov, head of sales of Clinerion. "With the expansion of our global footprint, we find ourselves in geographies previously not covered by any data collection platforms."

JIM MURPHY
CEO, Greenphire

GREENPHIRE AND EXOSTAR PARTNER TO DELIVER CLINICAL SITE PAYMENT SOLUTION

Greenphire and Exostar have formed a partnership that facilitates the adoption, accessibility, and use of clinical research site payment solutions. The partnership brings web-based Single Sign-On (SSO) functionality to Greenphire's eClinicalGPS, creating seamless and secure access to the global clinical site payment platform.

"There is a great deal of administrative burden placed on a research site to support a clinical trial," says Jim Murphy, CEO of Greenphire. "Greenphire's solutions are designed to reduce this burden and allow investigators and research staff to focus on supporting the trial, not tracking payments. This collaboration with Exostar brings simplicity to the user experience, making it even easier to take advantage of our powerful payment solution."

JEFF COWAN
VP, Technology
MedNet Solutions

MEDNET SOLUTIONS INTRODUCES ECLINICAL CLOUD INFRASTRUCTURE

MedNet Solutions has deployed its eClinical solution iMedNet via a secure cloud delivery

> The next level of important research questions to be answered are going to require larger data sets, and to a certain extent more therapy-specific data sets.
>
> **RICHARD DALY**
> DNAnexus

> The cloud has transformed how the industry thinks about doing research.
>
> **DR. GEORGE ASIMENOS**
> DNAnexus

ings from the process was the need for the field team to communicate with sites prior to electronic questionnaires being sent to them.

"We very quickly ascertained that if the sites received an email with no prior notification from our field team, they either ignored it or the communication went to their junk mail and they deleted it," she says. "Once we let the sites know the electronic site validation questionnaire was coming and that we were personally interested in their participation there was a higher likelihood of response. Our response rates have gone up from 63% when we first rolled out the technology to about 73% today."

Ms. Caruso adds that companies need to have the right clinical experts brought into the transformation because a successful solution is a marriage between people, process, and technology.

"It doesn't matter how good the technology is if you only have one piece of the equation — the experts, the process, and the buy in of the organization all have to be in place," she says.

Data Analytics Technologies

Predictive analytics and emerging technologies such as artificial intelligence and machine learning are significantly impacting the efficiency and accuracy of development processes.

At Novartis, the company is implementing multiple programs to collate and analyze data for more effective, personalized care plans in a much more efficient manner.

The company is using a program called Nerve, designed specifically for Novartis by analytics firm QuantumBlack, to combine data from multiple systems across departments. This includes more than 350 clinical trials from the past few years. This breadth of data gives the company a richer understanding of how a treatment works, and allows Novartis leaders to look at a particular trial comparison to those for other conditions, and not in isolation.

"In doing so, we can see how clinical trials can correspond to one another, and see how our approaches have changed through the years," says Christine Dingivan, M.D., global head of portfolio strategy and innovation, at Novartis. "By sharing this data across departments, we can enhance our ability to make important decisions and conclusions about clinical trials and developed drugs."

Novartis is also using TriNetX, a federated clinical data network of physicians, pharmaceutical companies and research organizations to collaborate on clinical trial data, information and patient recruitment. Novartis partnered with TriNetX to gain access to clinical data in real time from its proprietary network of healthcare institutions, representing more than 30 million patients in the United States and Europe.

"This also allows us to analyze patient populations and demographics for easier recruitment of patients," Dr. Dingivan says.

Novartis also is working with MC10, a company that is developing sensors that would attach to the skin with stretchable material. This new technology has the potential to offer

A modeling approach by pooling data from several trials is a great way to integrate prior knowledge. This way, we increase the power of statistical analysis.

DR. BRUNO REIGNER
Roche

a more precise measurement tool that can be used for real-time data capture in clinical trial modules.

The company also has software to develop a complete end-to-end system with mobile interfaces, cloud storage and analytical tools that offer the potential to help better understand the patient's body.

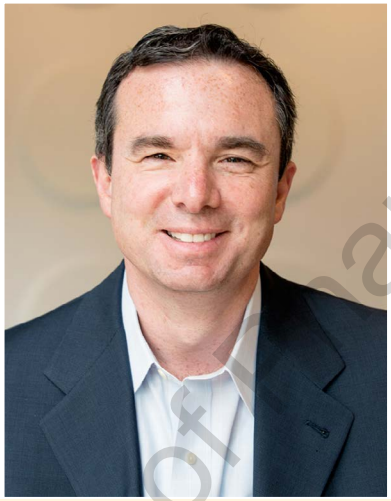
"But we're not just changing the devices we use in trials; we're completely reimaging the clinical trial process away from traditional investigative sites to the patient's home and local healthcare communities," Dr. Dingivan says. "Within our Global Drug Development group, we're exploring a decentralized trial model. Using telemedicine, connected sensors, patient engagement apps and direct data capture tools, we want to implement a patient-centric approach, with a more seamless, personalized experience. We were an early collaborator with Science 37, a mobile technology and clinical trial company using a patient-centric network model to create a digital, remote clinical trial experience."

She says this program moves beyond the trial site altogether, so that a patient can be enrolled through a network provider and undergo some trial related activities through video-conferencing, and in-person visits with nurses when needed.

Determining Dosing for Specialty Populations

Roche's Tamiflu, an antiviral drug that can make flu symptoms milder and can shorten the duration of illness, had a unique design and dosing challenges. Tamiflu was first approved in 1999 for adults and then later for children older than 12 months of age. But determining the dosing for the antiviral for children under 12 months of age was a special challenge for the company.

Scientists at Roche and the National Institutes of Health had to design studies and dosing regimens for Tamiflu for different age



The ability to leverage technology to run adaptive trials and make clinical trials much more effective and efficient is one the biggest trends.

MIKE CAPONE
Medidata

infants. The challenge was how to integrate, analyze, and present the data from these data-intensive studies in a way that would enable regulators to make a decision about infant dosing.

A critical part of the submission strategy was the development of mathematical models to analyze the pharmacokinetic and pharmacodynamic data and the incorporation of this information throughout the clinical pharmacology package submitted to the FDA to support infant dosing.

"We wanted to integrate knowledge coming from different trials," says Bruno Reigner, Pharm.D., Ph.D., head clinical pharmacology — established products, Roche Pharma Research & Early Development. "With this model, we could analyze all the raw data

Clinical Research Tools

environment. MedNet now leverages the processing power of Amazon Web Services (AWS), as well as ClearDATA's best-in-class, healthcare-exclusive security and infrastructure services.

"Migrating to this new cloud environment allows us to provide a more highly available/redundant solution and deliver a higher level of security and compliance," says Jeff Cowan, VP of technology at MedNet Solutions. "It also positions us to continue to grow and improve in terms of what we can offer our customers moving forward."

MONTRIUM ADDS REGULATORY SUBMISSION TRACKING TO REGULATORY NAVIGATOR

Montrium has released the Regulatory Navigator, an interactive intelligence dashboard integrated into RegDocs Connect, its regulatory EDMS. Equipped with business intelligence and intuitive regulatory document management, pharma organizations now have the tools to significantly improve the quality of their content while speeding up the submission timeline.

"Traditionally, life-sciences companies have struggled with disconnected regulatory landscape, where information is managed in several systems, and in multiple regions," says Paul Fenton, president and CEO, Montrium. "The Regulatory Navigator, paired with RegDocs Connect, marries essential RIM functionality with powerful document authoring and management, allowing regulatory teams to create, plan, and track the entire regulatory timeline, in one place."

XAVIER FLINOIS
President
Parexel Informatics

PAREXEL LAUNCHES PATIENT SENSOR SOLUTION FOR CLINICAL TRIAL DATA COLLECTION

Parexel has launched a patient sensor solution, a new offering that securely captures, transmits, stores, and visualizes study subject data in clinical trials. The solution is powered by the Perceptive MyTrials Analytics platform and enables an end-to-end services and technology solution that facilitates the remote collection of study subject data via medical devices.

"Due to evolving regulatory and payer standards in today's healthcare market, there is a growing need to leverage alternative data sources in clinical trials," says Xavier Flinois, president, Parexel Informatics. "Wearables and sensors have the potential to transform Phase I-IV trials as well as observational studies. However, infrastructure and multifunctional expertise are needed to validate the appropriate use of medical devices to generate clinical and quality-of-life endpoints."

Clinical Research Tools

Additionally, Parexel has launched a mobile app for the ClinPhone RTSM (randomization and trial supply management) service. The app is designed to enhance clinical trial supply management processes, increase patient safety, and improve the chain of custody record for clinical supplies.

SIMULATIONS PLUS RELEASES LATEST VERSION OF GASTROPLUS

Simulations Plus has released version 9.5 of its flagship PBPK modeling program, GastroPlus. Enhancements include: new PBPK models for antibody-drug conjugates; new models for subcutaneous and intramuscular injection formulations; revamped workflows for building in vitro-in vivo correlations; and improved reporting capabilities.

Walt Woltosz, chairman and CEO of Simulations Plus, says, "The cost and time to develop new drugs continues to increase, and simulation and modeling software is one of the most powerful productivity tools available to offset these rising costs. Our focus on improving the reporting capabilities in this new version should allow sponsor companies to more effectively communicate results to regulatory authorities and, ultimately, to assist with the drug approval process."

Additionally, Simulations Plus has released Version 8.1 of its ADMET Predictor molecular property prediction software.

TOM SKELTON
CEO
Surescripts

SURESCRIPTS INTRODUCES EPRESCRIBING SYSTEM

Surescripts has introduced Sentinel, which measures the accuracy of electronic prescriptions and delivers insights to pharmacists, prescribers, and technology vendors. The system links multiple data sources, including the Surescripts network, industrywide drug compendia, such as First DataBank, and the National Library of Medicine, to provide actionable intelligence that is accurate, scalable, timely, and detailed. The information is used to validate ongoing data quality improvements; identify opportunities to improve process efficiency; track e-prescribing utilization to identify trends and patterns; and inform research, white papers, and clinical information.

"We brought hundreds of industry leaders together to transform e-prescribing," says Tom Skelton, CEO of Surescripts. "With more than 70% of prescriptions delivered electronically today, this comprehensive approach will have a direct impact on patient care by

The burgeoning information content and the availability of modeling tools means that the pharma industry has to continue to evolve its development mindset to consider the stakeholders: payers, regulators, and patients.

DR. CRAIG RAYNER
d3 Medicine

coming from the different clinical studies and create a small meta-analysis. By doing this, we increased the power of the analytics."

Based on the results from this model-based analysis, Roche received approval for dosing in infants as young as 2 weeks old in 2012.

"These processes supporting the filing with the FDA took about six months," says Craig Rayner, Pharm.D., president of D3 Medicine, a Certara company that lead the clinical pharmacology program.

"Without the clinical pharmacology strategy incorporating the modeling activities, there likely would not have been labeling for an infant dose. If we had looked at the data in the traditional ways using a noncompartmental analysis of different data sets, it would have been very difficult to make the case because the data were so heterogeneous. Without the power of pooling and binding the evidence in a way that is defendable and scientifically credible, a likely outcome would have been the physician community being left to make decisions about dosing in infants on the basis of publications from clinical trials with important design differences."

Dr. Reigner says without this modeling, Roche may have needed to do additional or larger studies in infants.

"Pediatric trials are very difficult to conduct, especially those with children younger than 1 years old," he says.

Managing Trial Supplies

Biopharma company Tesaro was looking for a system to help it manage clinical trial supplies for an adaptive trial. Tesaro wanted to be able to adjust dosing and cohort sizes within specific patient populations to improve the productivity of the study and conserve resources. Leaders from Tesaro sought out Medidata, as the company had used Medidata's Rave product for a number of years.

The result was co-developing a new capability within Balance, Medidata's randomization and trial supply management solution, for pooling drug supplies. Tesaro helped Medidata develop everything from the user interface to some of the algorithms to make sure that correct drug inventories were in the right places at the right time.

"The days of investigators entering data into an EDC system are coming to an end," says Mike Capone, chief operating officer, Medidata. "In the new world, the focus is on new data coming in, such as lab data from sensors on patients or from mobile apps. Imaging is another great example of a new source of patient data. All of these factors will be coupled with machine learning and algorithms that will gradually transform the old data management process and allow drug companies and CROs to run much more efficient, much more patient-friendly clinical trials."

As a result, Tesaro decreased data entry time by about 35%. With the pooled drug supplies, the company saved about 40% on package waste and it reduced shipping costs by about 34%.

The process of co-developing a technology platform was so successful that Mr. Capone says Medidata is committed to partnering on future technologies with clients that are willing.

"We learned that when clients are willing to collaborate and spend time to jointly create a prototype and build a technology, it can lead to a better outcome," Mr. Capone says. "Tesaro shared information with us and taught us things about adaptive trials that proved to be invaluable."

Simona Cipra, VP of clinical operations from Tesaro, says the partnership with Medidata resulted in a drug supply management system that included the functionality and priorities it needed, which resulted in a pooling of investigational product at the depot and investigator site levels to maximize the efficient use of the drug.

"Also increased reporting functionalities have been implemented with our input," she says. "Lastly, we have also successfully implemented integration between Balance and our distribution partners and CT-Fast, our predictive modeling system. Coming in 2017 is full electronic drug accountability at sites from receipt of drug, through dispensing, patient returns, and destruction. All these technology enhancements contribute to increased efficiencies, visibility, and risk reduction."

Ms. Cipra says despite some of the obstacles associated with technical expertise, sys-

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Clinical Research Tools

helping pharmacists and prescribers identify and fix inaccuracies and avoid time-consuming errors."

MARK HEINOLD
CEO
TrialScope

TRIALSCOPE LAUNCHES SOLUTION TO TARGET DISCLOSURE RISKS

TrialScope has launched Atlas Global Compliance, a software-as-a-service (SaaS) solution that ensures clinical trial sponsors are tracking and managing global clinical trial disclosure compliance appropriately. Atlas enables sponsors to quickly ensure that their trials are compliant by combining key information from all sites in the trial into one, easily accessible view.

Mark Heinold, TrialScope CEO, says, Atlas and the expansion of TrialScope's portfolio of transparency and compliance solutions, reflect two shifts in the marketplace: increased complexity and risk and a growing need for broader, more meaningful views of global transparency initiatives.

JENNIFER GOLDSMITH
Senior VP
Veeva Vault

VEEVA INTRODUCES DOCUMENT EXCHANGE SYSTEM

Veeva Systems has launched Veeva Vault SiteExchange, a cloud application that allows life-sciences companies, CROs, and sites to easily access and exchange information during clinical trial execution. Veeva Vault SiteExchange streamlines collaboration among clinical teams for improved visibility across studies and increased operational efficiency to speed the research and development of new treatments.

"The effective and timely management of documentation, information, and end-to-end processes is critical to the success of clinical trials," says Jennifer Goldsmith, senior VP of Veeva Vault strategy. "Veeva Vault SiteExchange fills a significant gap by creating a common way for sponsors, CROs, and sites to exchange information and accelerate the development and delivery of new treatments."

Successfully Implementing New Technologies


Ron Waife

Often there is a disconnect between the state and ability of the industry to adapt to technology on the one hand, and the pace of change in technology and the advocacy for new uses of technology on the other hand.

"We've been preaching for 25 years the importance of what we call organizational preparedness, which means the ability of sponsors to understand their own capabilities, anticipate the impact of new technology or new processes, and then prepare for that adoption before the software or process change is decided on, purchased, the pilot and implementation begin, and the training starts," says Ronald Waife, president, Waife & Associates.

Sponsors have to take steps to make sure that the upcoming implementation of change is going to be successful. Sponsors have to look at the impact a new technology is going to have on how their people do their daily work, whether they are ready for yet another change, and how they will realize the promise of the new technology. Mr. Waife says there are other questions that should be addressed:

- How will the sponsor make the technology work for the organization?
- What are the expectations?
- What metrics will be used to judge whether the implementation was successful or not?
- If the timeline is too long, should the company do something else?

"All of these questions, and others, have to be posed and answered before and during the consideration of the acquisition and implementation of new software or a new technology; this also applies to any process organizational change," he explains.

Additionally, before any new technology is implemented, the governance of the project needs to be aligned — from budgeting all the way through installation and training.

"Often companies don't invest in resources past the starting line; that's where the frustration sets in," Mr. Waife says. "People think there is something wrong with the technology, when instead there was something wrong with how the company went about the project itself."

tems integration, realizing the full potential of the technology investment, and change management, there are three key areas where clinical trial technologies can positively impact the clinical development ecosystem.

"The first is operational efficiencies and cost," she says. "Cloud-based technology has changed the way clinical research is planned and executed. From study design, financial planning, site interactions, to data collection and operational management, technology is driving cost and timelines down. Second, is the interaction with the patient. Technology helps identify where patients are, how to connect with them, and how to augment clinical data with patient data. The third area is data aggregation and decision making. The vast amounts of data and the way that data are available have dramatically changed the way that decisions are made and how research will be conducted in the future. The real-time visibility to data greatly improves the ability to address risks.

"The tricky part is determining how all the new potential solutions are best integrated with one another and not have systems dictate solutions but support them," she adds. "Company ambition to adopt technology can be difficult for already busy departments that would need to focus on change management with every implementation. It is much easier to just keep doing things the old way."

Ms. Cipra says Tesaro will need to integrate learning and metrics more closely into the decision-making process and become more adaptive to what they learn.

"We are certainly learning that we need to bring on more systems and process experts to implement technology solutions and ensure they meet their full investment potential," she says. "Technology enhancements need to be a planned budget item and teams need to be able to implement technology in a way that immediately benefits the company. The skill-sets we look for will evolve to include more technical capabilities."

She says they recently started a function called technical data management to maximize and customize technology solutions to generate data in a meaningful way.

Patient Engagement Technologies

mHealth and digital technology use by the industry is growing and is having the biggest impact on patient empowerment and patient engagement.

"The use of digital technology in clinical trials in fresh and new ways will continue to change the landscape and create new opportunities to make a meaningful impact going forward," says Craig Lipset, head of clinical innovation, worldwide research and development, Pfizer.

Pfizer has conducted more than 20 clinical studies over the past six years that have included different types of wearable technology as part of the protocols. About two years ago, Pfizer launched a program called mClinical meant to provide study teams with better access to a range of mobile tools, such as electronic informed consent, retention apps, and smarter ways of using electronic diaries.

In April 2016, Pfizer and IBM launched Blue Sky, a collaboration to develop remote monitoring solutions for patients with Parkinson's disease. The approach relies on a system of sensors, mobile devices, and machine learning to provide real-time disease symptom information to clinicians and researchers.

The collaboration seeks to create a holistic view of a patient's well-being by seeking to accurately measure a variety of health indicators, including motor function, dyskinesia, cognition, sleep, and daily activities such as grooming, dressing, and eating. Insights from these data could help clinicians understand the effect of a patient's medication as the disease progresses, enabling doctors to help optimize the patient's treatment regimen as needed.

"Patients with Parkinson's measuring their on and off events is a cornerstone of an endpoint but it's largely based on patients having to self-report their ons and offs with different diaries," Mr. Lipset says. "Sensors, coupled with better and smarter ways to capture self-reported data from patients, are going to enable us to have smarter ways to measure patient progress more robustly."

Patients have been at the heart of the development of the Blue Sky program.

"Increasingly, we are bringing patients in when we are planning and designing those tools to get their input for what requirements and what features make the most sense for them," he says.

Mr. Lipset says it's too early to evaluate results from the Blue Sky program, but an important learning from this program was the need for artificial intelligence and the ability to compile multiple types of data to get the type of insights researchers are looking for.

"To have a rich and validated measurement that can support our research and development programs, we often need much more than just the data that come from a single gadget or a single device," he says. "We need to make sure that we can look expansively at different types of data that may be meaningful. We also need to have the right resources internally or partners externally that can help us build and validate the algorithms that are needed so we can pull the data together to be as powerful as possible."

Pfizer is laying the foundation to expand this work around digital biomarkers into other therapeutic areas.

Mr. Lipset says the use of wearables will change R&D strategies and impact the types of development resources companies needed going forward.

DIA Exhibitor News and Updates

The annual DIA conference in Chicago is expected to draw thousands of attendees and exhibitors. Here is a selection of news highlights from some of those exhibitors.

ACM GLOBAL EXPANDS LAB FACILITY

ACM Global Laboratories, an independent central lab specializing in high-quality central laboratory testing and diagnostic lab services, has expanded its European laboratory operations with a new, state-of-the-art 15,000-square-foot facility in York, England.

The facility is being used to assemble and ship investigator collection kits to sites throughout Europe, including central and Eastern Europe, the Middle East, and Africa. The new expansion comes at a time when kit volumes have increased significantly and ACM prepares for further expansion and growth in this area.

Visit Booth No. 2412

JULIE ROSS
President, Advanced Clinical

ADVANCED CLINICAL JOINS ACRP WORKFORCE DEVELOPMENT STEERING COMMITTEE

Advanced Clinical is the latest member of the multi-stakeholder ACRP Workforce Development Steering Committee. The committee is charged with reviewing and approving core competence standards for clinical research professionals developed by the ACRP Workforce Development Task Force, whose contributors include broad representation from leading industry and academic organizations across the global clinical research enterprise.

"I am thrilled that Advanced Clinical is a member of the ACRP Workforce Development Steering Committee further expanding our relationship with ACRP," says Julie Ross, president of Advanced Clinical. "This opportunity will continue our commitment to support excellence in clinical research as well as the potential to modify the model for how we hire and train clinical research staff."

Visit Booth No. 2404

CHESAPEAKE IRB STREAMLINES SITE ACTIVATION AND ETMF FILING

Chesapeake IRB has integrated its IRB platform with TransPerfect's Trial Interactive electronic Trial Master File (eTMF) and study start-up solution to streamline global trial management for sponsors and CROs.

CIRBI (Center for IRB Intelligence) is Chesapeake IRB's completely paperless, cloud-based, 21 CFR Part 11-compliant protocol submission and management platform. CIRBI streamlines electronic submissions for all IRB actions and provides complete and rapid delivery of all IRB data and artifacts through its advanced IRB-Connect technology.

Trial Interactive is a Web-based, 21 CFR Part 11-compliant platform that eliminates the redundancies inherent in paper-based study start-up and TMF management. By providing real-time access to clinical trial documentation as well as automated status notifications for protocols and investigative sites, the integration reduces the time and costs of manually managing IRB-related documentation.

Visit Booth No. 830

CHILTERN RANKED AS TOP CRO

Chiltern was ranked as one of the top three CROs in the 2017 CenterWatch Global Investigative Site Survey this year. The company also came in as a top-rated CRO in the 2015 survey. The survey asked principal investigators and study coordinators to rate the CROs they worked with during the past two years in six categories. Chiltern was recognized specifically for its open communication, timely drug availability, and ranked among the top-three CROs in 17 out of the 37 attributes measured.

"We view our sites as an integral partner," says Jim Esinhart, Ph.D., CEO, Chiltern. "Without them, neither we nor our clients can be successful. With that as our foundation, we are interested in how sites view us when working together. We work hard to try to design our processes around the needs of the site."

Visit booth No. 1807

COGNIZANT LEADERS SAY AI IS THE NEW MACHINE THAT COULD DRIVE THE FOURTH INDUSTRIAL REVOLUTION

Three Cognizant leaders — Malcolm Frank, Paul Roehrig and Ben Pring the authors of Code Halos — have written What To Do When Machines Do Everything: How To Get Ahead In A World Of AI, Algorithms, Bots And Big Data.

Malcolm Frank is an executive VP and chief marketing officer at Cognizant; Paul Roehrig is the founding managing director of Cognizant's Center for the Future of Work, and the chief strategy officer for the company's digital business; Ben Pring is a VP at Cognizant and director of the Center.

The authors of the book have identified the patterns they've lived through, for instance of how opportunities crystalize and affect the IT services business. For example, when business management solutions were built on top of database management software, the market for such solutions and the software took off.

While much of the current debate on how AI will affect humans has centred around automation and job loss — "automation is eating our clients' businesses and it is also eating the IT services companies' businesses"— there are four other things to remember, Mr. Frank says. First, AI bots will enhance human ability in every field — doctors to lawyers to professional sportspersons.

"Being able to access new types of endpoints, we can use digital biomarkers as part of a precision medicine strategy, which has to be incorporated early into the clinical development plan and brought to bear in our protocols throughout development," he says. "It also means we need different types of roles and expertise for a project like Blue Sky to come to fruition, which has required clinicians sitting side-by-side with engineers."

Lilly is another company conducting pilot programs using wearable sensors to understand the disease progression or improvement using activity trackers that are good surrogates for the actual disease. Additionally, the company is looking at how to use connected care, such as a device or sensors to remotely and continuously measure glucose or other types of biometrics.

The company is considering pilot programs in Alzheimer's, Parkinson's, and diabetes, says Joseph Kim, senior advisor in clinical development innovation, Lilly.

"These programs are in various stages of

DIA Exhibitor News and Updates

Today they often rely on informed guesses, but in the days to come the ability to crunch massive amounts of data on the internet will give them a data-driven set of options, and even grade those options according to the ones most appropriate to proceed with.

Next, smarter products, which will be the result of instrumenting everything (building sensors that can talk to a computer into everything around us) from asphalt roads and bridges to airplanes and heart-lung machines, will help us take far more data-based decisions on what needs urgent attention and what can wait

Mr. Frank and his co-authors call the third piece "a new abundance," and financial services is one of the best examples, armed with robo-advisory services.

The fourth piece is about invention and innovation, powered by AI's computing abilities. There are some areas where the use of AI is at a nascent stage, but which will go mainstream well within our lifetimes. Areas like biotechnology will become much bigger than IT in 10 years, or the virtual reality and augmented reality market will be larger than the TV market.

Visit booth No. 1043

DRUGDEV LAUNCHES UNIFIED SUITE FOR CLINICAL OPERATIONS

DrugDev unveiled DrugDev Spark, a unified suite of proven technology solutions. The system reduces the number of systems sites and study teams need to run the study, and operates on a shared data standard featuring the DrugDev Golden Number. The system is available as pure self-service SaaS, full business process outsourcing, or a hybrid of the two.

Additionally, DrugDev has added eConsent Mobile Solution to the Spark suite. Designed to focus attention with documents that are easy for all patients to read, the fully validated eConsent solution uses explanatory videos, audio narration, and glossary of terms. In 2016, DrugDev acquired SecureConsent, which has been providing electronic systems for informed consent for global studies since 2005.

Visit booth No. 536

ERT TRIAL OVERSIGHT UNLOCKS HIDDEN INSIGHTS WITHIN DATA SILOS

ERT Trial Oversight is comprised of two cloud applications targeted to address critical areas of the clinical trials process, site feasibility, and clinical trial management. On average, seven disparate data sources are used for every trial. ERT Trial Oversight seamlessly integrates all data sources to deliver clarity across a complex clinical landscape. The tool provides near real-time visibility across sponsors, CROs, and vendors to enable more effective and timely collaboration.

Visit booth No. 1319

DR. STEVE CUTLER
CEO, ICON

ICON RECOGNIZED FOR EXCELLENCE IN VACCINE DEVELOPMENT

ICON was awarded Best Clinical Research Organization at the Vaccine Industry Excellence (ViE) Awards.

The ViE Awards honor individuals and organizations that continually set standards of excellence and have made outstanding achievements in the vaccine industry over the past 12 months.

"We are very proud to be recognized as the world's best CRO in vaccine development," says Dr. Steve Cutler, CEO, ICON. "Over the past year, we have expanded the capabilities of our Vaccine Centre of Excellence to provide commercial and government clients with the services, site relationships and geographic footprint they need to develop vaccines for a wide range of infectious diseases and global viral epidemics. This award is recognition of the hard work and dedication of the ICON vaccines team and I'm delighted to see their efforts being honored as the industry's best."

ICON's Vaccine Centre of Excellence combines in-depth vaccine experience, extensive laboratory testing, enabling technologies, and longstanding site partnerships to help commercial and government clients take time and cost from their vaccine programs. In 2016, ICON acquired ClinicalRM, which enhanced its capabilities in infectious diseases, vaccine development, and the response to bio-threats and global viral epidemics.

Visit booth No. 1607

INC RESEARCH OFFERS INVESTIGATOR PAYMENT OFFERING

INC Research has expanded its Functional Service Provider (FSP) service offering to include investigator payment processing. Streamlined, on-time, global investigator payments traditionally have been overlooked in the CRO industry as many specialized investigator payment providers lack the resources, technology and global payment execution. INC Research is leveraging the insights gained from its strong site relationships across the globe to improve its own processing of investigator payments.

"INC's long history in working under the FSP business model, along with our proven track record in delivery of customized payment processing solutions for clinical research sites, are combining to create an exciting new offering for our customers," says Tara Fitzgerald, president, clinical development services and head of the company's FSP offering.

Visit booth No. 2015

adoption and often depend on the patient's familiarity with technology," he says. "For example, patients with diabetes are very used to using devices to manage their diseases. People with Parkinson's and Alzheimer's maybe less so. The ease with which we can start applying these technologies and start to change the culture around clinical research are also really important; we can't forget how culture can drive, enable, or create barriers to digital adoption."

Mr. Kim says an important learning for the company has been to consider patient input around new technology as part of the process.

"For some patients, they have a mantra: 'nothing about me, without me,'" he says. "We're changing our mindset here at Lilly particularly in clinical innovation. We have stopped designing things for patients and are moving toward designing things with them. The best way to do this is work directly alongside patients to help create the right experience, the right content, etc. We are adopting a design research methodology versus doing things in an ivory tower." PV

DIA Exhibitor News and Updates

KELLY GRATZ
President,
Adheris Health

INVENTIV HEALTH'S ADHERIS PARTNERS WITH SMARTSTORY

Adheris Health, an inVentiv Health company, and SmartStory Technologies, have formed a partnership to accelerate patient education and support. This partnership enables Adheris Health to leverage the SmartStory platform to deliver personalized, authoritative, and disease-specific digital content via SMS text to patients to improve patient performance and outcomes.

"Enhancing the patient-support ecosystem with unique text technology enables patients to better navigate their care while allowing our healthcare clients and retail partners to deploy comprehensive and integrated adherence communications," says Kelly Gratz, president, Adheris Health.

Visit booth No. 1107

LIFELINES NEURODIAGNOSTIC SYSTEMS INTRODUCES INCEREB NEON FOR NEONATAL APPLICATIONS

LifeLines he Incereb neon is an FDA-approved device designed to address the difficulties of EEG recording in the neonatal intensive-care unit (NICU). The neon lessens the discomfort for the baby, has a gentle conductive paste that is well-tolerated on delicate skin, and has a clean, sleek design that is less frightening to parents.

Visit booth No. 305

TAREK SHERIF
CEO, Medidata

MEDIDATA EXPANDS CLOUD PLATFORM WITH CONTENT AND DOCUMENT MANAGEMENT

Medidata has added regulated content and document management capabilities to its Medidata Clinical Cloud platform. Medidata has agreed to acquire CHITA, a cloud-based content management and collaboration system built on Box Platform, a suite of enterprise-grade content management and collaboration APIs, including electronic trial master file (eTMF) and standard operating procedure (SOP) software solutions.

"We're excited to add a new dimension to the powerful architecture that has cemented the Medidata Clinical Cloud as the industry standard for clinical trial technology driving scientific breakthroughs," says Tarek Sherif, Medidata's CEO. "The life-sciences industry has long struggled with manual, siloed processes for document and content management, creating significant challenges that delay trial timelines and impact overall time to market."

Visit booth No. 1318

MEDPACE EXPANDS MEDICAL EXPERTISE

Medpace has hired Marco Tangelder, M.D., Ph.D., as senior medical director of medical affairs. Dr. Tangelder is a clinical epidemiologist by training with more than 20 years of academic, pharmaceutical, and biotech industry experience, mainly in the development of antithrombotic therapies for a broad range of indications. In addition, Douglas Lee, MB BCh, has joined the CRO as senior medical director of medical affairs. Dr. Lee is an experienced drug developer with about 20 years of experience in both clinical medicine and drug development.

Visit booth No. 1118

QUINTILESIMS ANNOUNCES ALLIANCE WITH SALESFORCE TO BUILD NEXT-GENERATION SOLUTIONS FOR LIFE-SCIENCES FIRMS

QuintilesIMS has entered into an alliance with Salesforce to offer life-sciences companies new capabilities to move treatments more efficiently and effectively from molecule to market.

QuintilesIMS is building new solutions on the Salesforce Platform, taking advantage of built-in cloud, mobile, social, and artificial intelligence (AI) capabilities. These solutions will help life-science companies better manage clinical trials, accelerate patient recruitment, improve efficiency, and effectiveness of marketing activities, as well as achieve other key commercial objectives as they bring new therapies to market and beyond.

Visit booth No. 1723

SCHULMAN IRB LAUNCHES INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) SERVICE

Schulman IRB has launched its commercial institutional biosafety committee (IBC) service. The commercial IBC service provides comprehensive support for research sponsors and sites conducting research involving recombinant DNA (genetic engineering), offering research sponsors, CROs, and institutions an independent option for establishing IBCs when required by federal guidelines.

Led by Daniel Eisenman, Ph.D., Schulman's IBC service supports clinical, preclinical, and nonclinical research, providing all components to complement an existing IBC or build and administer an entirely new IBC. NIH Guidelines require both IRB and IBC review for gene therapy research funded by NIH or taking place at sites that receive NIH funding. The IBC reviews safety aspects of research involving recombinant DNA, including risks associated with genetic modifications and experimental procedures.

Visit booth No. 816

UBC IS REMOVING OBSTACLES TO IMPROVE HEALTH

To help patients access their medications as quickly as possible, United BioSource (UBC) is offering electronically enabled patient access tools to biopharmaceutical manufacturer clients. Its suite of services, for both the pharmacy and medical benefit, includes electronic enrollment and signature capabilities, real-time eligibility and coverage determination tools, as well as electronic prior authorization and support.

While prescriptions for traditional medications can be quickly filled for patients with appropriate coverage, specialty medications often require more robust benefits investigation, prior authorizations, and appeals processing.

For patients diagnosed with a rare or orphan disease, wait time to initiate therapy could extend to days, weeks, or longer, depending on the level of administrative and financial hurdles the patient must overcome. For patients who may have experienced a delay in diagnosis or a misdiagnosis due to the rarity of their disease, additional delays in treatment can lead to further health complications.

Manufacturers of specialty medications often offer the services of a patient access center, or a "hub"

that serves as a centralized point of contact and helps patients and healthcare providers navigate the special requirements that may be associated with these higher-cost therapies. These patient access centers may also provide nursing support, patient education and outreach, and refill assistance, among other services, which help patients access and adhere to their

UBC's patient access centers now offer advanced electronic processes to determine a patient's benefit structure, eligibility, deductible balances, copay responsibility, out-of-pocket balances, pharmacy options and any coverage restrictions.

This capability often replaces manually collecting information through faxes and phone calls. A process that could take days or even weeks to complete can now be performed within minutes.

Visit booth No. 604

PETER BENTON
President and Chief Operating Officer, Worldwide Clinical Trials

WORLDWIDE SURVEY RESULTS REVEAL CRO ENGAGEMENT IS ON THE RISE

A survey by Worldwide Clinical Trials taken at last year's DIA annual conference reveals that 62% of respondents are more likely to engage a CRO partner for clinical research than they were five years ago, demonstrating the increasingly vital role that CROs are playing in modern drug development, and the importance of partnering with a CRO that offers medical and scientific expertise. The sample size was comprised of almost 300 drug development leaders and executives from pharmaceutical and biotechnology companies.

In response to a question about the impact of innovative approaches from a CRO, almost a third (29%) of respondents said innovation in overall trial management would have the greatest impact on clinical development, with just more than a quarter (26%) saying innovation in patient recruitment and retention would have the second biggest impact.

When considering barriers to a new drug development, those surveyed by Worldwide selected the cost of discovery research and clinical development, regulatory guidance, and the risk associated with the clinical development process as the most critical issues.

In terms of choosing the perfect CRO partner, respondents listed the capability for the CRO to deliver high-quality data as the most important factor (83%), closely followed by the ability for the CRO to deliver on time (76%), and within budget (68%).

Interestingly, the findings demonstrate little variation in when respondents are likely engage with a CRO partner, with later phase investigations (Phase II to Phase III) narrowly ranking the highest, over earlier phase investigations.

Visit booth No. 1316

RED ZONE

Provided by: WIRB-Copernicus Group

Three Tips for Reaching Your STUDY ENROLLMENT GOALS

By Suzanne Caruso, Vice President Clinical Solutions, WIRB-Copernicus Group

Finding sites that will enroll patients into a clinical trial is the holy grail of clinical study success. Yet, time and again, many studies fail to enlist study sites that achieve their study enrollment goals. Reasons for this shortfall abound – sponsors feel obliged to investigators they know, self-reported data from sites may not reflect reality, sponsors are limited to the sites offered to them by their CRO. Yet it behooves the study sponsor to find study start-up and patient recruitment partners with the tools and resources to help them meet, and even exceed, their enrollment goals. How do you find such a partner? Here are three things you should ask prospective feasibility/enrollment partners when researching which one is going to get your study where it needs to be – on time and on budget.

1 **How does your investigator data inform performance on future studies?** Often solutions tout the amount of data they have on investigators, but unfortunately the data is generalized at a high level and unable to be predictive of the investigators performance on your study. You need a solution that can evaluate the key criteria of a successful investigator for your protocol then determine which of the investigators conducting work currently should be approached based on their ongoing study and enrollment rate profile.

2 **How does your solution increase investigator response rate?** One of the major barriers of creating investigator interest in your trial is the burden you are asking the investigator to take-on right from the start. Specifically, in responding to a lengthy feasibility questionnaire. Choose a solution that reduces the investigator burden by leveraging information already known about the investigator prior to reaching out such as by auto-populating known demographics and training records.

3 **Does the feasibility solution have the ability to analyze the data received from the investigators in a way that automatically prioritizes sites with the highest level of interest coupled with the site's ability to successfully conduct the study?** Feasibility questionnaires result in thousands of data points which need to be analyzed and organized in a tool with a sophisticated study-specific scoring algorithm that prioritize investigators for clinical teams, saving clinical teams a tremendous amount of time.

These tips will help ensure that you are partnering with a site feasibility and patient enrollment provider that is focused on helping you predictably achieve 100% of your enrollment goals, on time and on budget. When evaluating prospective partners, be sure that they have a solution that allows sponsors to harness the power of performance analytics and insights with a streamlined feasibility service focused on ensuring you have the information you need to make the right investigator decision. ●