



A New Era of COLLABORATION: KNOWLEDGE SHARING



To innovate in an efficient, cost-effective, and timely manner in today's drug development environment, companies won't be able to go it alone; they will need to share data and collaborate in new ways.

There was a time when a drug-maker would own and guard every aspect of its research and development in house. That time is long gone, however, and in today's environment more and more companies are looking to share non-competitive data and collaborate with others to accelerate drug discovery and development. Using collective data and technology can increase the effectiveness and outcome of research as well as decrease timelines so that discoveries can be found, or discarded, earlier.

Clinical data sharing projects have been found to enhance research, improve communication between stakeholders, and increase speed and accuracy of clinical trials. Therefore, if the industry wants to innovate in an efficient, cost-effective, and timely manner in today's drug development environment, it is going to have to share and collaborate on its data.

According to Janice Chang, head of delivery excellence, corporate affairs at TransCelerate, collaboration among biopharma companies has evolved from a preference to a practical necessity.

"Collaboration is no longer optional," she says. "By driving efficiencies in the drug development process through collaboration, companies are able to focus on new innovations with the ultimate aim to deliver more effective drugs

to the patients who need them."

As an example, just this summer, UCB became the first mid-cap biopharma company to join an online portal (clinicalstudydatarequest.com) that offers responsible data sharing. The new portal, which has several large biopharma companies as members, will provide access to data from key studies for UCB's core approved medicines. The portal allows researchers to request access to anonymized patient-level data and supporting documents from clinical studies to conduct further research.

"We realize that we can't do all that is needed by ourselves," says Roger Palfaman, head of Innovation Super Networks at UCB. "We are a midsized company with finite resources and we know that there are many people out there with the capabilities and insights who could help us create transformational medicines. We want to work together with other companies to make sure innovations get turned into tangible transformational therapeutics for patients, and really, this can only happen through collaboration."

Janssen Research & Development is another example of a company that is sharing large datasets covering multiple diseases. Janssen's

goal is to combine data from other companies that have complementary ideas to drive the discovery of new biology. The R&D innovator has



“The next generation of targets will be much more complex, and as an industry we know we can't do this in a vacuum; we have to do this via partnership.”

DR. GAHAN PANDINA
Janssen Incubator /Autism Knowledge Engine

TransCelerate Initiatives

TransCelerate BioPharma, a nonprofit organization focused on advancing innovation in research and development has 11 initiatives focused on the shared goals of increasing quality, patient safety, and accelerating development timelines. Several of those focus on data sharing broadly across the ecosystem. The following are some examples:

» To share data, the industry first needs to standardize data. As such, TransCelerate works closely with multiple stakeholders under the C-FAST coalition with CDISC, FDA, and the Critical Path Institute. TransCelerate's Data Standards project is actively working on publishing therapeutic area clinical data standards in multiple therapeutic areas. Jointly with CDISC, TransCelerate also supported the launch of the CDISC Share environment earlier this year, which is a "global electronic repository for developing, integrating, and

accessing CDISC metadata standards in electronic format." The Share environment provides wide access to rich metadata and controlled terminology to improve consistency and traceability of clinical data throughout a study.

» The Shared Investigator Platform work stream is currently developing a first-of-its-kind, collaborative platform that will transform the way clinical trial sites interact with sponsor companies in executing clinical studies. This platform is aimed at being an industry utility, widely adopted by clinical sites and sponsors, eliminating the use of multiple, complex platform environments in execution of clinical trials by sites. By bringing sponsors and clinical sites on to a single platform and enabling single sign-on for executing studies for multiple sponsors, this platform will provide single-access point for investigators for clinical studies information, enhance

accuracy of information and data exchange, and reduce study start-up time tremendously. This platform will provide the technical foundation to enable further efficiency-enhancing data sharing initiatives across sponsor companies, such as sharing of placebo and standard of care data, in the coming years.

» The Investigator Registry project is actively working on a consolidated repository where sponsor companies can share general information about their investigators broadly. A common challenge when it comes to maintaining investigators' info is the duplication and incomplete data set maintained by trial sponsors. The value proposition of having 19-plus sponsor companies coming together to consolidate their investigators' profiles and leverage the consistent data set for clinical trials execution is unprecedented and game changing.

Source: TransCelerate
For more information, visit transceleratebiopharmainc.com

multiple collaborations with both academia and biotech partners in the immunology area and is actively supporting consortia in the pulmonary disease, RA, and IBD arenas.

As biological research shifts from analogue to digital, attacking complex problems requires many people to come together and share their skills, new ideas, methods, and datasets, says Mark Curran, Ph.D., VP, systems pharmacology & biomarkers, immunology therapeutic area, Janssen Research & Development.

"It is difficult for any one team to have enough information to make firm conclusions, particularly in the analysis of rare genetic variants," Dr. Curran says. "I feel it is essential for academia and pharma to come together in precompetitive environments to share these types of datasets rapidly so that discoveries can be made and transformational medicines developed and delivered to patients and healthcare professionals."

The collaboration between Janssen Research and Development, and the San Diego Supercomputer Center (SDSC) at the University of California, illustrates how super computer analytics can speed the path to discovery, in one particular case by almost four years. According to a Janssen report, the bulk of the analysis on the SDSC project was completed in six weeks using more than 300,000 core hours of computer time, which would have

taken more than four years of 24/7 compute time on an eight-core workstation.

High-performance computing is key to maximizing high-content datasets and big data paradigms, Dr. Curran adds. With 340 teraflops of computing power, 64 terabytes of main memory, and 300 terabytes of flash memory, SDSC's supercomputer, Gordon, is ranked among the 50 fastest supercomputers in the world. However, the biggest challenge lies within correctly understanding the information and identifying the critical pieces of biology that will allow next-generation medicines and solutions to be created.

"Our collaboration accelerates the path to new discovery and creates new partnerships, which will undoubtedly provide new insights into rheumatoid arthritis genetics, but this will also foster new analytical methods for this type of data," Dr. Curran says.

Janssen has explored other areas in which supercomputing is essential to gain insights.

"In addition to our work with genome sequencing, we have partnered with other institutions to apply high-performance computing to areas such as network pharmacology in inflammatory bowel disease," Dr. Curran says. "As with our RA project, without the analytic capabilities enabled by a supercomputer, it is simply not possible to rapidly explore extensive high-content datasets."

According to Dr. Curran, these types of collaborations and data sharing are extremely important for the future of healthcare.

"It is critical to bring different disciplines together through innovative partnerships and collaborations," he says. "The opportunity in biology to generate large datasets requiring high-performance computer infrastructures to enable exploration is a relatively new area of our science. It is exciting and promising to provide amazing insights to human biology and disease. By bringing the right people together, combining the hardware and the software, we will advance the field and bring new medicines to patients living with severe and debilitating diseases, particularly in the field of immunology where we look to continue to pioneer science."

Collaboration and data exchange through digital systems will become the primary solution for the industry to meet the many challenges in today's drug development, says Bhaskar Sambasivan, VP, head of life sciences, NA & UK, at Cognizant. Cognizant is working with TransCelerate to develop a first-of-its-kind, subscription-based platform that will transform the way clinical sites collaborate with pharmaceutical companies on clinical trials.

"The advantages of data sharing across pharma companies are many," Mr. Sambasivan says. "For one, data sharing allows for better

UCB's Technology Platform Access Automates Discovery

In March 2014, UCB opened a new laboratory in the U.K. that contains cutting-edge robotic equipment that enables the fully automated discovery of antibodies. The company is looking to partner with academic and research groups for collaborative drug-discovery projects involving antibody targets that will use the findings of the new lab.

The robots in the lab greatly increase antibody discovery capacity, some reports say as much as cutting antibody discovery time by half. The program screens B lymphocytes to find the few rare ones that can produce antibodies that are useful in drug development.

In conjunction with strong antibody engineering and expression capabilities, plus structural biology expertise, this represents a novel and efficient route to the generation of high-quality antibodies, not only against human targets but also for the generation of research tools for proof-of-concept models.

Source: UCB BioPharma. For more information, visit ucbpharmaco.co.uk

protocol designs and less amendments leading to reduced drug development cycle times and thus faster target times to market for patients in need, as well as leading to high patient retention and engagement.

"Another benefit is that the collaborative exchange of data on observational or early clinical research can lead to fewer trials and better trial efficiency for all investigators," he adds "Sharing of demographics and other relevant patient recruitment data of trial and site recruitment data will lead to lower cost, reduced screening visits and better outcomes for trials, and lastly, sharing of safety data can also reduce severe adverse events during trials and minimize patient dropouts during trials."

Within Janssen Research & Development, there is another example of collaborating to collect and analyze pertinent patient information. The Janssen Incubator is partnering to develop an Autism Knowledge Engine, the first comprehensive digital platform designed to facilitate research and clinical trials to optimize the development of novel medicines for autism spectrum disorder.

Gahan Pandina, Ph.D., senior director and venture lead of the Autism Knowledge Engine, says the goal is to develop treatments for autism



“ Modern cloud technology — the true, multitenant variety — eliminates the barriers to knowledge sharing. ”

PAUL SHAWAH / Veeva

spectrum disorders, but there are several issues that need to be addressed before anyone can successfully move forward. For example, there is currently no objective system of measures to diagnose and track outcomes in clinical trials involving participants with autism. Autism can only be diagnosed through expert interview and observation of behavior. Autism Spectrum Disorder is a highly complex and heterogeneous disorder. Individuals with ASD often receive uncoordinated, fragmented care from different providers.

"Over the past couple of years, we have been looking at how we might address some of the challenges of ASD research," Dr. Pandina says. "About a year and a half ago we developed a project to develop a system of tools and technology that can help us optimize clinical trials for autism. In fact, we have emerging biological targets in the brain that we think could potentially be viable targets, but because of the many challenges we needed to develop better tools to help know how to go about this research in the best way."

The implications of Janssen's efforts will be broad reaching, and Dr. Pandina predicts that sharing and collaboration is the only way the industry can move forward in terms of developing new therapies as fast as they are needed.

"The industry has done all it can with well-known targets and developing novel treat-



“ It is essential for academia and pharma to come together in precompetitive environments to share datasets rapidly so that discoveries can be made. ”

DR. MARK CURRAN

Janssen Research & Development



“ Our goal is to create transformational therapeutics for patients and that can only happen through collaboration. ”

ROGER PALFRAMAN / UCB



“ The collaborative exchange of data on observational or early clinical research can lead to fewer trials and better trial efficiency for all investigators. ”

BHASKAR SAMBASIVAN / Cognizant

Janssen Research and Development Explores Data Sharing Platforms

WHOLE GENOME SEQUENCING WITH SAN DIEGO SUPERCOMPUTER CENTER

Janssen Research and Development, San Diego Supercomputer Center (SDSC) at the University of California, San Diego and the Scripps Translational Science Institute (STSI) are collaborating on a project to conduct whole-genome sequencing of 438 patients with rheumatoid arthritis to better understand the disease, as well as explore genetic factors of patient response to a biologic therapy discovered, developed, and currently marketed by Janssen in the United States.

"We're currently participating in a transformation of the life sciences that will take decades to fully explore," says Mark Curran, Ph.D., VP, systems pharmacology & biomarkers, immunology therapeutic area, Janssen Research & Development. "At the core of this exploration is high-performance computing and the data scientists who can use the capabilities to ask new questions."

The whole-genome sequencing (WGS) analysis project used one of SDSC's supercomputers, Gordon, and clearly demonstrated the effectiveness of innovative applications of flash memory technology to rapidly process large data sets that are pervasive throughout human genomics research.

The analysis began with 50 terabytes of read data generated by DNA sequencers from samples originally obtained from each of the study participants. These source data were fed into a 14-step processing pipeline using open source software tools. Key components of the analysis were mapping the DNA read sequences from each patient against a reference genome and calling to identify the variants between the two.

This collaboration may have significant implications for more than just RA, since the underlying predisposition to diseases like RA and other autoimmune diseases is genetic.

"We have made significant progress identifying genes associated with RA by using genetic mapping with single nucleotide polymorphisms," Dr. Curran says. "However these association studies have not been able to identify causal mutations, which would direct 'drug hunters' to new targets with a high degree of confidence. Full genome sequence analysis provides a new layer of granularity to genetic analysis that we hope will lead to new targets, biomarkers, and therapeutic solutions for patients living with RA and other autoimmune disorders."

Supercomputers like SDSC's Gordon and IBM's Watson will also impact the research landscape of tomorrow, he adds.

"It is clear that computer engines such as Watson will help with decision paths in the clinical arena," Dr. Curran says. "This will help physicians make more rapid diagnoses and identify the best treatments for patients. As outcome databases grow and are shared between different institutions, these machines will be critical to precision medicine and using real-world outcomes to drive treatments. In the research arena, we are generating larger and larger datasets and it is essential to not only capture these data but to have the computing infrastructure to allow scientists to sort and analyze the information."

JANSSEN INCUBATOR CREATES KNOWLEDGE ENGINE FOR AUTISM SPECTRUM DISORDER

The Janssen Incubator, within Janssen Research & Development, is developing the Autism Knowledge Engine, the first comprehensive digital

platform designed to facilitate research and clinical trials to optimize the development of novel medicines for autism spectrum disorder (ASD). Collaborating with Microsoft, the venture brings together talent and expertise from a key information technology organization to develop a robust approach to therapeutic assessment and development. Microsoft HealthVault software provides a personalized electronic health record system to create ASD-specific treatment and developmental milestones.

The venture team takes an integrated collaborative approach, working with Autism Speaks, the world's leading autism advocacy organization, to provide scientific guidance, and leverages the experience, capabilities and leadership of the Janssen R&D Neuroscience Therapeutic Area, and other scientific experts in the field of ASD and biosensor technology.

The system features three main components for collecting data from natural settings.

First, there is an integrated personal electronic health record system that uses Microsoft HealthVault, designed specifically for children with ASD, their families, and their care teams, that places special emphasis on cross-care-provider communication via Web and mobile applications, such as eye gaze and electrocephalogy for example, because verbal communication is too difficult for children with ASD. The EHR will provide symptom tracking and detailed information on clinical and medical history to help identify subpopulations for proof-of-concept studies and inform development of new treatment options.

Second, home- and lab-based biosensors are linked to symptoms and underlying biological processes of ASD to provide objective measures of symptoms to improve assessment of treatment outcomes.

And third, there is a de-identified research data warehouse with data analytic tools that create a unique, integrated database of information, while preserving patient anonymity.

ments using traditional approaches," he says. "The next generation of targets in the brain will be much more complex, and as an industry we know that we can't do this in a vacuum. We have to do this in partnership and work together as a team to identify and interrogate these targets to develop new therapies. For ASD, where no medications exist for the core symptoms, we must find a new approach. It's a much different process than it used to be."

Factors Driving the Collaboration Trend

The pharmaceutical industry is moving toward a more collaborative environment with other pharma and biotech, academia, and non-traditional partners. These collaborations are increasing because they have the ability to speed the development and launch of new medicines. By sharing knowledge, resources,

and experience throughout the drug development process, pharma companies can reduce costs and time to market, while providing needed solutions to the world's health crisis.

This new model is being driven by several factors. First and foremost is technology. Supercomputers, the cloud, EHRs, apps, and wearable devices that have the ability to track patient data all allow the collection and analysis of data on a very large scale.

Partnering isn't new to the industry, but how it's done in today's environment is. In the past, companies would predominantly engage in individual relationships with each partner, but that was as far as the information would go. According to Dr. Palframan, companies, including UCB, are now engaged in multi-partner relationships with academics and companies to form strong coherent networks. (See related article: New Models for Academic Partnerships.)

"Today, we are identifying the challenges, considering the best way to meet them, and figuring out what are all the components we need," he says. "Then we determine what we can do within UCB and what we need externally as we can work on bringing together networks to collaborate to move forward the innovation to make that new therapeutic intervention. We might bring together two or three partners from different disciplines as part of a partnership. The research may not always benefit UCB as much as another partner, but we believe this approach makes the network stronger and improves our ability to create innovative medicines."

On the clinical trial side, document sharing systems built on multitenant cloud platforms enable controlled, process-driven collaborative clinical trials that can be tracked and measured against KPIs and improved over time.

"Fortunately, technology is creating a path for industry collaboration that won't be blocked by country lines or cubicle walls," says Paul Shawah, VP, CRM strategy at Veeva. "Modern cloud technology — the true, multi-tenant variety — eliminates the barriers to knowledge sharing."

This is important, he says, because to bring life-saving drugs to market quickly, safely, and cost-effectively, the R&D process must extend well beyond the walls of the pharma company and include multiple partnerships and external collaborators — some that even go beyond national borders.

"Cloud technology is critical to making these partnerships, and ultimately the R&D process, more effective, speeding study start up, increasing efficiency, and enabling inspection readiness," Mr. Shawah says.

A second factor driving collaboration is the rising cost of drug development. The increasing amounts of clinical evidence needed to obtain regulatory approval is driving the industry to tackle the growing problem of inefficiencies in clinical trials, says Michelle

“ Sponsors are now seeing real possibilities in a flexible, unified operating model that facilitates collaboration with research partners. ”

MICHELLE MARLBOROUGH
Medidata Solutions



Marlborough, VP, product strategy, at Medidata Solutions. Given the growing complexity of clinical trials, there is an increasing demand for tools that can facilitate and foster knowledge sharing, from trial design software and data capture right through to applications that check the most important data to make sure the information is accurate, complete, and consistent, she adds.

"With the maturation of technology solutions such as cloud-based platforms, sponsors are now seeing real possibilities in a flexible, unified operating model that facilitates collaboration with research partners, such as CROs, to reduce the risks and costs of clinical development and accelerate outcomes," Ms. Marlborough says. "This model allows life-sciences companies to aggregate clinical trial patient data across studies and drug programs, and therefore benefit from rapid and easy access to relevant, high-quality, and analysis-ready data."

Technology and cost are definitely facilitators of knowledge sharing but another driver is a change in attitude and a new sense of urgency around emerging healthcare problems.

"We can't afford to spend decades waiting for these treatments to emerge or else the re-



“ Through collaboration, companies are able to drive efficiencies and focus on new innovations in the drug development process. ”

JANICE CHANG / TransCelerate

sults of the diseases will bankrupt our healthcare system," Dr. Pandina says. "The need is so great that we must develop therapies much sooner rather than later, and this is only going to happen in partnership. As an industry we must benefit from scientific advances as quickly as possible; once something is learned we have to act right away. We can't rely on everyone doing all aspects of clinical development anymore. We need partnerships that allow us to benefit from science sooner or to more quickly determine if a drug is going to fail."

Dr. Palframan agrees. He has observed some in the industry moving from progression-seeking behavior to truth-seeking behavior. This refers to when low-viability drugs are continually advanced through the phases of development despite the fact that in all likelihood they will fail to provide superior value to patients. A report last year in *Nature* by The Boston Consulting Group attributes this to R&D organizations' putting more value on the continuation of a program rather than designing studies to get to the truth, failing fast and failing early.

"To have the right data to make robust decisions, we have to collaborate," he says. "We need to have all the data necessary to make good decisions and no one company can possibly do it all. We all need to move to be more collaborative, with truth-seeking behavior focused on having maximum impact for patients." **PV**



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Benefits and Challenges of DATA SHARING

Experts outline the opportunities and difficulties of data/knowledge sharing.



JANICE CHANG
*Head Delivery Excellence,
Corporate Affairs,
TransCelerate*

BENEFITS: Ongoing engagement with health authorities is also a necessary step throughout our collaboration efforts. We are actively collaborating with regulatory agencies in the regions where clinical trials are conducted. Regulators recognize the need for the industry to collaborate, and their perspective should be reflected in our efforts.

As with any change, there is the mental barrier of “Can we or should we really share this data?” Fortunately, as the members of TransCelerate ramp up their collaborations, there is increasing trust and enthusiasm for our mission to improve the clinical trials environment for the betterment of all stakeholders across the industry. Any initial barriers are now past us but we still spend significant efforts to bring consensus to all the projects we run. TransCelerate’s focus is to drive collaboration in the R&D arena, particularly with regard to clinical trials, and thus increase innovation beyond what the individual members and other stakeholders could achieve working in isolation. The members of TransCelerate just needed the right catalyst to bring the collaborative efforts to fruition. TransCelerate has provided the platform for sponsor companies to come together and exchange appropriate data and knowledge, but also for industry stakeholders in the broader ecosystem such as the clinical sites, the regulatory authorities, the CROs, and other industry groups to get engaged through our efforts.

CHALLENGES: Our member companies all have a global presence, and therefore the solutions we develop must be globally applicable. The different privacy and regulatory requirements across countries certainly provide unique challenges when it comes to design and

adoption of our solutions. To address these nuances, we proactively work with regulatory and privacy experts from our member companies to ensure our solutions adhere to local privacy and regulatory guidelines.



MICHELLE MARLBOROUGH,
*VP, Product Strategy,
Medidata Solutions*

BENEFITS: A data-sharing platform for clinical trial R&D provides the framework for a single, homogenous data source. This reduces the volume of manual data entry and risky reconciliations, since a data point entered at a given time during a clinical trial becomes automatically available across the entire platform. It also facilitates and accelerates both data monitoring and verification, and reduces the need for traditional data cleaning prior to analysis. When electronic data capture systems are integrated with a wider range of data sources (e.g., clinical assessments, lab data, and patient reported outcomes) that all conform to Clinical Data Interchange Standards Consortium (CDISC) standards, a single, data-sharing platform eases the operational complexity of trials and opens the door to real-time data access. And as data gathering extends beyond the hospital, clinic and doctor’s office to incorporate data gathered from mobile devices, a single data-sharing platform will be able to more fully leverage richer mobile data sets without increasing the cost of monitoring and data cleaning or the burden on clinical trial sites.

CHALLENGES: The industry has made significant progress when it comes to processes for capturing and storing clinical trial data. However, understanding, exploring, and analyzing data across multiple, disparate IT systems — used by diverse clinical trial teams worldwide — remains a critical business challenge. In addition to a range of tech-

nology solutions from third-party vendors, many life-sciences companies have substantial customized legacy IT systems to support their R&D capabilities. While suitable at the time they were built, today such proprietary systems hinder the implementation of standards and, as such, collaboration across the industry. Often, data collected at study sites using legacy systems are not aligned with common standards, including those established by the Clinical Data Interchange Consortium (CDISC). Cloud computing solutions offer a modular interoperability model based on service-oriented and standards-based architecture, as well as the flexibility to interface with legacy systems. These new technology solutions can support the complexity and rigorous needs of clinical research today and in the future, while fostering knowledge sharing and collaboration within organizations and across the broader life sciences industry.



BHASKAR SAMBASIVAN
*VP, Head of Life Sciences,
NA & UK, Cognizant*

BENEFITS: Regulatory developments and technological innovation are opening up new opportunities for companies to use lifecycle collaborative management to bring together parts of the value chain that have traditionally been relatively distant from each other. Collaboration will become increasingly important across the R&D/manufacturing interface and across the pharma/patient interface. The interface between pharma and patient is becoming increasingly important for a number of strategic reasons. With fewer new molecules and blockbuster products left to be discovered and developed, companies have to turn more to optimizing the particular effects of existing molecules for individual patients and segments of patients. In parallel with the decline of the blockbuster drug, governments and healthcare payers are coming under im-

mense pressure to contain costs. In the future, most medicines will be paid for on the basis of the results they deliver.

CHALLENGES: Because many factors influence outcomes, pharma companies will need to have more knowledge and understanding of how and why outcomes vary at the point of use and to be able to use that insight to optimize drug characteristics to a patient's therapeutic needs, whether that is through product formulations or delivery mechanisms, and to feed that information back into development, formulation and manufacturing.



PAUL SHAWAH
VP of Product Marketing,
Veeva Systems

BENEFITS: Speed, visibility, and compliance are the greatest benefits compa-

nies gain when leveraging a data or document share platform such as a purpose-built eTMF solution. Running a clinical trial requires adherence to very specific processes and protocols as well as the management, organization, and submission of an immense amount of information. Of course, this takes a lot of time and coordination. Manual movement of data and documents via paper, email, fax, or online file shares is inherently inefficient and a compliance risk. Extra steps are required, for example, just to keep track of document versions and where they are stored or archived, plus there are blind spots throughout the trial both for the sponsor and its partners. But with all parties working from a single document sharing system, there's end-to-end visibility. It's easy for all participants to follow efficient workflows, adhere to compliant SOPs, and automate processes like document versioning to save time and help ensure you're always inspection ready. Plus, over time, companies gain reliable performance data to measure

against for ongoing process improvement across the enterprise.

CHALLENGES: Barriers can be real or perceived. New applications built in the cloud have eliminated many of the very real barriers that existed just a few years ago such as the high up-front costs of purchasing and implementing — and later, upgrading — new client/server systems, difficulties providing system access to partners outside a firewall, and internal costs of technical knowledge and user training. With today's cloud-based systems, there are no high infrastructure or maintenance costs, and secure access to these systems from any device in the cloud is simple. Upgrades with multitenant cloud applications are automatic and pre-validated for IQ and OQ, ensuring users are always benefiting from the latest compliant technology. And, because modern cloud solutions are often modeled after consumer apps, training is fast and easy. Essentially, the cloud has made what were once real barriers just misperceptions. **PV**

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