White Paper

Making Intelligent Connections Possible: Power your clinical trials with better devices

MIKE BRUHNS, IQVIA

The advanced therapy sector has experienced exponential growth in recent years related to the number of technologies and vendors entering the medical data devices market. Additionally, a need for more specific, higher-capability devices across multiple geographies has emerged for many clinical trial operations, owing, in part, to the increased uniqueness of the drugs and therapies undergoing development.

The proliferation of these devices, as well as the diversity of the applications that demand their use, has created a challenging paradigm for trial sponsors to overcome. There are many variables that attend the selection process for these devices; moreover, each of these variables must receive due consideration if drug developers and trial sponsors hope to identify the optimal device for a given study.

With a vendor-agnostic view of the device market and a strong portfolio of partnerships with leading device manufacturers, IQVIA can custom tailor a connected device solution that is specifically optimized for your trial. Additionally, IQVIA supports end-to-end trial logistics, including procurement, kitting, and distribution of devices, all the way down to tracking expiration dates, allowing sponsors to focus on trial outcomes.

FINDING THE RIGHT DEVICE SUPPLIER FOR YOUR TRIAL

The process for identifying, selecting, and ultimately implementing connected devices in clinical trials can be overwhelming. The demand for connected devices in clinical trials has grown significantly, driven by a need for better, more expansive, more varied data, and more recently, by renewed bids to improve patient experience and reduce the burden for trial sites. The impact of the COVID-19 pandemic on on-site trials has been widely recognized; the net result has been a significant increase in demand for virtual technologies and telemedicine strategies that mitigate these challenges.

The search for the right device hinges on a few key factors. Chief among these is a concept called horizon scanning, which is simply a comprehensive evaluation of the current marketplace to determine what's available, what represents innovation in the space, and what is in the pipeline. This evaluation is important because new devices are emerging nearly every day, pioneered by both large medical device manufacturers and small vendors, startups, think tanks, and universities. While this diversity of choice is important, it can also create additional analytical burden for clinical trial sponsors, as the variability between devices, what they measure, how they measure, and how they are integrated into various systems can make selecting one a complex task.

Complexity is best addressed through developing a deep understanding of the trial protocol, the study team's requirements, and other considerations essential to the ultimate success of the trial. This drives a holistic view of both the vendor and the device, and into the technology itself, through activities like vendor assessments that encompass quality, security, data privacy, legal, and finance considerations. Equally important is to take a deeper dive into a potential device vendor, evaluating their core competencies, therapeutic experience, global reach, compliance, strategic direction, and other factors that could impact a trial.

This deeper understanding can help companies find more than a device for their present application – it can lead them to a device partner capable of growing

and adapting alongside them. Because IQVIA is not a device manufacturer, it relies on its vendor partners to help identify and develop custom device solutions. This is an important consideration, as many medical device vendors or manufacturers are designing and building for commercial applications rather than clinical trials. This mindset is part of what makes vetting vendors with a partner like IQVIA advantageous. There is a particular disparity between the concept of what makes a great device for commercial use and what makes a great device for clinical research use. By working to co-develop a clinical research device, or modify or configure an existing device, companies and their partners can optimize devices for use in clinical trials.

ASKING THE RIGHT QUESTIONS WITH IQVIA

In the clinical trial space, there are dozens of considerations around data collection, drug administration, tracking, and other variables supported by the use of medical devices. This complexity necessitates approaches that incorporate comprehensive road mapping, horizon scanning, and contingency planning. Recently, IQVIA has worked to prioritize country-level regulatory approvals to ensure that connected devices are available in regions around the world, where the industry is seeing clinical research expanding. China has emerged as one country where sponsors are keen to conduct trials, though it possesses very difficult regulatory approval processes and complex importation protocols. By working with device manufacturers to secure device approvals in China, partners like IQVIA can make it easier and faster to run their clinical research in that area.

While IQVIA's Connected Devices portfolio includes dozens of validated, integrated solutions, this represents only a portion of what it can offer customers. Every trial is unique, so having access to medical experts to delve into a trial's unique requirements, its study outlines, and how to best support protocol development and protocol writing can help ensure that the offered solutions are optimized to the trial. If the outcome of an evaluation identifies a specific device not already in IQVIA's portfolio, IQVIA would work to vet the vendor, qualify them, and onboard them into the portfolio, as well as validate and integrate the device into IQVIA's world-class, 21 CFR Part 11-compliant platform.

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Ultimately, the goal is to ask the right questions in order to both optimize the device selection and minimize risk. One example of common devices that may require added optimization are wearables such as biosensors. There are numerous considerations a trial sponsor may need to make in order to facilitate biosensor selection, such as whether the trial requires point-in-time data or continuous data, or if it requires raw or derived data. These considerations often lead to new ones – for example, trials utilizing derived data should ensure the algorithms employed are validated for the trial's specific endpoints. Other factors that impact this evaluation include the locations of the trial, where its data cloud is located, or whether it is GDPR compliant, as well as simpler questions, such as whether the device is waterproof, how it can be recharged, and other considerations related to patient centricity or ease of use. This is the value a connected device service provider like IQVIA can provide: through prior experience, in-house expertise, and a knowledgeable network of suppliers, IQVIA can help identify the right questions to ask and the answers to each.

Arguably, the most overlooked aspect of trial design is logistics. From varying importation laws for some countries to fluctuations in enrollment between sites, the dangers imposed by improper logistical planning can delay timelines and create additional site burdens. Addressing these challenges requires thorough and current regulatory knowledge, particularly from regulatory experts with boots on the ground. Inventory hubs in countries with longer processes are one way to accelerate deployment; another common paradigm that can create added complexity are multi-modality studies, which incorporate multiple devices in support of the same trial. IQVIA's logistic services can provide site-based, or even patient-based kitting and configurations, so that when sites open the box, they have all the devices and a configured laptop or tablet that is ready to go, greatly simplifying the logistics of a trial.

At IQVIA, the central objective for clinical trial support is to reduce site burden, remove the roadblocks that disrupt studies, and simplify the process for patients and providers. To this end, IQVIA has shipped more than 100,000 medical-grade devices to over 60,000 sites across more than 100 countries, all with greater than 98 percent on-time delivery. Partnering with a connected device solutions provider that can help identify the right devices for a protocol, support their successful deployment in a clinical setting, and offer insight into the larger data- and patient-driven outcomes of a study is key to facilitating faster, more fruitful trial outcomes.

About IQVIA

IQVIA (NYSE:IQV) is a leading global provider of advanced analytics, technology solutions and clinical research services to the life sciences industry. IQVIA creates intelligent connections to deliver powerful insights with speed and agility — enabling customers to accelerate the clinical development and commercialization of innovative medical treatments that improve healthcare outcomes for patients. With approximately 82,000 employees, IQVIA conducts operations in more than 100 countries. Learn more at www.iqvia.com.

About the author

MICHAEL (MIKE) BRUHNS
Director, Device Strategy,
Vendor Partnerships and Logistics,
Connected Devices, IQVIA

Mike is the Director at IQVIA for Connected Devices in charge of strategic device partnerships and global logistics. Mike's 20+ years of experience spans various industries. He is passionate about optimizing solutions and creating win-win partnerships to build the broadest, most innovative portfolio of medical grade devices for use in global clinical research, across all service lines, modalities and therapeutic areas.

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