PharmaVOICE
SPECIAL PUBLICATION

VOICES OF TRANSFORMATION

Industry experts share their insights on the state of clinical trials today and tomorrow.

WHAT'S NEW

Dozens of companies operating in the clinical trial arena announce their new products, services, and tools.

THE FUTURE OF CLINICAL TRIALS IS NOW

PharmaVOICE

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A Look to the Future

The future of clinical research and development is here. The global pandemic of COVID-19 has ushered in a new age of digital care, forever changing how clinical research is to be conducted. All stakeholders, from patients to sites to sponsors to CROs to technology companies, are embracing virtuality. In some cases, the technology has been around for some time, just not implemented fully. And in other cases, innovative tools are being employed. The coronavirus has provided the impetus for companies of all types to adopt and adapt to new ways of assuming and providing care — in a sustainable fashion — through the digitization of many of the processes normally conducted in person. While it's not expected that all clinical trial procedures and processes will become digital and or will be conducted virtually, the advantages of doing so are many — cost-wise and resource-wise.

The opportunities ahead are ripe for those entities that are moving beyond pilot-stage projects and embracing technology solutions that progress patient-centricity to new levels.

And public opinion is on the side of progress. With no less than 100 different manufacturers with vaccines and treatments in clinical trials, the public's interest in clinical research studies is trending positively and moving the needle in terms of the public's perception of the pharma industry.

According to MC-Rx, a full-service pharmacy benefit manager (PBM), Gilead, the company that developed the antiviral drug remdesivir, has already pledged 1.5 million doses of the drug at no cost to COVID-19 patients. Other companies, such as Johnson & Johnson, Pfizer, and AbbVie, have donated more than a combined $125 million for COVID-19 disaster relief. AstraZeneca has partnered with Oxford BioMedica to develop and market vaccines, potentially by the end of the year. Even the U.S. Department of Health and Human Services is partnering with pharma companies to expand drug manufacturing for needed medications during the global pandemic.

In this special eBook, thought leaders from many of the companies that are forging the future share their insights on what's ahead from virtual trials to rare disease patient recruitment apps to the supply chain.

You will also find COVID-19 related news as well as other announcements from selected 2020 virtual DIA exhibitors.

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Basics/Data Analytics

- EDC/DM
- eSource
- Pre-Screening Log
- Data Coding
- General Log
- Risk Management

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- ePRO/eDiary Web
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- eConsent

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Graham Belgrave
Senior VP, European Operations
Advanced Clinical

As an industry we have improved many of our processes as a result of COVID-19, which is a definite positive.

A New Remote Reality

Despite the many innovations and brilliant scientific and medical advances, the life-sciences industry is still fairly risk averse. Graham Belgrave, senior VP, European Operations at Advanced Clinical, says one potentially positive outcome is that companies will be "encouraged," or perhaps forced would be more accurate to consider, to deploy and use the plethora of elegant and functional e-solutions and remote capabilities, some of which have been around for some time. "The pandemic also has kick-started many other potential solutions to access, treat, evaluate, and manage research subjects and as the new normal takes shape, I think we can expect to see some, perhaps radical, alternatives come to the forefront," he says.

Managing a widely dispersed global team based in offices is normal business for many organizations, and yet what occurred upon lockdown is anything but normal. "We are fortunate to have superb business technology and platforms in use throughout the company; these are designed to protect both our client's confidential information and to also be GDPR compliant," Graham says. "Following FDA guidance to ensure explanations relating to COVID-19 of missing data, our biostatistics and data management team developed a COVID-19 Impact EDC page to capture all relevant data in one place. This will dramatically reduce the number and need for mid-study updates and provide all this data in one place."

Graham says Advanced Clinical is working with sites and clients to transition whenever possible to virtual patient visits, while some sites are also minimizing patient's on-site attendance through home visits or telehealth. "What has clearly become perhaps self-evident is the absolute need for processes that match the new normal, for timely, frequent communications, robust and compliant systems, and perhaps most importantly, collaboration," he says. "I believe that this spirit of collaboration, communication, and thinking outside the box will prevail and a return to the status quo would indeed be a retrograde step. I strongly believe that remote working, RBM, and tele visits will continue as will the ongoing innovation associated with Internet-based applications that increase the speed and utility for all parties to communicate and safely and compliantly share information from remote locations. In addition, risk assessment and mitigation steps for new study protocols as well as new or modified requirements for SQV and SIV will continue."

Graham says, perhaps, more radically, there will be a "blurring" of the CRA and DM roles, perhaps in some instances a blended role within these new paradigms. "I do not see the removal of the need for face-to-face and on-site visits, albeit perhaps at a reduced level, after all I would submit that the establishment of effective working relationships is far easier, at least initially, face to face," he says. "Overall, I do believe as an industry we have improved many of our processes as a result of COVID-19, which is a definite positive."

Find out more at AdvancedClinical.com

Advanced Clinical

Dr. Joanne Santomauro
CEO and Founder
Ancillare

Shoring Up the Supply Chain

Clinical trial design must adapt to the changing global footprint and needs of the end users — the investigators and patients.

The COVID-19 pandemic has created numerous challenges for everyone worldwide. In this current environment, clinical trials must adapt to changing conditions and innovate for the future. Dr. Joanne Santomauro, CEO and Founder of Ancillare, says assurance of clinical supplies is critical to overall success and more emphasis must be placed on ensuring supply chain execution before study kick-off.

"Many trials are looking toward virtual/direct-to-patient models to limit interactions and create ease of access for patients globally," she says. "Clinical trial design must adapt to the changing global footprint and needs of the end users — the investigators and patients. Supply chains need to evolve to be easier to access in all markets and must allow for patient centricity to encourage trial completion."

Dr. Santomauro knows that supply chains must be efficient and flexible to promote programs to enable accessibility globally. Further, data analytics and technology are key to further success. "As the industry evolves, new technology platforms are available to provide predictive analytics to help build the most efficient and effective clinical trial platform," she says. "By embracing these new inputs, the industry will be able to work through a paradigm shift that allows for much greater odds of success before a program is even launched. Finally, the role of partners in the industry will become more specialized and more integrated into clinical trial development. Instead of a one-size fits all model that forces programs through an inefficient outsourced model, partners with specific focuses will grow with sponsors to provide global expertise and maximize efficiency across all areas of the clinical trial system."

Ancillare works with major pharmaceutical, biotech, and clinical research organizations to deliver transformative technologies that bolster the supply chains that are critical to success.

Prior to COVID-19, Ancillare had been working feverishly on bringing this new technology to market and now this work is more important than ever in the near and long term. Dr. Santomauro says Internet of Things (IoT) applications that provide solutions to monitor product flows across the chain, control inventory, offer safety, security, and quality control of shipments within the chain together with systems that facilitate asset management at trial close-out are a few of the areas of focus. "Finally, data science that focuses on analyzing current and historical data that ultimately delivers results to better predict the future provides opportunities for future growth," she says.

Ancillare provides to the market a unique model that combines the physical execution of the supply chain with the necessary data analytics to ensure that materials are acquired, distributed, and managed globally. As this model continues to grow and clinical trials are performed in unique applications, the Ancillare model will continue to provide sponsors with the platform to execute efficient clinical trials.

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Find out more at ancillare.com

Nina Wachsman

Jake Wachsman

Principals of Augur Health LLC

Humanizing Patient Recruitment

The principals of Augur Health found their goal streamlining clinical trial recruitment for rare disease achievable through the latest AI-driven technology platform — Know Rare, an innovative turn-key, patient-focused recruitment platform that connects rare disease patients to interventional clinical trials.

"Know Rare shortens the time from identification to screening by using AI technology to match an applicant's profile to clinical trial eligibility requirements," says Nina Wachsman, one of the two principals of Augur Health LLC, which developed the Know Rare technology platform. "Applicants are able to go directly from inquiry to scheduling a screening appointment in real time, reducing the significant drop off that occurs due to lag time in recontacting inquiries from potential study participants."

Personally connected to the rare community, the two founders are committed to accelerating trials, which is particularly important during the current pandemic. "Due to COVID-19, more people are engaging online every day to find out about clinical research for a vaccine or treatment for the virus," Nina says. "With delays due to the pandemic, sponsors are eager to get back on track and under pressure to achieve milestones, so accelerating identification and screening, which our platform does, will be essential."

The two founders are using their extensive marketing experience and digital expertise to bring value to patients, sponsors, and study centers. "New technologies will be part of the solution for both access and for trial recruitment," says Jake Wachsman, who led the development of the platform. "The industry, healthcare providers, and even the FDA were forced by the pandemic to embrace technology at an accelerated pace; it has proven its worth and will continue to do so."

The Know Rare platform not only provides transparency across the process to study centers, sponsors, and patients, it also creates a user experience that engages the target audience in the right way. "People can log in, fill out an application once, and through specially created algorithms are instantly matched to specific treatment studies from clinical trials.gov," Jake explains.

To maintain engagement, patients can take self-assessments, which adds to their profile, making study matching dynamic, with next studies shown correlating to the updated profile. The screening appointment made through the platform can be for a virtual visit, which can be more efficient for the study center and may further accelerate screening and recruitment. "We have taken a big leap into the development of the Know Rare platform because we believe the future is patient-focused," Nina says. "With technology to streamline processes and accelerate trials, patients will more easily find and access clinical studies for rare diseases. All of our combined experience tells us this is where we can add the most value and help bring new therapeutics for rare diseases through trials faster and more efficiently."

Find out more at knowrare.com

Jim Mahon
VP, Chief Strategy and Marketing Officer
ERT

The Opportunity to Operate Differently

One of the few positives from the pandemic, according to Jim Mahon, VP, chief strategy and marketing officer, at ERT, is the forced opportunity to operate differently. "All stakeholders have been forced to adapt, and in many instances been surprised by the enduring benefits of digital virtual technologies. I see a post-pandemic scenario where the industry emphasizes optionality and leverages advanced technologies to better engage patients in clinical trials and optimize in-person investigative site visits for important complex trial aspects that uniquely require the capabilities of sites."

Jim believes there will be more virtual site visits, which will minimize the need for patients to travel to investigative sites, and increased device integrations with consumer and medical data capture tools, all of which will simplify patients' participation in clinical trials and improve their overall engagement. "By doing so, the industry will benefit from more streamlined clinical trials, expanded patient engagement and accelerated clinical development times," he says.

In this new environment, the industry needs reliable solutions that enable the capture of important safety and efficacy data to keep current trials on track, regardless of whether trial patients have physical access to investigative sites and personnel.

In this new environment, the industry needs reliable solutions that enable the capture of important safety and efficacy data to keep current trials on track, regardless of whether trial patients have physical access to investigative sites and personnel. "Our infrastructure and flexible approach to new product development is enabling us to accelerate our investment in a broad range of virtual trial capabilities that are meeting industry needs and helping our customers continue and start new clinical trials, during and after the pandemic," Jim says. "We will continue to emphasize optionality across our technological innovations so that our customers are best positioned to successfully execute their trials across any protocol complexity or virtual/ physical continuum.

"ERT has always been at the forefront of delivering innovative solutions that help our customers accelerate clinical development," he continues. "This hasn't changed during the pandemic. If anything, COVID-19 has amplified our approach to informed decision-making and calculated risk-taking related to new product introductions."

With the industry changing at a record-setting pace, ERT is committed to meeting with customers regularly and incorporating their input to ensure the virtual trial capabilities being delivered continue to meet their needs during this unprecedented time. "Personally, I've always thrived in dynamic situations and I challenge my team to always keep striving and reaching for improvements and growth," Jim says. "Today's challenges offer an opportunity to realize that growth in an accelerating environment."

ERT®
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Find out more at ERT.com

Eran Gordon
Senior VP, Business Operations, Research & Development Solutions
IQVIA

Keeping Patients Engaged Now — And in the Future

At IQVIA we are focused on ensuring we make a real difference in patients' lives around the world and delivering on our mission to advance human health.

Patients today are far more healthcare and technology savvy than in the past, and they need to be treated as valued partners in the research process. "This crisis has shown us just how important it is to keep patients engaged and educated throughout the trial and after," says Eran Gordon, senior VP, business operations, Research & Development Solutions, IQVIA. "It is becoming apparent to key stakeholders in the industry, including regulatory agencies, trial sponsors, and study teams that patient-centric technologies and approaches such as virtual tools and models, remote monitoring, and telemedicine are viable solutions well beyond COVID-19."

Eran adds that real-time, technology-enabled approaches provide a necessary lifeline to continue clinical research, all while enhancing patient engagement with more diverse patient populations, accelerating recruiting, and lowering the burden of trial participation.

IQVIA is passionate about its journey to improve outcomes for patients and move healthcare forward. "Our long-standing commitment to push the limits of innovation has enabled us to aid our customers and patients during the COVID-19 pandemic," she says. "Our solutions leveraging artificial intelligence, machine learning, virtual trials, decentralized trials, telehealth, and direct-to-patient recruitment are keeping trials moving in the short-term. For example, we are using our extensive access to data coupled with our talented data scientists to enable forecasting clinical trial recovery at a site level throughout the world. Furthermore, we are advancing COVID-19 trials specifically to connect stakeholders to better understand treatment and prevention."

Recently, IQVIA launched the COVID-19 Trial Matching Tool, one of the world's first online screening platforms, matching individuals with specific COVID-19 studies. And, its COVID-19 Active Research Experience (CARE) Registry provides opportunities for the patients to receive information related to the disease, symptom progression, and treatment outcomes. "We are proud to be closely involved in developing treatments and vaccines for an illness that has impacted the lives of so many globally," Eran says.

We will continue to build on our advances in human data science and technology to ensure we meet our customers' needs in real time.

"It is our responsibility to not only advise and help solve many of our customers' challenges, but to lead the way in leveraging today's environment to influence the long-term, including, protocol design and simplification, patient recruitment, regulatory reviews, clinical processes, supply chain, technologies, and tools. We need to achieve agility with patient-centric design and the right technological infrastructure. From planning clinical trials to using real world data and advanced technologies to shorten timelines and improve the impact of research investments our ultimate goal remains getting therapies to patients faster."

"At IQVIA we are focused on ensuring we make a real difference in patients' lives around the world and delivering on our mission to advance human health," she says. "My role as a healthcare leader is to inspire and enable this mindset now — more than ever."

IQVIA

Find out more at IQVIA.com

MaryAnne Rizk, Ph.D.
Senior VP,
Digital R&D Strategy
IQVIA

The industry is innovating at the pace of change, which is exciting for sponsors and patients.

Orchestrating Outcomes in the Digital Age of Care

Innovative technology solutions are forging the next steps in the industry's evolution to orchestrate outcomes toward the digital age of care. The first step is understanding patients' needs across their journey, which allows us to intelligently orchestrate their experience. "The industry shift from site-centric to patient-centric allows us to design the what, why, and how with the patient at the center," says MaryAnne Rizk, Ph.D., senior VP, digital R&D strategy, IQVIA.

By delivering the value provided by purpose-built`solutions for trial sites and sponsors in both clinical and real-world settings, companies can accelerate innovation and transform decision-making. From site access to patient recruitment to drug delivery, flexibility and agility are key in the digital age of care.

"IQVIA Technologies is helping to ensure our customers can continue to study disease, help patients, and continue to innovate," Dr. Rizk says. "We are committed to helping improve patients' lives and patient safety. We are transforming clinical development through our digital technologies, our data, and our services. Our focus is on making sure that we empower our customers to create more innovative, more precise, and faster clinical development solutions."

IQVIA's cloud-based technologies are intuitive, intelligent, and interoperable — and most of all, they anticipate and meet the needs of the patient to elicit the type of authentic responses that result in meaningful data. "We are helping our customers improve the way patients engage in the clinical setting," Dr. Rizk says. "Our strategy is to design orchestrated clinical trials that dramatically improve the patient experience."

Across IQVIA's Orchestrated Clinical Trial portfolio, the emphasis remains on the patient, helping them understand how to enroll in a study and assisting them in every step of the process. "IQVIA's Digital Patient Suite includes an integrated set of tools that follows the journey of a patient from recruitment and compliance to retention and return," she says. "We have enabled turn-key solutions that orchestrate the anticipated patient journey. From simple to use Saas eConsent, to IP medical drug dispensation, and telehealth engagements, we have developed a concierge experience for patients. This will make a huge difference in patient recruitment and enrollment. We are committed to transforming the experience so that patients look at clinical research as a care option."

Within its Orchestrated Clinical Trials platform, IQVIA has more than 20 different applications as part of its strategy to digitize clinical research. Ultimately, IQVIA's perspective on digital innovation for clinical trials is grounded in value. With so many different opportunities to apply digital solutions, depending on where an organization is in its maturity or openness to innovation, being focused on value keeps a one-size-fits-all solution off the table.

With a future that envisions data and digital going hand in hand, there will be a need for best-in-class partners to disrupt traditional processes with solutions that create the shortest critical path to success. "The future of the industry is orchestrating around patients to drive innovative outcomes," Dr. Rizk says.

IQVIA

Find out more at IQVIA.com

Richard Gliklich, M.D.
CEO
OM1

The Future State

Covid-19 taught the industry not to rely so heavily on the time and manual effort of clinicians and research staff to keep the research enterprise functioning.

"Our focus in real-world data is through automated data networks — the first step in learning health systems — where research and practice are intertwined and interoperable systems enable both. That is where our industry needs to move with our clinical partners to get to a new future state," says Richard Gliklich, M.D., CEO of OM1.

Dr. Gliklich says focusing on collecting, processing, delivering, and applying real-world clinical data to accelerate medical research will advance personalized healthcare. "Initially, our most significant opportunities came from our novel technological approaches to developing data networks and processing that data, which enabled more complete and rapid data collection at lower costs. These enabled our customers to move from traditional registries and post-marketing surveillance programs to large, automated, RWD collection with minimal provider burden."

He notes as a result of 21st Century Cures Act, interest in comparator cohorts or external control arms has grown dramatically as companies seek to test results of early phase trials in real-world data (RWD) sets and regulators demonstrate willingness to use such data in certain approvals. "However, most companies are still only seeing the tip of the opportunity iceberg with clinical RWD," Dr. Gliklich says. "For forward-thinking organizations, RWD is viewed as a strategic asset across the product lifecycle. These companies leverage our data and machine learning models for understanding the market for early discovery, identifying disease subtypes, designing and executing clinical trials, including identifying patients, lowering costs for meeting post-marketing requirements, demonstrating comparative effectiveness and value, and partnering with providers and payers.

"At the same time, the role of RWD in personalizing healthcare is still in its infancy, with most success still limited to oncology, but we see the opportunity here in the longer term as enormous," Dr. Gliklich continues. "Being able to apply AI on top of condition-focused, high-quality RWD to deliver targeted treatments and care based on individual benefit:risk profiles and phenotypic biomarkers will be paradigm shifting for life-sciences companies, providers, payers, and most importantly, patients."

Find out more at OM1.com

Dr. Sy Pretorius
Executive Vice President,
Chief Medical & Scientific
Officer
Parexel

Even when we can't meet face to face, as innovators we ensure life goes on.

This year, the DIA Global Annual Meeting is one of several conferences that has nimbly adapted to circumstances by becoming a virtual event. At Parexel, we also find ways to meet the challenges the world throws at us. Take our Decentralized Clinical Trials, for example. They represent an opportunity to rethink and refresh how research studies are conducted, while keeping the patient at the heart of this emerging paradigm.

Developed within our Patient Innovation Center, our flexible Decentralized Clinical Trial solutions provide both fully virtual and hybrid, as well as side-by-side options. And it's never been more important than now to ensure that research studies continue, at the same time as doing all we can to protect patients, families, and clinical trial personnel. Having the capability to conduct some or all of the study away from clinical sites, by bringing as much of the trial as is practical into a patient's home, is a key factor in this.

With more than 70 Decentralized Clinical Trials already underway or complete, and experience in excess of 200 remote patient engagement strategies, Parexel is leading the way as a prepared partner to the industry. Our Decentralized Clinical Trials combine in-house expertise and patient/caregiver insights with the very latest technologies to create bespoke strategies that can help sponsors meet their goals, even under the most testing of circumstances.

So together, let's keep working to ensure treatments continue to get to the patients who need them most.

The future of clinical trials is now. And, by making it easier for patients to participate in research today, our Decentralized Clinical Trials are defining a better pathway to the medicines of tomorrow.

Find out more at parexel.com/Decentralized

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Gregory T. Simpson
VP and Head of Marketing
Saama Technologies

A New Remote Reality

Clinical trials will never go back to pre-COVID-19 patterns, due to the significant, pandemic-driven acceleration of technology adoption. "Pre-pandemic, remote monitoring and decentralized trials were underutilized," says Greg Simpson, VP and Head of Marketing, Saama Technologies. "Now, with clinical research associates — CRAs — sheltering in place, leveraging technology like remote monitoring is a priority. Companies that previously had office-based workforces realize the benefits of working from home and are shedding office space. Tech CEOs, such as Twitter's Jack Dorsey, who knew the value of remote work, are announcing that employees can work from home permanently. Once a CRA and his or her company realize the benefits inherent in monitoring all sites from one location simultaneously, they'll never go back to previous, less productive ways."

There's also a parallel with the known patient recruitment advantages inherent in decentralized trials, and COVID-19 highlighted additional benefits. "Near-real time patient monitoring, including adverse events and increased accuracy of sensor and wearable data, offers greater advantages than patients completing monthly diaries in site parking lots," he says. "COVID-19 has enabled clinical trials to peer into the future and see how promising it looks. There is no turning back."

COVID-19 has enabled clinical trials to peer into the future and see how promising it looks. There is no turning back.

The single biggest change the industry needs to make is to enable the technology used for clinical studies to catch up to the technology used for scientific research. Just as clinical research has traditionally depended upon in-person engagement in studies, so has B2B technology marketing. A high percentage of connections made between sponsors and tech partners begin at in-person events. "As a B2B tech marketing leader serving life sciences, I'll adjust my approach by accelerating adoption of marketing technology — MarTech," Greg says. "I'm a firm believer in leveraging technology as much as possible and doing more of what works and less of what doesn't."

As a board member of a financial institution, Greg is acutely aware of concentration risk; a high level risk arising from more concentrated portfolios being less diverse, where returns on the underlying assets are more correlated. "Applying that concept to B2B marketing has enabled me to achieve an optimized balance of leveraging what has worked in the past, while incorporating new marketing technology and also pulling other marketing levers," he says. "As a result, no matter what the future brings, my marketing efforts are diversified and not significantly impacted if one tactic, like in-person events, is disabled."

Find out more at saama.com

During these fast-moving times, we are pleased to showcase news from selected 2020 DIA Annual Meeting exhibitors.

Advanced Clinical

In March 2020, Advanced Clinical, a clinical development organization, was named a Crain's Best Places to Work in Chicago 2020 finalist. Honored by this distinction, Julie Ross, president of Advanced Clinical shared, "As employers continue to offer more competitive benefit packages and workplace perks to attract top talent, it's encouraging to know that Advanced Clinical ranks as one of the preeminent businesses in an impressive pool of employers in the Chicago area," she says. "Our employees are at the heart of our organization's success. This distinguished award and recognition affirms our commitment to ensuring they feel valued for the significant contribution they make every day to create a better clinical experience for our clients and communities around the world."

In other news, Advanced Clinical in February continued its global expansion into eastern Europe with the opening of a new office in Kyiv, Ukraine. To lead efforts in Kyiv, Andrii Paliichuk was appointed as the managing director and project manager of Ukraine. Mr. Paliichuk holds a Master's degree in science and chemistry and is PMP certified. He brings a wealth of experience in running a CRO business in Ukraine and acting as project manager on local and global studies. His extensive clinical expertise includes oncology, central nervous system (CNS), gastrointestinal (GI), and rare disease. In addition to Ukraine, Romania, and Italy, Advanced Clinical also has established European operations in Frankfurt, Germany; Amsterdam, Netherlands; Guildford, U.K.; Madrid, Spain; and Paris, France.

Also in February, the company was recognized by ClearlyRated, earning the Best of Staffing Client and Talent Awards for the fifth consecutive year. Best of Staffing winners are proven industry leaders in service quality based solely on the ratings given to them by their clients and the consultants they've helped place.

For more information, visit advancedclinical.com.

Advarra

In June 2020, Advarra, an institutional review board (IRB), institutional biosafety committee (IBC), research technology solutions, and quality and compliance consulting services, has added two senior executives to its rank: Jivan Achreja as chief technology officer and president, technology solutions, and Bryan Spielman as chief growth officer.

Both Achreja and Spielman fill newly created roles and will report directly to Advarra's CEO, Gadi Saarony. These strategic new roles help accelerate Advarra's development of integrated solutions that can better empower clinical trial research and advance human health.

Leading Healthcare Companies Announce COVID-19 Research Database

In April, Advarra joined a consortium of leading healthcare companies to launch a COVID-19 Research Database, a secure repository of HIPAA-compliant, de-identified and limited patient-level data sets made available to public health and policy researchers to extract insights to help combat the COVID-19 pandemic. The database is a pro bono, cross-industry collaboration. Additional collaborators include: Aetion, AnalyticsIQ, Arcadia.io, Berkeley Research Group, Boston Health Economics, Change Healthcare, Datavant, Elsevier, Glooko, Health Care Cost Institute, Healthjump, Helix, Medidata (a Dassault Systèmes company), Mirador Analytics, Munich Re Life US, Office Ally, Omny Health, Parexel, Prognos Health, QIAGEN, Snowflake, Sumitomo Dainippon Pharma, Symphony Health, and Veradigm.

Also in April, Advarra, acquired IRB Company Inc. (IRBco), an AAHRPP-accredited central IRB that has conducted research reviews in the U.S. since 1981. Advarra continues to expand its presence as the largest provider of integrated IRB services in North America.

"Advarra builds on its commitment to advance human health and better enable clinical trials with this acquisition," says Gadi Saarony, who was named CEO of Advarra in February.

For more information, visit advarra.com.

AiCure

AiCure, a leading artificial intelligence (AI) and advanced data analytics company, and Science 37, an industry leader in virtual clinical trials, have entered into a collaboration to support and deliver enhanced technology for virtual trials. As the first endeavor for the new partnership, the two companies will use a virtual or decentralized research model — in which patients participate from home — to evaluate an investigational treatment for major depressive disorder (MDD) in a clinical trial this summer. AiCure will enhance the quality of data collected and reduce both the time and cost of conducting the trial by providing real-time monitoring of patient dosing and novel insights into patient behavior. AiCure's proprietary platform will monitor remote dosing adherence and measure digital biomarkers, including facial and vocal expressivity, to evaluate depression in patients. The platform will also enable remote registration, training, and micro-reimbursements to patients for increased patient participation. In addition, there will be real-time access to patient-quality metrics, which allows for quick, data-driven modifications to study requirements and improves the predictability of study timelines.

In April, AiCure introduced its digital biomarker platform to remotely detect subtle changes in a patient's condition. The platform leverages computer vision and AI to gather and analyze visual and auditory cues directly through the patient's smartphone camera, pinpointing critical patient responses and behavioral trends with the frequency and accuracy needed to elevate the integrity of clinical trial data. By aggregating clinically sound insights in a patient's natural environment, AiCure empowers pharmaceutical companies to improve their understanding of disease symptomology, drug dosing side effects, and stratified disease variations, ultimately supporting improved health and trial outcomes.

Also in April, AiCure appointed Ed Ikeguchi, M.D., as CEO. Formerly, Dr. Ikeguchi served as the company's chief medical officer.

For more information, visit aicure.com.

Ancillare

Ancillare, a global clinical and ancillary supply chain leader serving the end-to-end ancillary supply chain management needs of large- and middle-market pharmaceutical, biotechnology, and medical device companies, as well as contract and medical research organizations, has launched its new Ancillare Digital Communications Platform (ADCP).

ADCP is an interactive communications portal that marries Ancillare's 16 years of rich clinical trial ancillary supply data with AI, analytics, and collaboration technology. The platform provides sponsors with real-time predictive insights into the Clinical Trial Ancillary Supply Chain (CTASC).

This platform, built by Ancillare's technology team, offers sponsors a central access point to track the flow of ancillary supplies in their clinical trials. Its key capabilities will include inventory information and alerts, shipment tracking, real-time document collaboration, trend analysis and forecasting, EDI and sponsor single sign-on functionality.

The launch follows the appointment of Ancillare's new VP of global information technology and infrastructure, Deighton Liverpool. Under his guidance, Ancillare's leadership team is executing on plans to further streamline the ancillary supply chain through innovative technologies.

For more information, visit ancillare.com.

Axiom Real-Time Metrics

Axiom Real-Time Metrics, which delivers intuitive, powerful, and cost-effective eClinical solutions and services around an entire study, is responding to the unique and unprecedented circumstances of the COVID-19 global pandemic. Andrew Schachter, founder and CEO of Axiom, shared, "Being a global company, we are responding to our clients in this time of change and need for collaboration and innovation. Axiom is continuing to provide solutions to our clients at an accelerated pace. We are able to adapt our technology quickly to support

the present requirements of all studies — whether it be increased remote monitoring and documentation, various configurations of our ePRO (electronic patient reported outcomes) tools, providing mobile hardware to sites and patients, adapting Fusion study databases to suit affected study changes, or anything else — we are at our clients' disposal — whatever it takes."

For more information, visit axiommetrics.com.

BBK Worldwide

While COVID-19 has severely affected many industries, scientific pursuit for a host of medical conditions is also threatened by sharply negative effects of the pandemic on clinical research for non-COVID-19-related pursuits. This is evidenced by an industry-reported 65% decline in new patient study enrollment in March 2020 relative to March 2019, according to a study conducted by BBK Worldwide, a leader in patient experience, enrollment, and engagement, in May. The industry is adapting by borrowing from the zealous approach associated with COVID-19 research by deploying extraordinary collaboration and patient-centric services to achieve timelines for as many studies as possible.

"Although Phase I trials involving healthy adults leery of virus infection are the most affected, even trials related to life-threatening conditions are seeing significant reductions, with oncology trial enrollment down by 48%," says Rob Laurens, principal, quality assurance, BBK Worldwide. "Coupled with the need for a response to this pandemic is the need to ensure the continuity of existing trials and the start of new research. At BBK, we're making a difference by deploying any reasonable means to support patients already enrolled in important studies relevant to them and the rest of the world."

The application of innovative solutions that break down barriers to enrollment has a positive effect on study completion timelines, meaning treatment options are available for those in need on a more efficient basis. BBK's analysis of responses from more than 19 countries, 400 sites, and 800 patients demonstrates that baseline support to participants, such as immediate reimbursement for study-related out-of-pocket expenses and arranged travel itineraries for visits combined with high-quality provisioned ground transportation, increases compliance and retention.

In a February study, BBK Worldwide found unexpected similarities between healthcare consumers and clinical trial participants. The survey challenges the long-held belief that the clinical trial experience should be approached differently than the healthcare consumer experience. The latest "Study Voices" survey — part of an ongoing series of surveys — explores patient attitudes towards technology, healthcare affordability, physician access, transparency, and quality of care. It features responses from 2,067 individuals — 63% of whom identify themselves as healthcare consumers and 38% of whom identify themselves as clinical trial participants.

"We chose to explore this topic because historically the industry has approached clinical trial participants differently than healthcare consumers — based on the belief that what works to engage healthcare consumers won't work to engage clinical trial participants," says Aaron Fleishman, director, market development, BBK Worldwide. "As we see the emergence of a new, empowered healthcare consumer, we wanted to put this belief to the test."

The survey results showed no discernible difference between participants in clinical trials and the general public in terms of the way they think about health decisions and how they manage their health. For example, use of wearable devices (e.g., health trackers) was consistent across both groups. On a scale of 1–10, with 1 being never and 10 being always, 19% of healthcare consumers ranked their use of wearables between 8–10, and 16% of clinical trial participants ranked their use of wearables between 8–10.

Findings confirm the importance of access to health information, proximity to a specialist, and appointment reminders for healthcare consumers and clinical trial participants alike. Both groups preferred multiple avenues of communications when engaging with their doctor, with 51% of clinical trial participants ranking email communication as very important compared to 44% of healthcare consumers; 66% of clinical trial participants ranking telephone communication as very important compared with 57% of healthcare consumers; and 38% of trial participants ranking text messaging as very important compared to 40% of healthcare consumers.

Another important takeaway from the survey is that the patient's relationship with the doctor is still the most important thing, regardless of whether they are a healthcare consumer or a clinical trial participant. The increase in new technologies and expansion of communication channels cannot replace the personal connection that patients clearly seek.

For more information, visit bbkworldwide.com.

BioClinica

In May, Bioclinica, a provider of clinical science and technology expertise to assist the life-sciences industry, launched a specialized program for the adjudication of adverse events that could result from COVID-19 infection. Bioclinica's new program provides an out-of-the-box clinical endpoint committee solution. This solution combines world-class medical expertise, an experienced adjudication management team, and a cutting-edge endpoint adjudication platform to help pharmaceutical and medical device researchers discern COVID-related adverse events from those not associated with COVID-19.

"For ongoing clinical trials that might be impacted by COVID-19, we recognize that time is of the essence; COVID-related maladies can significantly confound the safety analysis of ongoing clinical trials," says Dan Gebow, Ph.D., senior VP of research and development at Bioclinica. "As a company founded and led by scientists, we understand the importance of having the best research tools at our fingertips – especially when adapting to a rapidly changing landscape as we are experiencing during this pandemic."

Bioclinica's COVID-19 Clinical Adjudication Solution is designed to quickly evaluate a clinical trial protocol and charter to determine if novel COVID endpoint adjudication pathways should be added. Researchers can elect to utilize Bioclinica's pre-programmed COVID Source Document collection system, COVID Adjudication Pathways, and expert adjudicators, or they can customize each component to best suit their trial.

Bioclinica's expert physician adjudication network was formed in partnership with C. Michael Gibson, M.S., M.D. of Boston Clinical Research Institute (BCRI) and Harvard Medical School. The network consists of experienced adjudicators from Cardiology, Pulmonology, Neurology, Hepatology, Gastroenterology, and other specialties impacted by the deadly virus.

In April, BioClinica teamed up with VivaLNK, a provider of connected healthcare solutions, to provide a remote patient monitoring (RPM) solution for pharmaceutical clinical trials. Designed for at-home monitoring of subjects on an automated basis, the solution enables remote recording and monitoring of continuous changes in one or more vital signs (e.g., body temperature, heart rate, respiration rate) during the observation period of a trial. One example of this remote monitoring solution that is already deployed for clinical trials uses VivaLNK's wearable temperature sensor and Bioclinica's information management platform developed to support cardiac safety services. The temperature sensor, applied to the subject's underarm, continuously sends axillary body temperature to the cloud via a companion mobile application. From the cloud, the data are then integrated into the Bioclinica information management platform and presented to clinicians and study sponsor medical teams using a web portal.

For more information, visit bioclinica.com.

BioNJ

New Jersey is being touted as a national leader in a report issued by BIO/TEConomy, "The Bioscience Economy: Propelling Life-Saving Treatments, Supporting State & Local Communities," which analyzes the bioscience industry's economic footprint across the nation. The study details each of the biosciences subsectors including, biotechnology, pharmaceuticals, healthcare technology systems, agriculture and therapeutic devices. In the report, New Jersey was cited amongst the national leaders in the biosciences in its size, specialized concentration of employment, and

diversity of strengths. New Jersey has a high degree of industry specialization with 83% greater concentration of bioscience industry employment relative to the nation (location quotient is 1.83). Further, the state stands out in its breadth of industry strengths with a specialized employment concentration in four of the five industry subsectors, a distinction that is shared only with Puerto Rico. New Jersey is in the top tier of states in the innovation activities of inventors, who have been awarded 7,374 patents during the 2016-19 period in bioscience-related technology classes. Venture capital investments have steadily risen in recent years and totaled $2.29 billion from 2016 through 2019.

"We couldn't be more proud of New Jersey's continued national leadership in the biosciences industry and in the medical innovation it brings to patients around the world," says BioNJ President and CEO Debbie Hart. "The fact that more than 50% of all novel FDA approvals came from companies with a footprint in New Jersey in 2019 and the cutting-edge work that our companies are doing in the area of cell and gene therapy and COVID-19 — New Jersey is home to the first ever FDA CAR T approval and the first saliva collection method approval for COVID-19 by Rutgers University — is a further testament to the strength of the Garden State's biosciences ecosystem."

For more information, visit bionj.org.

Cardinal Health

In May, Cardinal Health Specialty Solutions released survey findings noting that more than 90% of oncologists said social determinants of health (SDOH) such as financial security, access to food, and social isolation are significantly impacting outcomes for cancer patients. The findings provide important insights at a time when the impact of social and economic factors on health are being examined more closely, as a result of the COVID-19 pandemic.

These findings were released in the seventh edition of Oncology Insights, a research-based report series analyzing the views of more than 160 U.S. oncologists. This edition focuses on the implications of SDOH on cancer treatment and issues related to caring for a growing number of cancer survivors.

Two-thirds (68%) of the participating oncologists said at least half of their patients are negatively impacted by SDOH. Financial insecurity/lack of health insurance (83%) was by far the most cited barrier for patients according to participating oncologists, with access to transportation (58%) and health literacy (53%) also among the top responses.

The respondents said responsibility for programs to address SDOH falls across all players in the healthcare system, and most (76%) perceive that assistance programs are not readily accessible, while 81% say they and their staff are constrained in the amount of time they can spend assisting patients with social needs.

"Our survey shows that oncologists believe a patient's social determinants of health are critically important when it comes to outcomes," says Bruce Feinberg, DO, VP and chief medical officer of Cardinal Health Specialty Solutions. "Yet addressing social determinants isn't a simple matter, and oncologists believe that everyone in the healthcare system must play a role in the solution."

The report also looked at oncologists' views on supporting the growing numbers of cancer survivors – a good news development that also presents challenges to care. Key findings include: 86% of respondents agree they are seeing a greater number of cancer survivors in their practice than they did five years ago; nearly three-quarters of participating oncologists said they need more training in supporting the needs of cancer survivors, particularly in management of side effects (56%) and stress management (45%); desired strategies for managing the growing number of cancer survivors varied greatly, but most participating oncologists anticipate hiring additional advanced practice providers to help do so.

For more information, visit cardinalhealth.com.

Clinical Ink

In June, Clinical Ink, a global clinical trial technology company, announced it helped expedite the study of a treatment for cytokine storm, the immunological reaction associated with severe cases of COVID-19. Clinical Ink purpose-built and deployed the electronic study environment in just 15 business days, including the study's full schedule of assessments, a full complement of edit checks and logic, and complete user acceptance testing.

"When you want to receive and analyze data quickly, being able to condense build times to meet urgent deadlines makes all the difference," says Clinical Ink CEO Ed Seguine. "Furthermore, our eSource platform allows overtaxed caregivers to streamline data entry. Data is visible for remote monitoring in real time — of particular importance when sites are inaccessible and a vital consideration for this disease condition, which can change rapidly and dramatically."

The drug under investigation is a novel intravenous anti-inflammatory. This new molecular entity is a granulocyte macrophage colony stimulating factor antagonist that already has Phase I safety data from a clinical trial in volunteers and patients with ankylosing spondylitis.

THRIVE BEHAVIORAL HEALTH
MEETING PEOPLE WHERE THEY ARE

In April, the company made a commitment to donate several hundred mobile phones and tablets to Thrive Behavioral Health for individual and family mental tele-health services, which are largely replacing in-person sessions during the COVID-19 crisis. Thrive, a behavioral health organization with multiple facilities serving families in the Baltimore-Washington area, served more than 19,000 people in 2019. As the pandemic has spread and public safety restrictions imposed, the ability to reach patients in their homes via tele-medicine and virtual outreach has become a critical lifeline for many of these patients.

For more information, visit clinicalink.com.

Cognizant

Everest Group® PEAK MATRIX™ LEADER

In May, Cognizant was named a leader in business process services (BPS) for life-sciences companies by consulting and research firm Everest Group. In the Life Sciences (LS) Operations – Services PEAK Matrix Assessment 2020, Cognizant was noted for its investments in digital technologies and significant client base, as well as revenue and employee count buoyed by several multi-year and multi-segment client engagements. Analyzing the market share, strengths and areas for improvement of 24 global service providers, Everest Group found Cognizant to be a leader. Cognizant's service portfolio and cost-efficient, automation-driven capabilities in the pharmacovigilance segment were cited as examples of its value against competitors. Additionally, the report recognized Cognizant's acquisition of Zenith Technologies, which strengthened the company's IoT capabilities and demonstrated it as a leader in embedding advanced technology within operational platforms.

For more information, visit cognizant.com.

Covance

LabCorp, a global life sciences company, in March announced that its Covance Drug Development business has formed a global immunology and immunotoxicology (I&I) unit dedicated to the specific needs of biologic drug development. This team brings together Covance's operational expertise in flow cytometry, immunoassays, and cell-based assays with its scientific expertise in immunotoxicology study design, direction, and operation to provide a more comprehensive offering for large-molecule drugs.

"With the formation of this team, we continue to demonstrate Covance's commitment to strengthening our biologics solutions with key investments in scientific staff, technology and

facilities," saysJohn Ratliff, CEO of Covance. "Biologics make up more than one-third of biopharma's pipeline. Integrating our scientific and operational know-how into a seamless group allows us to deliver even richer scientific insights and faster cycle times for clients' biologic programs, which helps our clients bring cutting-edge new drugs to patients faster."

For more information, visit covance.com.

Cytel

Cytel Inc., in April, launched an open-access global COVID-19 Clinical Trial Tracker to help facilitate greater collaboration between researchers, policymakers, clinicians, journalists, philanthropists, and other critical stakeholders who need to understand the complex dynamics of the global response to finding a solution to the COVID-19 outbreak.

This will enable them to make more informed and pragmatic decisions on how to channel scarce resources. Clinicians and local government need to know what trials are taking place in their community to ensure that the right patients receive the right exploratory treatment, while philanthropists and federal policymakers deserve a one-stop shop to determine which are the most promising early phase treatment results.

Funded in part by The Bill and Melinda Gates Foundation, a leader in global health solutions, this live dashboard offers an overview of all the trials taking place in the international effort to tackle the pandemic. One of the most difficult challenges facing those seeking a COVID-19 treatment is how little data exists about this disease. Early investigators are relying on guesswork to determine which therapies to investigate. Collating information in one place on the growing numbers of trials will enable decision-makers to compare treatments more easily as they determine which to investigate further.

Joshua Schultz, CEO at Cytel, says, "While much of the world is isolating, the scientific and clinical communities are coming together to fight the COVID-19 virus. United by an unprecedented sense of urgency, there is a level of collaboration that we've not seen before, and, despite the current pressures on the healthcare system, hundreds of hospitals are still committed to working on clinical trials. At Cytel, we have been supporting numerous clients in developing statistically rigorous models for fast data analysis and addressing the various challenges the pandemic presents in the current clinical environment. We are committed to supporting the global effort – and launching the COVID-19 Clinical Trial Tracker offered an additional way to do that."

For more information, visit cytel.com.

Datacubed

Brett Kleger, former chief commercial officer at DrugDev (an IQVIA company) and VP of IQVIA Technologies, was named CEO of Datacubed Health. Dr. Paul Glimcher, Datacubed Health's founder and current CEO will shift to the roles of chairman of the Board and chief scientific officer. As Datacubed Health's new CEO, Mr. Kleger brings more than 20 years of experience as a life-sciences industry executive and a proven track record of growing early-stage tech companies into market leaders. As DrugDev's chief commercial officer, he took a company from its infancy to become the market leader in site-facing technologies to support clinical operations. He consistently increased sales, revenue, and EBITDA, which led to a high-value acquisition via IQVIA in 2017. Following the acquisition, he spearheaded the clinical technology growth across IQVIA Technologies.

In other news, Datacubed Health announced it is offering free access to Linkt, its virtual clinical trials platform, to studies focused on COVID-19 therapies or epidemiology. The company is offering use of these critical tools in an effort to advance both treatment options and our understanding of the disease. Datacubed provides an end-to-end solution from web enrollment and eConsent to daily instrument delivery and automated hospital entry tracking.

For more information, visit datacubed.com.

Deloitte Life Sciences

ConvergeHEALTH by Deloitte launched MyPATH for Clinical, a cloud-based digital platform designed to enhance the patient experience as well as the success and efficiency of global clinical trials in February.

MyPATH for Clinical is a modular, patient-centric platform that can help accelerate the execution of digital clinical trials by taking a holistic approach to connect clinical trial participants, investigators, and clinical research associates. It leverages modern cloud, mobile, and connected medical device technologies to address three core industry challenges: patient recruitment; patient engagement to drive retention; and protocol management. "The adoption of technology in clinical trials has focused primarily on the administrative, data capture, and data management aspects of running a trial," says Brett Davis, principal, Deloitte Consulting LLP, and general manager, ConvergeHEALTH by Deloitte. "We are launching MyPATH for Clinical with the goal of leveraging modern cloud, mobile, and wearable digital technologies to fundamentally transform the patient and investigator experience in clinical trials. As the clinical trial model transforms, we hope to help improve recruitment approaches, reduce dropout rates, and increase patient support during the trial for better protocol compliance."

For more information, visit www2.deloitte.com.

eClinical Solutions

eClinical Solutions LLC, a global provider of cloud-based enterprise software and software-driven clinical data services that accelerate drug development, in May released a list of core recommendations to sustain clinical research based on its recent joint study with the Tufts Center for the Study of Drug Development (Tufts CSDD).

"This ripple effect is significant for people with conditions ranging from cancer to heart disease to Alzheimer's," says eClinical Solutions CEO Raj Indupuri. "We are losing months of valuable research time for promising therapies, and some potentially revolutionary drugs because clinical trials are being disrupted. It is critical to use advanced data technologies to connect patients and researchers, wherever they are, to collect high-quality information for ongoing drug submissions and get new therapies to market."

To continue advancing clinical research during the pandemic, life-sciences companies should consider taking three steps: The first is to define an enterprise data strategy. According to the 2019 Tufts-eClinical Solutions Data Strategies & Transformation Study, more than 75% of sponsors rate six key data management duties as "somewhat or extremely time consuming and labor intensive," making it clear that improving data management strategies is an urgent priority for organizations looking to leverage scientific insights from a multitude of data sources. The study found that companies with formal data strategies perceive the majority of data activities as less difficult, have shorter cycle times, and see their analytical abilities to be more fully developed and mature.

The second step is to centralize data and automate the data pipeline. With the volume of external data sources most often cited as the cause of prolonged database lock cycle times, streamlining the collection of data will alleviate downstream trial delays. The Tufts-eClinical Solutions study saw a three week increase in the LPLV-DBL (Last Patient Last Visit to Database Lock) cycle time metric — a 40% increase since 2017. Manual efforts in combining data often results in additional data reconciliation work that contributes to these cycle time delays, making it more crucial than ever to implement data pipelines where data is integrated and mapped in an earlier, automated way.

The third is to build data sciences and analytics competencies. The increased use of AI and advanced analytics to automate the clinical trial process means building data sciences skills to support these new models will be critical to accelerating drug development. This is why three out of four sponsors are expanding the role of data scientists in their organizations.

For more information, visit eclinicalsol.com.

ERT

In June, ERT, a global leader in clinical endpoints data collection, released results of a recent industry survey that indicate an acceleration in the adoption of virtual clinical trials due to the COVID-19 pandemic. According to the survey report, Virtual Trials and the COVID-19 Pandemic: The State of the Industry, 82% of clinical trial professionals polled stated that their organizations are incorporating virtual trial technologies due to the pandemic.

Government imposed stay-at-home orders have posed a challenge to clinical trial sponsors and CROs as traditionally clinical trials revolve around patients' physical access to investigative sites. An alternative to this is the virtual clinical trials paradigm in which patients are at the center of new medical product development and elements of the process such as screening, visits, and data transmission are managed electronically from remote locations.

The survey found that 79% of participants report the biggest issue keeping them up at night is screening for new clinical trial patients; 32% report the primary issue impacting trials over the next 6-12 months is trial management; 25% of participants report the primary issue impacting trials over the next 6-12 months is patient recruitment and enrollment; and 75% say the most common ways to collect data in a virtual clinical trial are telehealth and patient-used devices.

In April, ERT, announced a first-of-its-kind partnership with AliveCor, the leader in AI-based, personal ECG technology. The partnership enables ERT to capture digital cardiac safety data with KardiaMobile 6L, the only FDA-cleared personal ECG for patient-administered 6-lead data collection.

By combining AliveCor's advanced technology with its proven software and workflow platform, ERT customers can continue to develop new medical treatments during the COVID-19 pandemic, regardless of whether trial patients have physical access to investigative site personnel. The device's ease of use, combined with ERT's centralized overread and data collection methodology make it an ideal solution for ensuring patient safety during ongoing clinical trials. The company also offers multiple options that enable trained healthcare professionals to advance respiratory clinical trials by collecting high-quality spirometry data during patient home visits. ERT's At-Home Respiratory Solutions enable clinical trial sponsors to continue developing new respiratory treatments while patient access to investigative sites is limited due to COVID-19 stay-at-home mandates.

For more information, visit ert.com.

Firma Clinical Research

In May, Firma Clinical Research, the niche service provider for patient-centric home healthcare, and Yourway, an integrated courier and clinical packager in the global clinical trials supply chain market, joined forces to provide coordinated supply and product deliveries and administration services for virtual/decentralized clinical trials. The collaboration between the two clinical study service providers supports patient retention and compliance, while also helping CROs and sponsors improve the efficiency of clinical trial management.

Yourway and Firma are working together to ensure a seamless process for the delivery of supplies and drugs needed for in-home visits to clinical trial patients. In addition, collected bodily samples and other materials are shipped from the patient's home through a courier. In-home patient care is performed by an approved healthcare provider.

For more information, visit firmaclinicalresearch.com.

ICON

In May, ICON, a global provider of drug and device development and commercialization services to the pharmaceutical, biotechnology and medical device

industries, named Kristen Buck, M.D., as chief medical officer.

Dr. Buck joins ICON from Optum Insights (part of the United Healthcare group) where she was senior VP and chief of clinical development. She led the clinical operations and regulatory groups to create a real-world evidence and outcomes clinical trial business. Her experience ranges over multiple therapy areas including GI, neuroscience, dermatology, ophthalmology, oncology, cardiovascular/metabolic, immunology, renal, women's health, orphan diseases, liver, and psychiatry.

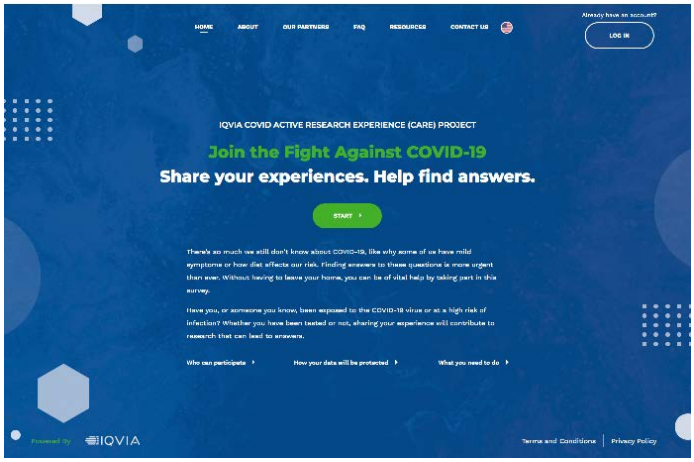
In other news, in April ICON launched the Coronavirus Observatory — a free tool that provides real-time updates on COVID-19 vaccine trials, and delivers unique insights into the key issues driving online Coronavirus conversations.

The Coronavirus Observatory applies powerful AI analysis and data visualization to COVID-19 news and social media, providing updates on the latest vaccine trials, with insights into trending topics driving Coronavirus reporting. The Coronavirus Observatory also breaks down the global impact of the virus, looks at trending topics per country, and highlights important perspectives from the key organizations, including non-governmental organizations, public health authorities, and the medical science community.

For more information, visit iconplc.com.

IQVIA

In May, IQVIA, a leader in human data science, launched HCP/O Engagement Management, the industry's first end-to-end, orchestrated healthcare professional/organization (HCP/O) solution that enables the planning, management, contracting, and payment of HCP/Os globally. The partnership with HCPs and HCOs across life-sciences companies are driving critical research, education, marketing, commercial, and patient-focused activities at the core of our industry. HCP/O Engagement Management supports compliance efforts by automatically updating and adapting to regulations and business rules while meeting the business process needs of customers. HCP/O Engagement Management delivers next-level value by providing a simple, streamlined solution to manage all interactions with industry sponsors and ensure efficient processes and communication.

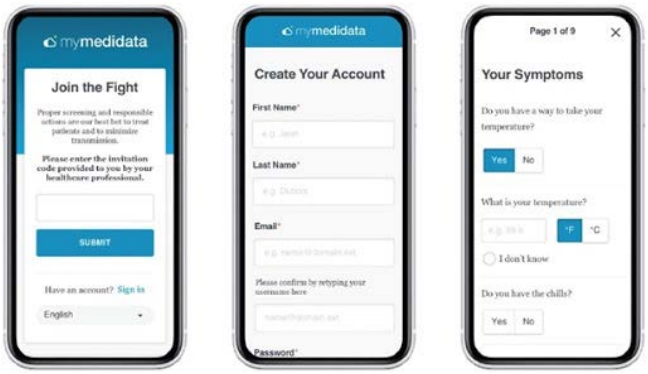


In April, the company, launched its COVID Active Research Experience (CARE) Project at helpstopcovid19.com. The IQVIA CARE Project is an opt-in registry available to anyone — to advance understanding of COVID-19 through shared information about disease prevalence, symptom progression, and treatment outcomes. The registry offers U.S. residents who may have been exposed to COVID-19 an opportunity to enroll in the registry. The registry launched initially in the U.S. in English, with plans to expand to other regions and languages. Additional functionalities to come will include access to graphics of aggregate registry data as well as links to safety and care guidelines.

Also in April, IQVIA launched a new technology-enabled COVID-19 Trial Matching Tool at c19trials.com, which is one of the world's first online platforms that matches individuals with specific COVID-19 studies to accelerate clinical research projects. This unique solution combines publicly available information, IQVIA data and tools, and an algorithmic logic that generates a questionnaire dependant on previous responses to match patients and investigators to accelerate ongoing COVID-19 clinical research projects within the U.S. Patients can easily and quickly navigate an otherwise complex search process to find relevant trial options for them.

For more information, visit iqvia.com.

Medidata



In April, Medidata, a Dassault Systèmes company, launched myMedidata, an advanced, intuitive platform for patients to enable flexible participation in clinical trials for new medicines and vaccines. myMedidata provides a unified experience for patients, encompassing all of the capabilities of Medidata's industry-leading, regulatory-compliant Rave platform and Patient Cloud tools.

This first release of myMedidata includes a research-based COVID-19 symptom tracker, which is designed to support research studies and advance scientific understanding of the virus. It will be made available to Medidata customers free of charge. This app will provide sponsors the ability to collect symptoms directly from research participants who may not otherwise be able to continue with traditional site visits. It also allows researchers to recruit large registries of individuals to monitor their health status with respect to COVID.

In March, Medidata and Medpace Inc. entered into an agreement to integrate Medidata Rave Imaging with Medpace's imaging systems and workflow. The goal is to create a seamless platform for capturing, managing, analyzing, and storing images and imaging data for clinical trials. Medpace is a contract research organization (CRO) with a wholly owned and fully integrated imaging core lab that offers a suite of global imaging services to enhance and expedite biopharmaceutical and medical device development.

For more information, visit medidata.com.

OM1

In May, OM1, a real-world outcomes and technology company, announced a strategic partnership with the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) connecting the Foundation's Reg-entSM clinical data registry to OM1's real-world data and evidence platforms.

Ear, nose, and throat (ENT) medical disorders are considered among the most common medical conditions affecting Americans. For example, in the U.S. more than 29 million patients have sinusitis and more than 48 million suffer from hearing loss. Other ENT disorders include chronic ear infection, snoring and sleep apnea, allergies and hay fever, swallowing disorders, nosebleeds, hoarseness, dizziness, and head and neck cancer.

The AAO-HNSF Reg-ent registry collects data on these conditions and their treatments. The registry has thousands of members and includes almost 25 million patient visits. The data is used to guide the best ENT care with a focus on improving quality and patient outcomes. The AAO-HNSF and OM1 partnership will enable otolaryngologists, researchers, and life sciences companies to more rapidly and effectively leverage and collaborate around clinical data for real-world evidence, outcomes, regulatory, and personalized medicine programs.

For more information, visit OM1.com.

Parexel

In May, Parexel, a provider of solutions to accelerate the development and delivery of innovative new therapies to improve world health, from clinical through commercialization, co-hosted a virtual summit of its recently launched Site Advisory Council and its Patient Advisory Council with the Society for Clinical Research Sites (SCRS), the global organization unifying the voice of the clinical research site community to create greater site sustainability. The focus of the summit was on further leveraging the site perspective in improving the patient experience in clinical trials, especially in light of

the shift to remote and virtual trial tactics during the COVID-19 pandemic, as well as eliciting direct feedback and recommendations on how to best support both patients and sites during and after the pandemic.

The virtual meeting, attended by 20 patient, caregiver and site representatives across Europe and the U.S., focused on strategies for optimizing site-patient relationships, facilitating continued access to trials during the pandemic through innovative decentralized clinical trials, and harnessing pandemic awareness to educate people about the importance of clinical research. Output and feedback will be used to inform clinical trial designs both during and after the COVID-19 pandemic.

Also in May, Parexel launched the #KeepingPatientsFirst integrated real-world evidence (RWE) research platform collating critical evidence and accelerating patient and physician access to insights on treatment and outcomes in COVID-19. The platform is powered by Microsoft Azure in collaboration with the company's Parexel Informatics division, enabling physicians and researchers to better understand and adjust treatments in real-time. The robust and patient-centric technology solution reflects learnings from both organizations resulting from their cloud technology alliance established in 2017.

#KeepingPatientsFirst is focused on aggregating, analyzing, and predicting real-world COVID-19-related disease progression and outcomes using state-of-the-art machine learning, artificial intelligence and analytics. The study is now available to provide patients and healthcare providers a leading reliable source for rapid access to pooled real-time analyses on multiple COVID-19 therapies thus facilitating informed, individualized treatment decisions and accelerating the identification of promising therapies. This epidemiological approach will also help to characterize and define an unprecedented worldwide event, including documenting the real-world patient journey from awareness to diagnosis to disease resolution, speeding the evaluation of potential COVID-19 therapies.

For more information, visit parexel.com.

Quest Diagnostics

In May, Quest Diagnostics, a provider of diagnostic information services, received emergency use authorization (EUA) from the FDA for the Quest Diagnostics Self-collection Kit for COVID-19 (self-collection kit). The self-collection kit is for individuals to self-collect a nasal specimen at home or in a healthcare setting when determined to be appropriate by a healthcare provider.

The self-collection kit allows an individual to swab the front part of the nostril and may be used on children (supervised by an adult) as well as adults. Specimens are shipped overnight via FedEx at room temperature (without a frozen cold pack).

Specimens collected using the kit may be tested with the Quest Diagnostics SARS-CoV-2 RT-PCR test that received an Emergency Use Authorization in March. RT-PCR testing aids in diagnosing infection with SARS-CoV-2, the virus that causes COVID-19.

For more information, visit questdiagnostics.com.

Saama Technologies

In May, Saama Technologies, an AI clinical analytics platform company, and iNDX.Ai, a multi-omics data analytics and translational research platform company, launched the COVID-19 Command Center. The COVID-19

Command Center, based on a combination of Saama's Life Science Analytics Cloud (LSAC) and iNDX.Ai's iCore Platform, is a purpose-built, therapeutic area-specific data analytics platform that will accelerate the ability of life-sciences companies to expedite internal research and development programs for therapies to prevent and treat COVID-19.

Many biopharma organizations are sharing COVID-19 research data through organizations such as the recently established EndPandemic National Data Consortium, which six companies – including Saama and iNDX.Ai – have joined. The COVID-19 Command Center was created to provide sponsors pursuing in-house COVID-19 clinical development efforts only with the same powerful, state-of-the-art, AI-powered data analytics platform being used by the EndPandemic National Data Consortium. The COVID-19 Command Center, includes patient data from ongoing COVID-19 clinical trials in China, South Korea, and the U.S. with nearly 8,500 patients, including more than 3,000 positive cases. The COVID-19 Command Center delivers all the multiomics and clinical data analytics needed to manage COVID-19 clinical studies. From preclinical development to approval, researchers can optimize study design, patient selection, site activation and scientific analysis by dynamically visualizing, analyzing, and interrogating data faster than ever before.

Saama, as part of the EndPandemic National Data Consortium, has agreed to contribute its LSAC technology platform. The single goal is to integrate data from all ongoing and future clinical studies to dramatically accelerate analysis on COVID-19 and SARS-CoV-2 research in order to reduce the time to find a cure by up to 50%. Saama's unique platform will allow researchers to dynamically visualize, analyze, and interrogate data across all available programs.

For more information, visit saama.com.

Signant Health

In March, Signant Health appointed Ian Jennings as chief commercial officer to help support the next phase of Signant Health's growth as a leading advocate of patient focused technology solutions.

He brings 30 years of commercial technology experience in the life-sciences industry, with a proven track record of developing and leading successful sales and marketing teams in clinical and healthcare innovation. Leveraging experience from ClinPhone, Parexel Informatics, Exco InTouch, and ERT, Mr. Jennnings will help to shape the strategic direction for Signant Health's commercial teams as the company strives to evolve its unique solution portfolio to add greater value to customers and to all participants in the clinical research and development process.

For more information, visit signanthealth.com.

Syneos Health

In April, Syneos Health, a fully integrated biopharmaceutical solutions organization, announced a volunteer program to enable clinically qualified employees to address the U.K. government's call for volunteers to support COVID-19 testing. Syneos Health joins the effort, supported by the Association of Clinical Research Organizations (ACRO), to help the U.K. identify 2,000 clinically qualified volunteers to administer throat and nasal swab tests at COVID-19 testing centers being established throughout the country. The company has extended the volunteer program worldwide to enable medical professionals who are called on by local governments to participate in COVID-19 support efforts, in accordance with country-specific guidelines. Syneos Health's 24,000 employees worldwide, include thousands of medically trained professionals with frontline healthcare expertise including doctors, nurses, infectious disease experts, and lab technicians.

For more information, visit syneoshealth.com.

UBC

UBC, a global late-stage and patient support services company serving the biopharmaceutical industry, in May introduced UBC Pathways Engage — a digital concierge that transforms traditional patient education, support, and communications through a combination of proprietary engagement methodologies and mobile messaging technology. UBC Pathways Engage is purpose-built to help patients start and stay on therapy.

This real-time virtual patient engagement platform features a digital concierge named "Linda" who creates meaningful, informative, and long-lasting relationships with patients via their mobile device. UBC Pathways Engage comprises a suite of intelligent conversational libraries that transforms traditional patient outreach into meaningful and long-lasting relationships.

For more information, visit ubc.com.

WCG/WIRB-Copernicus Group

In March, WCG, a provider of solutions that measurably improve the quality and efficiency of clinical trials, launched "The WCG Insights Program: Supporting best practices in a global pandemic." This evolving initiative is designed to share time-sensitive, critical information with the clinical research community in a collaborative effort to navigate the impacts of COVID-19 on ongoing and upcoming clinical trials. Informed by WCG's expansive view across the clinical trials ecosystem, the program features a dynamic weekly webinar series led by WCG experts and guest panelists.

"In the past weeks, many industry colleagues have reached out to us for guidance and for our perspectives on the many uncertainties that they are facing," says Donald A. Deieso, Ph.D., executive chairman and CEO of WCG. "We consider it a duty and a privilege to offer our guidance and support to share the best practices that will shape this era of discovery. After all, this is the time for all of us who are part of the global research community to share advice on how best to conduct clinical research during this pandemic, so no one feels like they are making decisions alone."

In addition, Metrics Champion Consortium (MCC), an industry organization dedicated to improving clinical trials via the development of standardized performance metrics, and part of WCG's Study Planning and Site Optimization division, launched a new forum designed to spur discourse on the impact of the coronavirus outbreak on clinical trials and how to tackle operational challenges associated with the ever-evolving pandemic. The weekly, virtual series — the MCC COVID-19 Community of Practice — connects MCC members, representing more than 80 organizations across the global life-sciences ecosystem, and provides them with opportunities to share knowledge and collectively think about how to proactively address common industry concerns around risks to trial integrity and benchmarking study performance.

In March, the company offered a new program to support initiation of protocols associated with mitigating the global spread of coronavirus. WIRB-Copernicus IRB is giving prioritized review to clinical trial protocols for COVID-19 prophylactic or therapeutic vaccines and therapeutic agents, conducted under an IND application. The company also is waiving the initial protocol review fees for that research.

To qualify, the COVID-19 protocol must be submitted before Sept. 1, 2020.

For more information, visit wcgclinical.com.