Envisioning a bold, new future of clinical development

NEW PATHS.
NEW POSSIBILITIES.
BETTER RESULTS.

IQVIA TECHNOLOGIES

New paths. New possibilities. Better results.

Technology is redefining the clinical development process as never before. As the industry makes leaps into the next frontier, IQVIA's many thought leaders, we refer to them as Visioneers, have always been ahead of the curve, provide their insights on re-imagining trial management, remote monitoring, clinical trial management systems, CRA monitoring, analytics — all through the lens of Connected Intelligence. A new frontier involving digital transformation is leading to new trial models, such as decentralized clinical trials, that are sustainable and scalable for the future.

The Visioneers

IQVIA TECHNOLOGIES

Nagaraja Srivatsan
Senior VP, Chief Digital Officer (CDO), RDS Technology Solutions

Srivatsan has more than 30 years of experience in growing businesses in the digital, data, AI, analytics, IT, and operations management areas across several industry verticals. Today, he is responsible for driving growth and leading product development and operations of IQVIA's R&DS technologies.

Connected Intelligence

For Srivatsan, the future of clinical trials, post-pandemic, is here and now. "The process of collecting data from three very specific stakeholder groups — patients, sites, and sponsors — has always been fragmented and broken," he says. "This also includes the execution when it comes to the experience, journey, and data flow. During the pandemic, the tenets of digital and digitalization emerged front and center on how to better engage with all three of these stakeholders."

The Patient Experience

Engaging patients whether at the site or at home has become a big transformation to the patient journey.

"Patients can now be engaged in a clinical study in multiple different settings," Srivatsan says. "Previously, what sponsors and others once considered to be regulatory barriers have become the new models in how to engage patients. This shift has accelerated what can be done — from collecting patient information and data to engaging with patients more often."

The Site Experience

Sites have always assumed the burden of managing multiple different technologies and different approaches to engage patients. "Now, the site and site experience has been completely enhanced — from using analytics and data-based approaches to recruiting patients to trial matching," Srivatsan says. "Sites are now able to schedule patients more appropriately for treatment as well as enter patient data across multiple different systems in a much more seamless, harmonized, and homogenized manner."

The Sponsor Experience

Traditional site visits and site monitoring to ensure trials and trial conduct are proceeding effectively also have been transformed, which was prompted by the pandemic to not only meet today's needs but also for the trials of tomorrow. "Centralized monitoring, remote monitoring, and risk-based monitoring are all now front and center for sponsors," Srivatsan says. "Specifically, this monitoring transformation is now enabling sponsors to engage with sites much more proactively rather than reactively."

The Transformation is On

Srivatsan believes many of the inhibitors that limited innovation are now gone. And the industry can take many of the lessons learned during the pandemic to drive future success, especially in terms of decentralized clinical trials, which he expects to become the new normal. "We are in the people and services business, so it's not just about the technology, we had to learn how to make sites comfortable with hybrid models, we had to answer patients' questions, and we had to work within an emergency-use regulatory framework so sponsors were comfortable," he says. "I think there's no going back."

At the same time, these technology transformations are the Holy Grail of clinical trials. "We've always looked at data and information retrospectively to tell us what happened during a trial, but as we look to the future to ensure sites, sponsors, and patients come together, we can be more predictive and prescriptive about how they interact."

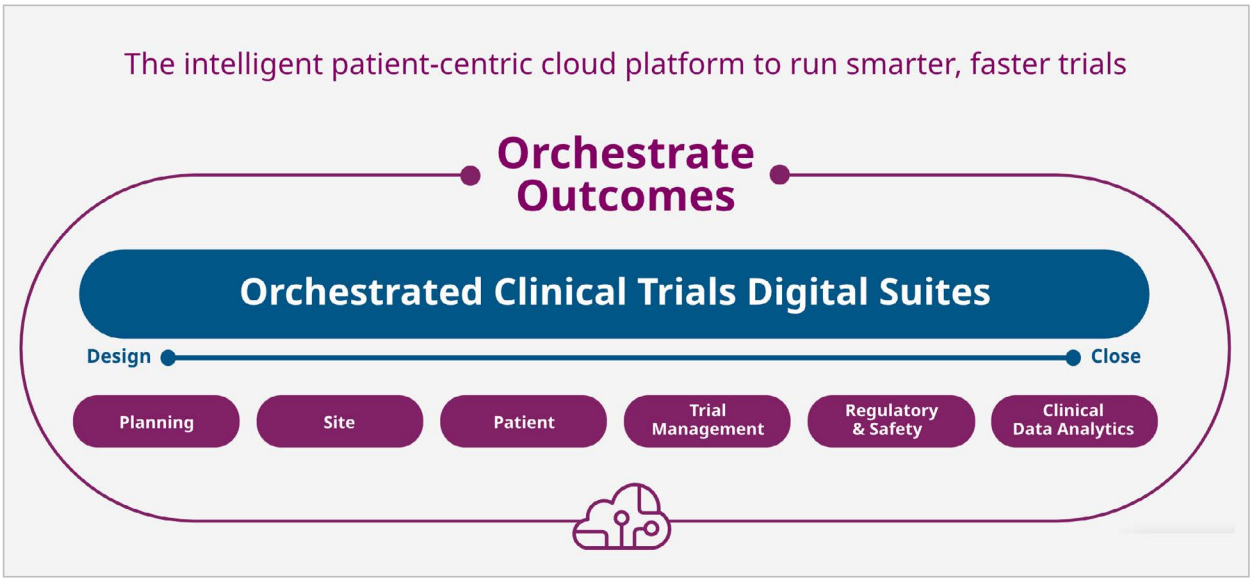
This means embracing digital tools and digitalization to gain better insights into site performance, patient outcomes, and sponsor responsiveness. "By leveraging data not just to understand what happened, but to predict and prescribe what should and what will happen, will allow us to determine better site selection, have more effective risk-based quality management, improve patient monitoring and safety, allow for enhanced patient recruitment and engagement, and improve overall study quality," Srivatsan says. "The goal is to use technology to simplify the entire process — and we believe the future is here and now."

THE GAME CHANGER:

Technology Revolution

Over the years, technologies such as natural language processing and AI, have allowed us to improve our processes and execute against insights gained from vast amounts of unstructured data. Clinical systems of the yesteryear were all about looking at structured data, whether it was EDC or other systems, the data was very structured information both from an input and output standpoint.

Now, we are now working with huge sets of data. With digitization we can go from understanding what happened to using AI or machine learning to build predictive or prescriptive models that can then tell us what we should be doing.



Orchestrating the Process

In his role as chief digital officer for IQVIA R&DS, Srivatsan continually evaluates IQVIA's internal processes to make sure the company is focused on developing digital tools and solutions to solve the industry's biggest challenges as well as address the obstacles that frontline clinical trial professionals face every day. "For example, we are doing some great work using risk-based monitoring as well as developing mobile apps that allow our monitors to be more responsive and efficient. We're looking at digitizing the study collection process; we are also looking at the submission management process. We have already launched IQVIA CORE, which is the seamless, dynamic integration of our unparalleled data, domain expertise, transformative technology, and advanced analytics applied across a portfolio of solutions."

Just as important is Srivatsan's other role which is to curate IQVIA's billion-dollar-plus tech business. "IQVIA is known for its data and services, but we are also a technology company, and my responsibility is to employ our full spectrum of technology to make the patient experience better; to disseminate data and insights for improved workflow decisions; to engage and activate sites faster as well as better; and enhance trial management."

To accomplish all of this, IQVIA has a suite of products called Orchestrated Clinical Trials (OCTs). OCTs ease the burden on sites and make it easier and more appealing for patients to remain engaged, produce faster trials to database lock, and speed time to market. This intelligent, intuitive, and interoperable patient-centric platform allows trials to run smarter and faster.

"These services help make the site experience better through improved activation, the patient experience better through enhanced engagement in decentralized trials, the sponsor experience better through higher quality trial management and risk-based monitoring," Srivatsan says. "We then use our core strength in data and analytics to drive insight generation as well as insight dissemination — we call this connected intelligence."

Connected Intelligence

While the idea of a digital transformation might be unsettling to some, Srivatsan is quick to make the assurance that the goal is not to replace humans with digital technologies, but to increase productivity. "I use a superhero metaphor to help explain the concept; we don't want to replace people with the Terminator, rather we want to make people more like Iron Man or Wonder Woman — by increasing their effectiveness," he says. "If we can use technology to increase productivity related to mundane tasks and activities not just by 1x or 2x, but by 10x, then digital transformation is allowing people to be more productive and more prescriptive."

To illustrate his point, Srivatsan points out the need to copy data from one place to another several times during the clinical process and then verifying that the transfer was successful each time, but by applying digital tools and digitization the process cannot only be streamlined but also provide confidence the process was secure.

"We are looking to enhance efficiency in all areas of the clinical trial process from protocol document to RFPs to communication interfaces," he says. "We are applying natural language processing, AI, and digital solutions to connect the data and drive faster, deeper insights — what we call Connected Intelligence — to tasks that can be done by our digital infrastructure."

Connected Intelligence is IQVIA's innovative approach to enabling life-sciences customers to discover powerful new insights, drive smarter decision-making, and get treatments to patients faster. Connected Intelligence brings together IQVIA's unique portfolio of capabilities to create intelligent connections across its unparalleled healthcare data, advanced analytics, innovative

IQVIA's Connected Intelligence in Action

The world is counting on the healthcare industry for innovations and scientific breakthroughs to improve societal health. IQVIA, recognizing that the healthcare industry needs to increase agility and accelerate results, has made significant investments and commitment to the healthcare ecosystem, and has the global scale and experience to deliver a completely new approach to moving healthcare forward.

- Connecting data, analytics, and services to accelerate more than 350 ongoing clinical research studies to find treatments and novel vaccines for COVID-19
- Deploying innovative technologies across 60 ongoing decentralized clinical trials spanning 40 countries utilizing IQIVA's virtual capabilities to enroll more than 170,000 patients globally
- Bringing together big data, advanced analytics, and healthcare expertise to help industry professionals better understand diseases, their spread and outcomes
- Accelerating drug discovery by creating intelligent connections across private companies, government agencies, and university researchers
- Linking real world data and healthcare expertise to enable contact tracing and COVID-19 testing protocols to reveal novel disease insights

technologies, and healthcare expertise to speed the development and commercialization of innovative medicines that improve patient lives. Connected Intelligence provides new levels of value across clinical, compliance and commercial stakeholders within pharma, med tech, payers, providers, and government organizations.

The Future of Success

"When I say we're living in the future right now, I mean we're on a journey of Connected Intelligence," Srivatsan says. "In clinical technology, we spend 80% to 90% of our time trying to connect data and engineer data. And we spend 10% to 20% of our time getting to the result and value of those efforts. We are on the cusp of deriving more value from our efforts. So, as I look to the future, just as we had the proliferation of apps coming into the marketplace thanks to the launch of Apple and Android, we're on the ground floor of what I call the algorithm or API marketplace. More of these models will become available, which we'll be able to scale and make available to everyone."

As a chief digital officer, Srivatsan says his goal is to make the journey of digital and digitalization happen. "But, all of this is about change management; the biggest issue is not technology, it's getting everybody to adapt to change," he says. "Even the best technology won't succeed, but if a solution can elevate and mitigate workloads, then there is more adaptability and adoptability and a greater chance of success."

Beenu Kapoor
VP, IT Digital Trial Management Suite

Beenu is an accomplished and results-proven executive with 25-plus years of R&D Clinical business and IT leadership experience in the biopharmaceutical industry and consulting. Her breadth of experience includes developing product strategy, building the TransCelerate Shared Investigator Platform (SIP), creating clinical business operational strategies, outlining business models and road-maps, leading business process transformation, and developing technology solutions to create a unique and differentiated enterprise value.


Visioneer

Reimagining Clinical Trials

As VP of IQVIA's IT Digital Trial Management Suite, Beenu Kapoor's vision is to improve the management of clinical trials through digital transformation. "We literally have to reimagine how clinical trials are done," she says. "Digital transformation is a trend that is here, and here to stay. Digitization is being applied and adopted in all walks of life — in all industries."

Beenu acknowledges that it's easy to get caught up in the buzz around digital transformation, which can be interpreted in different ways by different organizations and leaders. Sometimes the

IQVIA TECHNOLOGIES

term applies to the use of the latest technologies such as social media, mobile, artificial intelligence, machine learning, and other times it is used in context of design thinking to create novel ways to engage with stakeholders. "I believe digital transformation is about leveraging technology to engage with stakeholders using new business models by removing constraints, and in turn, creating exciting new possibilities that improve business outcomes with truly measurable business value," she says.

"When I envision digitally transforming the management of clinical trials, I am advocating for managing a trial end to end — from start to finish," she continues. "The functional silos, related business processes, and manual data handoffs that create friction need to be eliminated and technology is the answer."

For example, within a sponsor company there are teams that focus on protocol development and approval, teams that focus on study and site startup, teams that focus on clinical operations, monitoring, data management, and so on. Within each of these siloed functions there are approaches to achieve best practices, but Beenu points out that there is very little attention paid to what happens across these teams. "Whenever there's a handoff between teams, there can be friction," she says. "Data does not flow from one place to another efficiently. Business processes are choppy and chunked up. There are time lags between teams. My vision is to remove the functional silos and truly look at the end-to-end execution of clinical trials."

Beenu says to make this goal a reality, three things need to be considered: data and technology; stakeholders — patients, sites, and sponsors; and business models and processes. "By leveraging digital transformation, we will get the efficiency and effectiveness of improved patient safety, better data quality, reduced costs, and lower risks for study sites and patients."

Regulatory Guidance: Key to Moving Forward

Beenu says while technology has certainly been a game changer that has allowed companies to bend their business processes and think about new ways of operating, more important are changes in regulations and new regulatory guidances.

Regulators have begun to embrace the concept of patient-centricity, which is a departure from how clinical trials were viewed in the past when sponsors and patients were kept separate. "Patient-centricity, which is now at the heart of clinical trials, is driving the new model of decentralized clinical trials," Beenu says. "Regulators are encouraging a better understanding of patients, what their needs are, how will they participate in clinical trials, etc."

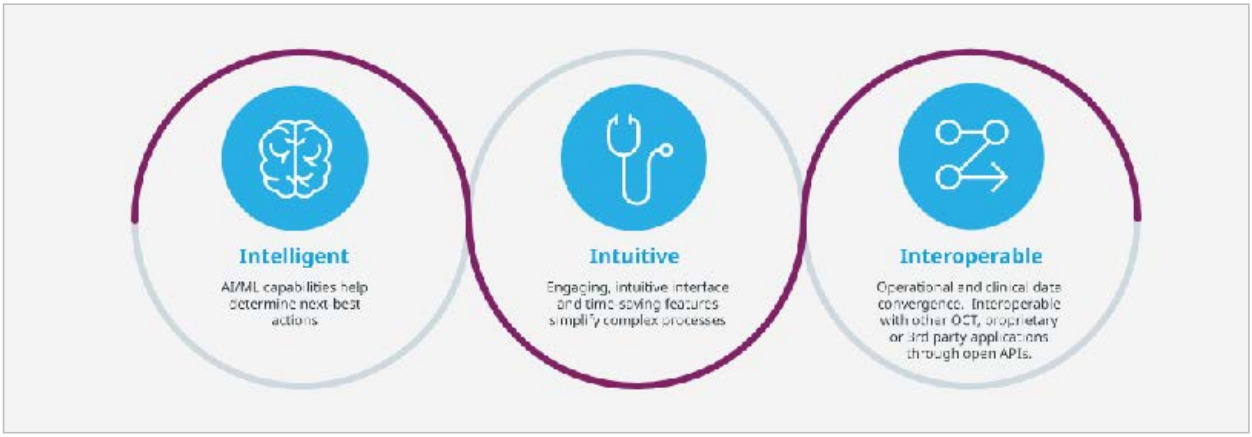
The pandemic acted as a catalyst to create this disruption and helped us to establish a new way

THE GAME CHANGER:

Regulatory Guidances

Technology is playing an important role by bringing point of care solutions to a patient's home, but it is the changes in regulatory guidances that are allowing us to create new business models.

Digital Trial Management Suite



of serving a subset of patients away from a research site. "Obviously, technology is playing an important role by bringing point-of-care solutions to a patient's home, but it is the change in the regulatory guidance that is allowing us to create a new business model."

In March 2020, the FDA addressed the need to ensure patient safety during the pandemic while participating in clinical research and issued an encompassing guidance for industry, investigators, and Institutional Review Boards. One of the key components was a section that paved the way for DCTs. The guidance, in short, stated that since trial participants may not be able to come to the investigational site for protocol-specified visits, sponsors should evaluate whether alternative methods for safety assessments (e.g., phone contact, virtual visit, alternative location for assessment, including local labs or imaging centers) could be implemented when necessary and feasible, and would be sufficient to assure the safety of trial participants.

This was an important turning point, one that allowed companies like IQVIA to employ technology transformation to address the safety needs of patients and the operational needs of sponsors.

Beenu says another regulatory guidance change around risk-based quality management (RBQM) is another game changer. The March 2019 draft guidance for industry entitled "A Risk-Based Approach to Monitoring of Clinical Investigations: Questions and Answers" updated the 2013 existing guidance and is changing how the industry approaches clinical trial monitoring. IQVIA notes that pharma sponsors can benefit from an RBM approach, but it requires a focus on change management and developing new workflows supported by integrating innovative technologies and multiple data sources.

"Technology, once again, is helping to improve data quality, but it was the guidance that helped us to reimagine and rethink how clinical monitoring could be conducted allowing for an integrated monitoring model to become a reality," Beenu says.

Opportunities Abound

Beenu believes that beyond the current opportunities that are available now to using digital transformation to reframe clinical operations, there are still unknown opportunities that will lead to further innovation, which she hopes will help prevent and eradicate disease and improve patients' quality of life. "One known opportunity is around what we call Connected Intelligence and leveraging artificial intelligence and machine learning when applied to data collected within clinical trials, be it structured data or unstructured data," she says. "Connected Intelligence is about providing an augmented decision-making paradigm to stakeholders. In other words, helping the user by suggesting the next-best action."

Beenu says there are three steps to enable this capability. Step one involves sorting and transforming the data. "Data, which can be generated from inside or outside of the enterprise, is then combined with unstructured real-world data generated through social media, connected devices, etc.," she says. "How this data is collected and transformed so that it can be used effectively is the second step."

Step two involves generating data insights from AI, machine learning, and other predictive analytics by leveraging learning platforms where hypotheses can be tested. "This helps us harness the full potential of the data selected during step one," Beenu says. "Step three is about providing that information and the next-best action to the user when and how they need it — be it on-demand or on a scheduled basis, through Alexa or on an app for example. These three steps combined allow Connected Intelligence to work for all clinical trial stakeholders."

A Vision for the Future

For years, Beenu has been working toward shaping solutions and envisioning a future in which clinical trials run more effectively and efficiently. "Today, my vision for clinical trials is to have personalized medicine, which is still in its infancy, become mainstream," she says. "I would like to see the traditional approach of one-size-fits-all trials evolve and accommodate the unique characteristics of individual patients or groups of patients by relying on the analysis of molecular and genetic profiles to aid in the assessment, detection, diagnosis, and treatment and management of disease.

"There are many advantages of personalized medicine that have been demonstrated in the field of oncology, but there are still ethical, social, and legal issues that need to be dealt with when we think of precision medicine or personalized medicine," Beenu continues. "The hope is that once again, a regulatory framework will help us accelerate this field and bring much-needed support to all patients in need."

Jennifer Aquino
VP, RDS Technologies (Digital Patient Suite)

Jennifer is responsible for developing technology and technology-enabled services that help sponsors manage randomization and drug supply activities as well as delivery services that support site and patient facing technologies. Jennifer has more than 30 years of experience in operational leadership, clinical technology and regulatory, and compliance in the bio/pharma industry. She served as the Chief Operations Officer for Cenduit, an IQVIA company from 2017 to 2020.

DCTs: Past, Present, and Future

The rapid adoption of decentralized clinical trial (DCT) elements during the COVID-19 pandemic, often implemented to mitigate site closures, will likely lead to more evidence showing the positive impact telehealth and other virtual technologies can have on clinical trial recruiting, retention, and diversity/inclusion goals.

Simply put, DCTs make trial participation easier for participants and give them fewer reasons to drop out, which can result in better, faster, and more consistent data. For sponsors struggling with retention issues, offering patients a way to participate in clinical trials from the comfort of their own homes could offer a powerful solution for the future.

Patient Support

The most impactful benefit from the swing of traditional site-based trials to DCT models is more access to clinical trials for all, especially for patient populations and geographic areas that were previously limited, says Jennifer Aquino, VP, RDS Technologies (Digital Patient Suite). "Patients benefit from the simplified technology of the new decentralized clinical trials and platforms that are available, which increases access to physicians through televisits," she says.

Patients aren't the only ones to benefit. Jennifer says trial sites will also see big gains in using DCT technology.

Site Support

"Within sites, investigators now have more time with their patients because they're able to leverage televisits and in-person visits where it makes sense," she says. "Sites have better access to patients who are typically out of reach."

Significantly simplified technology and one-stop shopping through DCT platform solutions makes it easier for patients to participate, which in turn makes it easier for investigators. Digitized

technology solutions reduce the challenges of running a study and allows investigators to focus on the trial instead of thinking about the platform and the complications involved with the associated processes. "This should also help lower the bar for physicians who can now participate in clinical trials," Jennifer says.

Thinking Ahead Allows for a Quick Pivot

Long before COVID, Jennifer had been working closely with IQVIA on a decentralized clinical trial platform. "About four years ago, several sponsor companies wanted to pursue DCTs, but they were still reluctant and uncomfortable," she says. "With the influence of COVID, DCT adoption and acceptance is at a much higher level. Early on in the pandemic, there were still a handful of sponsors that did not want to look beyond COVID in terms of DCTs thinking this would be a temporary stop gap. Today, I don't have a single sponsor that has not asked how can we continue with DCTs? We're changing the way clinical trials are being conducted. It is exciting to be able to execute our vision on such a broad scale."

Challenges and Opportunities

Conducting decentralized clinical trials is simpler in the United States because of new guidances than in some other countries where there are still challenges around regulatory constraints on data protection. Jennifer is hopeful that the time will come when industry and regulatory agencies around the globe can work together to solve this discrepancy.

Another challenge she has observed is that some sponsors are still trying to function under very siloed and disparate platforms, where processes are cobbled together without any integration. "While a challenge for sponsors, this presents an opportunity for us to make a real difference and educate sponsors on the new way the industry can conduct trials," Jennifer says.

Another opportunity aligned with DCTs is the use of digital sensors, also referred to as connected devices or wearables, and there is growing interest from patients and sponsors in this technology option. However, Jennifer says, there are still pockets of resistance. To counter lingering opposition requires more education, and the pharmaceutical and clinical trial community has to build trust with patients.

Jennifer's vision is to help expand DCTs globally, create an even greater patient-centric focus, and tailor trials and supporting technology in a way that benefits patients, thereby encouraging greater participation in the trial process, which in turn has the potential for more personalized medicines. "Patients are interested in

MEETING CLINICAL TRIAL CHALLENGES HEAD ON

- **48%** of trials miss their enrollment targets
- **85%** of clinical trials are delayed
- **58%** of endpoints in trials have doubled
- **70%** of clinical data collected in unstructured data sources

customized treatments, which improves compliance and lowers dropout," she says. "As exciting as all this is, and as fast as we are moving, there's still a lot to do."

The DCT Future

The DCT of the future will look different from today's model, Jennifer predicts. She believes there is even more opportunity for enhanced digitization of study procedures and increased use of sensors in all forms to acquire patient data, which would eliminate the need for patients, in the appropriate trials, to do any data entry.

Further, Jennifer's hopes that all populations can capitalize on the advantages provided by technology to improve healthcare. "Clinical trials need to be available to anybody who wants to have access," she says.

The opportunity to apply technologies to solve what have been historically complicated problems to improve access for patients and reduce costs for sponsors is going to be transformational across the industry. "If you had told me 15 months ago that across the globe, hundreds of thousands of patients would have been involved in a vaccine trial with urgency, it would have been very hard to imagine," Jennifer says. "However, today our imaginations are envisioning a time well beyond COVID."

THE GAME CHANGER:

Technology-Enabled Clinical Trials

Telehealth solutions and remote patient monitoring have created an entire new avenue to allow broad participation in clinical trials. The level of patient enrollment during COVID trials were at an all-time high. The opportunity to apply this experience to other therapeutic areas has already begun to spread.

Melissa Easy
VP, RDS Technology

Melissa Easy founded the clinical operations technology provider DrugDev, which was acquired by IQVIA in 2017, expanding the company's suite of site engagement tools, including an improved site portal, better site payment capabilities, and eConsent tools to improve the experience and understanding of patients participating in a clinical trials. Today, she leads IQVIA's Clinical Technologies activities, bringing pharma and investigators together with technology, service, and more open communications.


Visioneer

Moving Beyond Point Solutions

From countless conversations with sponsors of all sizes and working in multiple therapeutic areas, Melissa Easy, Head, IQVIA Clinical Technologies, knows that many of the digital solutions previously

viewed as "nice to have" for clinical trial optimization are now proving to be vital to support sites. "Clinical technologies are facilitating the necessary exchange of information and allowing the industry to continue its efforts to bring life-saving drugs to patients in need," she says. "Sponsors are deploying digital clinical technologies to boost support to sites and enable innovative drug development to continue not only during the COVID-19 crisis but well into the future.

"Historically, as an industry we have often focused on how to make things easier for sponsors and CROs and we haven't always factored in sites' needs," she continues. "By spending more time thinking about what sites need, we can reduce cycle times and increase quality. We talk a lot about being patient-centric, and we've stepped up what we do in that respect, but when it comes to sites, it's been lip service and that needs to change."

The problem, in part, is because instead of solving for the big picture, for most technology companies the focus was on providing individual point solutions. "Traditionally, what worked best for sites and the user journey wasn't always considered, and this is really important," Melissa says. "The burden on sites becomes immediately evident when we start to plot out their user journeys accounting for all of the different stakeholders they work with and the number of factors they need to account for in any given study. They may have to use technologies that are not all from the same vendors, all with their own individual log ins — or worse the same vendors but still different log ins for each study. We cry about the Post-It notes that are everywhere because every system has a different log-in, not to mention the look and feel."

First and foremost, from a site perspective, the technology needs to be user-friendly without requiring a lot of training. Also, systems need to be able to talk to each other, this eliminates the need to input repetitive information thereby creating one single source of the truth throughout an entire study. "We need to think more holistically about how we can support sites beyond point solutions," she says.

Digital Technologies to Improve Site Performance

One such technology is eConsent, Melissa says. "Before COVID, some sponsors were using eConsent as part of their standard operating process, and others for certain studies, and others were only thinking about it and needed convincing to use eConsent for their studies," she says. "When COVID changed everything, sponsors

THE GAME CHANGER: COVID-19

If the pandemic taught us one thing it should be that clinical trials can truly rock. Working collaboratively together — sponsors, CROs, regulatory bodies, sites — we can deliver incredible results. We do make a difference to peoples' lives. During COVID, we pivoted and applied all of the technologies and processes we had been successfully employing to a coordinated deployment for treatment and vaccine studies, including more than 160,000 active patients. We believe that with all of the knowledge that's been recently gained, will see trials accelerate and will see more patients participating in clinical trials — all of which means speed to market.

couldn't facilitate eConsent quickly enough into their studies. Regulatory authorities relaxed the rules around what sponsors could do and that changed how sponsors think about eConsent as well as decentralized clinical trials as a whole." Today, sponsors are setting new goals in terms of what percentage of a trial or how many trials should fall under a decentralized clinical trial or DCT model. "Forward-thinking sponsors are evaluating study by study, visit by visit, to determine what part of the trial can be tech-enabled. This is quite exciting to watch, and it means that we need to rely on technologies that support sites, or we will not be successful," Melissa says.

Another challenge for sites has been timely reimbursement. Typically, sites work with a tight cash flow, so it's more important than ever to deploy technologies and expertise that enable payments to be made in a timely fashion. Just as importantly, Melissa says, sites need 24/7 access to information on activities they have been paid for and payments they have not been paid for. "Sites often receive random checks in the mail without knowing which study or activity the payment covers, and these checks are often slow to arrive, ranging from quarterly to every six months," she says. "The COVID-19 crisis highlighted the need for sponsors to improve the timeliness and transparency of their payments processes."

Another challenge lies in the fact that sites are not one-size-fits-all facilities. Sites are different sizes and at different parts of their journey when it comes to technology. Melissa's vision is to be able configure a platform that has everything a site requires. "My goal is to get to a point that during contract and budget negotiations, sites receive a list of all of the options available similar to a menu," she says. "Sites can tick off what they need, and we deliver. However, this requires a broader perspective about the site experience and a commitment to support sites going forward."

Purpose-Built Clinical and Technology Solutions

IQVIA Decentralized Trials deliver purpose-built clinical and technology solutions that engage the right patients wherever they are. Either hybrid or fully virtual models have been fine-tuned through more than 65 DCTs across more than 10 therapy areas and 40 countries.

Because performing on-site visits and in-person meetings can be especially difficult for site training staff, some sponsors are now using the learning management modules of the IQVIA Investigator Site Portal to add remote training to the agenda. "Virtual SIVs and IMs become more feasible and productive by letting sites complete training either in advance or in real time with their CRAs," Melissa says. "Protocol and GCP trainings are assigned automatically based on role or task, and training records are updated with a complete real-time audit trail. Sites appreciate this organized, efficient, and high-

PURPOSE-BUILT DCT TECHNOLOGY TO BOOST STUDY PERFORMANCE

- Collect and disseminate data in real time
- Engage patients across the globe in multiple languages
- Securely track IMP shipped directly to patients
- Centrally monitor studies
- Collaborate across key stakeholders and systems
- Upload medical records and other visit documents

quality approach to training, which demonstrates how much their time is valued. It also reduces administrative work for sponsors as it avoids the need to capture data in an Excel spreadsheet to be entered later into the learning management system."

While DCTs are here to stay, Melissa says standardization is needed for further advancement. "Currently, everyone has a slightly different definition of what a decentralized trial is; for me, it is not 100% virtual," she says. "While I don't believe all studies will become 100% decentralized, I do think that most studies will have a component that is remote or virtual."

As a result, Melissa says, it's time to re-evaluate what this means in terms of the fair market value of these processes for sites. "Just because a piece of the trial will be done virtually, does this make it easier or harder for the site? And should we be paying them more or less? We need to rebalance or recalibrate expectations as we move toward a new normal that includes decentralized trials."

Tim Riely
VP, Clinical Data Analytics

Tim Riely has 20 years of experience delivering business intelligence, data management, and analytical solutions in leadership and consulting roles. Tim leads the IQVIA Clinical Data Analytics Suite, providing both SaaS solutions for the market as well as IQVIA's internal CRO needs. Tim is responsible for full delivery of R&D data and visualizations solutions for clinical operations, clinical data management and analytics-as-service products. Tim's background includes payer, provider, and clinical research technology experience.

Visioneer

Connecting Insights to Workflows

The technology landscape in clinical research has been defined by point solutions, content chaos, a lack of interoperability, and an inability to flex and scale with the changing needs of the business. These inefficiencies make it difficult for life-sciences companies to drive positive change in clinical research. Tim Riely, VP, Clinical Data Analytics, says having intelligence as a standalone capability is not enough. "What matters is connecting timely and relevant insights to help stakeholders make smarter decisions about the workflows they're responsible for," he says. "This enables sponsors, sites, and patients to improve clinical outcomes as well as enable faster development of new medications and safer patient experiences.

"The focus on connected devices opens up a huge opportunity to get additional insights, less expensively and with less burden to the patient, and as a result, a more complete picture of a patient during his or her time in the trial and the impact a given molecule may have," Tim adds.

Connected devices help alleviate the reliance on EDC systems, which still have a role, but the amount of data coming from nontraditional sources is increasing significantly, and with that new

data processing and analytics capabilities will be required. Tim adds that access to investigator data, past clinical study data, wholesale pharmacy data, and past study data from clinical research.com is very valuable, but unless those assets can be connected in a way that's meaningful, the insights to be gained are limited. "There has been a great deal of progress made not only in gaining access to those types of data assets but in the ability to connect them in a more meaningful way to drive insights, but the final best step is to use these insights to improve and develop workflows," he says. "A key aspect of Connected Intelligence in the context of connected data and data analytics, which is often overlooked is how to inject those insights into a workflow to drive an action."

Along with technology advances come new challenges, however. Clinical data review and clinical data quality become more difficult to manage due to the many new data streams. "We can no longer just use an EDC to create edit checks, address discrepancies, and enter data as clean," Tim says. "We need to bring the data together and develop tools and workflows in a different way."

For example, when structuring a decentralized trial, it's one thing to know that a patient had a certain event that may be captured in an EDC or PRO system, but there should be some

The Benefits of Using Clinical Data Analytics Suite

IQVIA Technologies CDAS enables users to rapidly ingest, standardize, and integrate data to generate insights from a variety of clinical and related nonclinical data within a single data ecosystem. As a result of accelerated insights provided by CDAS, users:

- Achieve shorter time to insight and action
- Establish interoperability among various systems
- Increase the value of their data by making the right decisions at the right time
- Reduce cost of ownership of R&D focused operational and strategic business processes

FOR PATIENTS

- Increased patient safety due to real time medical monitoring
- Increased patient retention rate

FOR SITES

- Enhanced data quality
- Increased completeness
- Timely availability
- Improved regulatory compliance

FOR SPONSORS

- Faster database lock with real time and proactive data management
- Minimized data harmonization efforts to introduce new sponsor specific systems for data exchange
- Supports clinical, operational, and real-world analytics
- Reduction in time to deploy standard KPIs and KRIs for clinical trial oversight and shortened development timelines and cost
- On-going productivity improvement by intelligently automating data mapping process by in-built AI and ML algorithms

expectations of data potentially coming from a connected device. Tim believes by just looking at data coming from either the connected device or EDC system, there is a chance to miss pertinent data points.

During the trial execution, there is a need to bring data together to make sure there is corresponding information coming from a variety of clinical systems, including EDC and connected devices. "Once this happens, we can bring in artificial intelligence and machine learning to provide greater predictability to the data being collected," Tim says. "This type of knowledge can transform decision making, by turning insights into action. By embedding intelligence directly into OCE and workflow technologies, it puts the best recommendations into the hands of end users at the most opportune moments based on AI- and ML-driven insights. This also allows trial staff members to take the right actions and make the best decisions."

Tim notes, for example, IQVIA's site risk analytics tools can be used to predict when an intervention may be required. "This visualization into the study allows for decisions to be made proactively, by injecting those same insights into a workflow tasks can be automatically created, or in other words take the next best action."

Opportunities for Greater Predictability

Connected Intelligence and connected devices provide the opportunity to predict whether or not a patient or his or her digital devices — such as an actigraphy device — are providing the right quality of data. "There are now algorithms that can determine the accuracy of patient data being collected based upon population data and based upon a patient's historical data collection," Tim explains. "These insights, which are available, are only valuable if they are injected into a workflow," he says. "There is nothing worse than having a patient participate in a study, leverage a device, and then, not get the value of the data because of an issue that could be easily detected."

While there are currently many tools and technologies

THE GAME CHANGER:

Connected Devices

The advent of connected devices, also known as patient wearables which helps to enable decentralized trials, is presenting opportunities to collect more data, more conveniently for everybody involved. Before the widespread adoption of some of these devices, including continues glucose monitors, ECG and actigraphy devices, smart watches, and more, there were many unknowns about the activities and vital patterns of healthy individuals, let alone patients with a given condition. The industry didn't use those data points because they were difficult to collect and there wasn't a lot of focus on this aspect for healthy individuals. There also was a great deal of burden for both sites and patients to collect information for just one data point. Connected devices now enable a better view of the entire patient journey, in a way that doesn't have the same impact on patients. Eliminating the burden leads to fewer patient dropouts.

available, the industry is still at the tip of the iceberg on applying these concepts to the data being collected to get the value that is available. "We have made good progress on integrating AI and machine learning and we made good process on business workflow automation," Tim says. "Now, we need to merge and combine these two."

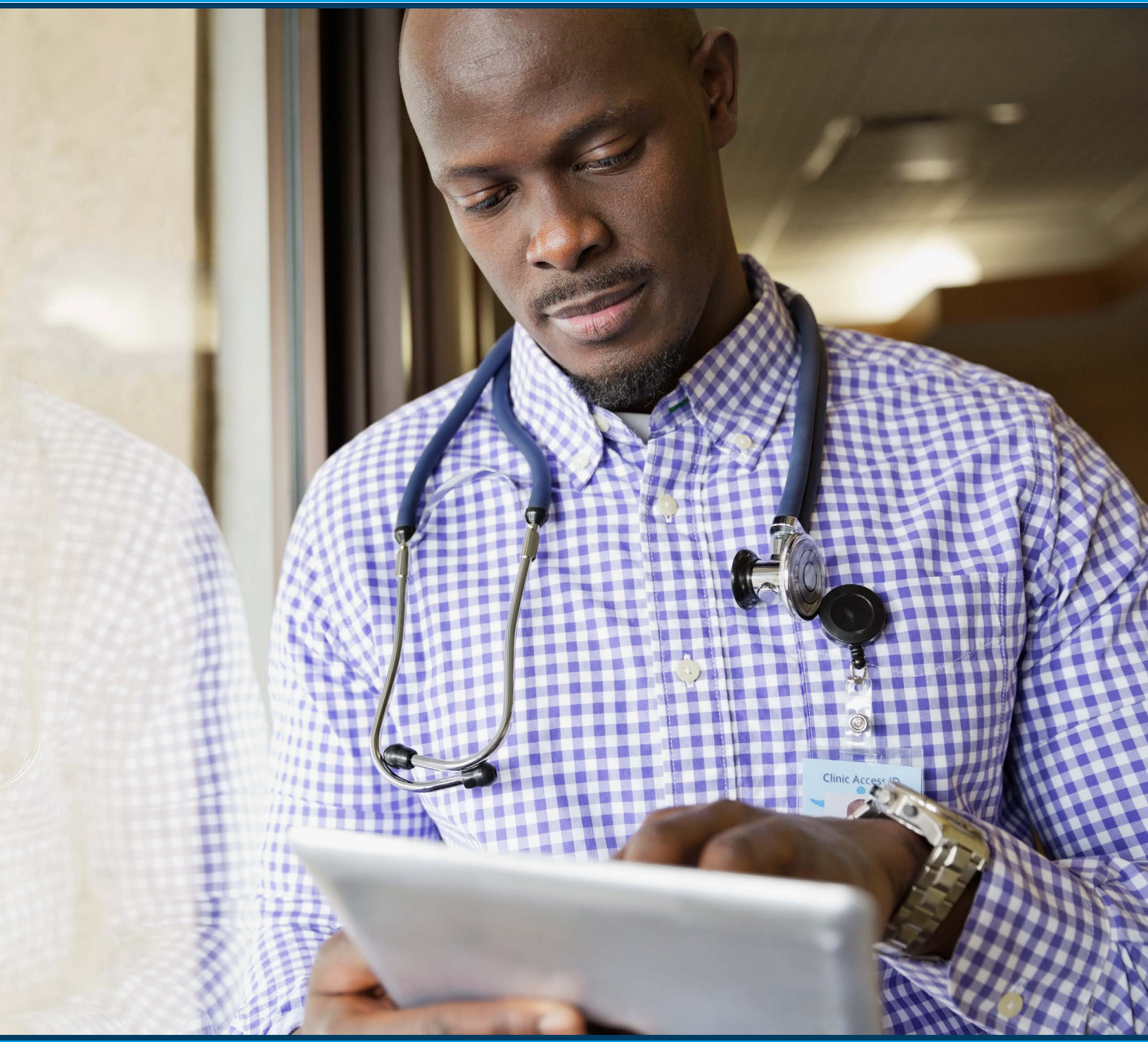
Decentralized Clinical Trials

Tim questions whether the traditional clinical model is sustainable for the future. "Rare disease studies or precision medicine studies, for example, will require more and more insights in order to address the needs of subpopulations of patients," he says.

DCTs enabled by technologies will allow sponsors and sites to identify these subpopulations of patients who are within two, three, or four hours of a clinical trial site or who are willing to travel to one in order to participate in the clinical study. "As we get into these populations that are narrower and narrower, it's going to be much harder to find patients who meet specific criteria to go to a particular site," Tim says. "And the burden on those patients who will have to go to a site will increase significantly as we tap into those smaller populations."

DCTs represent a huge opportunity to streamline the process for patients and sites, he says. "For a narrow patient population, sponsors can identify where those patients may be based on data assets collected, as well as identify physicians who are providing care," he says. "Trials can now be designed that allow data collection from those patients in ways that don't require they travel. In some cases, coordination with primary care physician is possible, which would further ease the patient burden. The importance of decentralized clinical trials is going to grow more and more."

Tim likens the evolution of DCTs to that of big data. "Four to five years ago, everything was being called big data, today it's just data," he says. "I believe the same will hold true for DCTs. In four or five years, we won't be using the term decentralized trials anymore because they will have evolved into clinical trials."



IQVIA TECHNOLOGIES