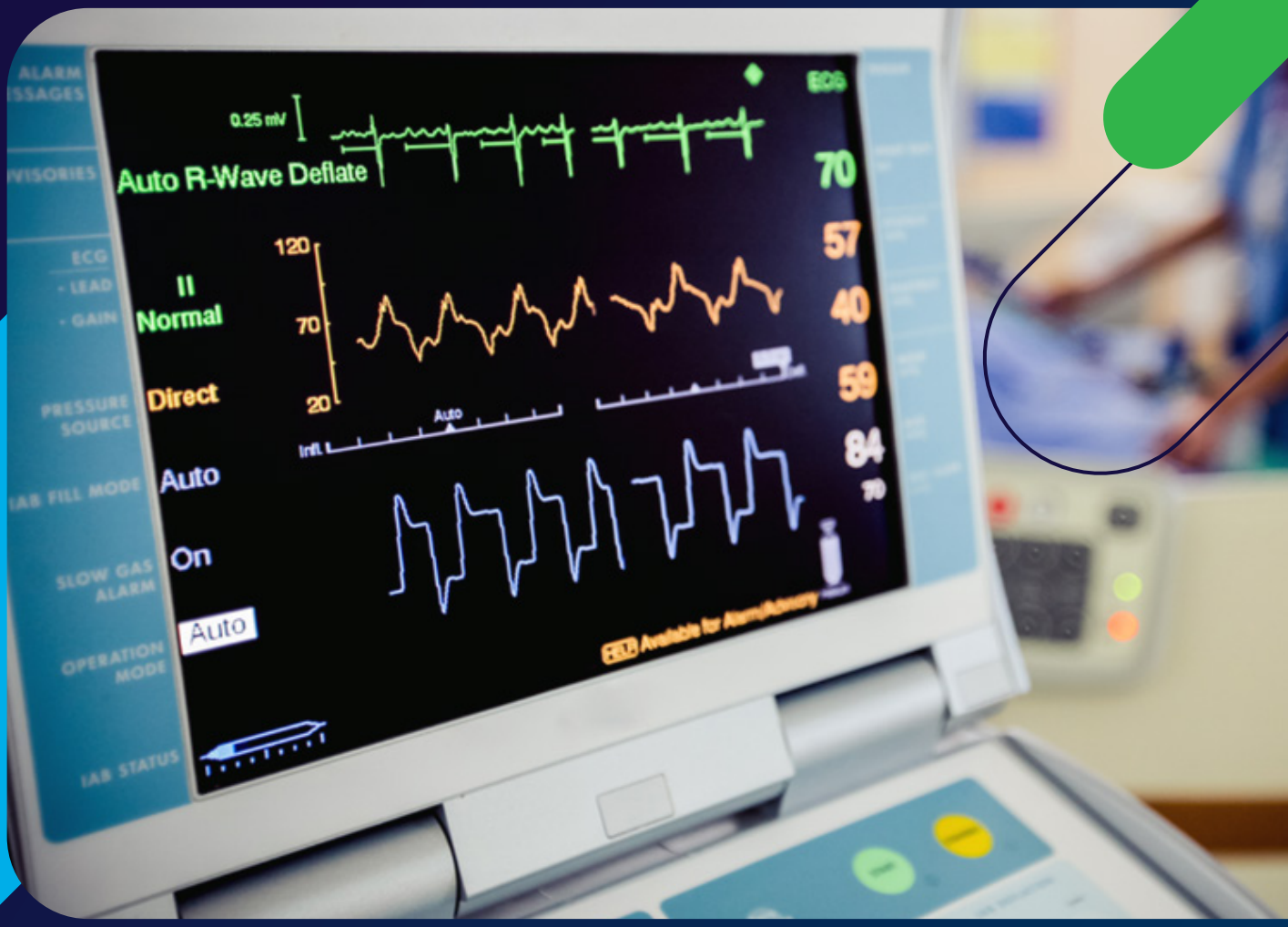
IQVIA TECHNOLOGIES



Medical Device Trial Integration

Expertise that helps eliminate device study risk

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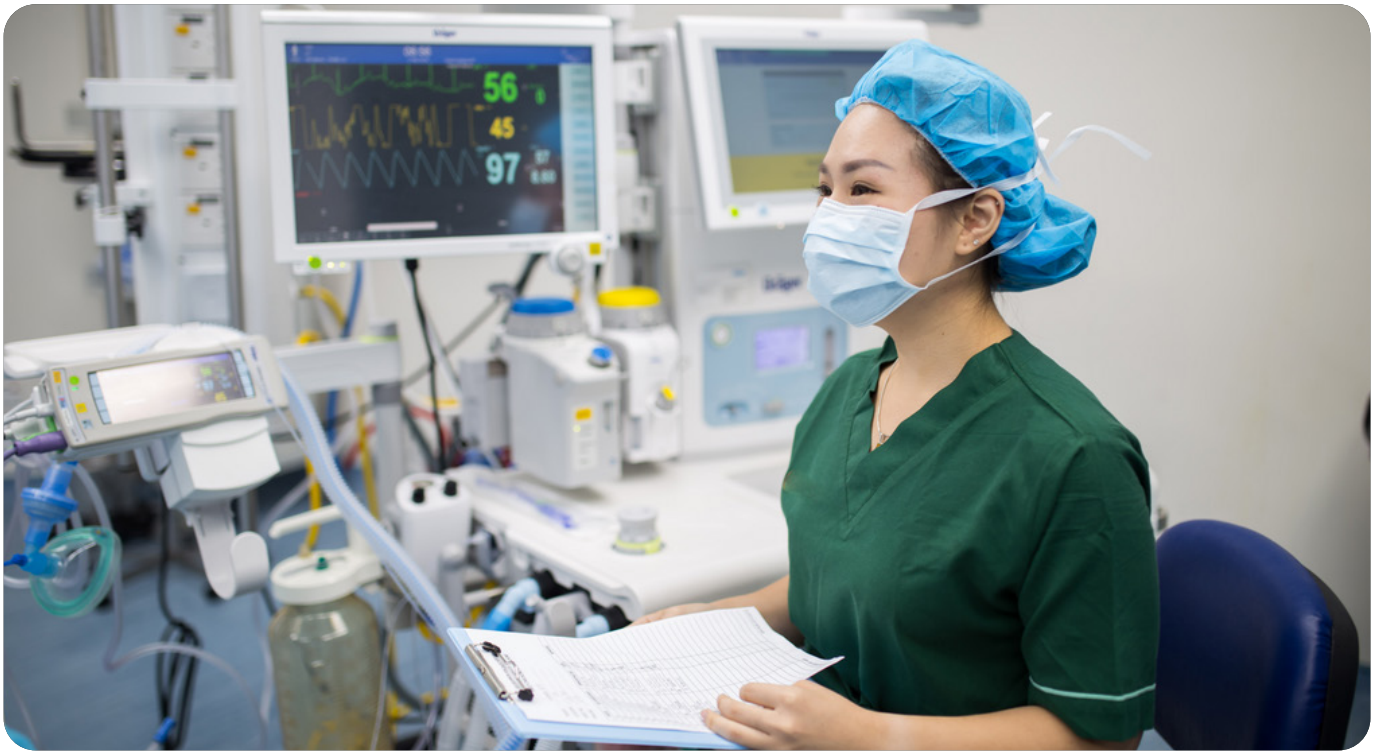
Getting your medical device trial right at every stage is critical

The average total cost for a company to move a low-to moderate-risk 510(k) product from concept to clearance is about $31 million. For a higher-risk PMA product, that figure skyrockets to $94 million[1]

Cardio devices. Spine breakthroughs. Knee advancements. Each medical device is highly unique and the same is true of every device trial. Technology advancements are novel and innovative, and study parameters vary widely. What's more, device study groups tend to be smaller than drug trial groups, yet patient unpredictability is common. And many device studies are challenging to blind, randomize, and control. Consider in-trial device modifications, ever-changing FDA regulations, unique patient challenges like device sizing, and diverse physician techniques, and you've got a challenging study on your hands.



[1]FDA Impact on US Medical Technology Innovation; A Survey of over 200 Medical Technology Companies, by The Advanced Medical Technology Association ("AdvaMed"), prepared by Josh Makower, M.D., consulting Professor of Medicine, Stanford University and Founder, President & Chief Executive Officer of ExploraMed Development

Insight and innovation make the difference

Our insight into different regulatory implications, combined with our IRT expertise and innovation takes your trial to the next level. Our IRT specialists can decipher, anticipate, and translate the many nuances of medical device trials. We work closely with study sponsors to pre-determine acceptable system functionality, giving you and your sites an intuitive structure, personalized reporting tools and seamless tracking. IQVIA aligns IRT systems to the requirements of medical device clinical trials.

We want your trial to be a success at every stage — from study design to execution to reporting.

AN EVER-CHANGING REGULATORY LANDSCAPE

Regulations for medical device trials change constantly. For example, a CE Mark no longer guarantees marketability or early revenue. Some devices require an additional five years of clinical studies post-CE marking and something as simple as knowing a device's detailed history can make or break a study.

Source: Medical Device Sector Review, ADMET, May 2014

Special considerations for medical device studies

When dealing with drug studies, sponsors are concerned about expiration of materials and accurately forecasting materials needs. Medical device trials add other layers of complexity

Medical device studies must consider a variety of factors in implementing IRT solutions, including unpredictable patient enrollment, critical device implantation, and ad-hoc device changes due to size or inadvertent contamination

Due to differing regulatory oversight and standards, sponsors need very detailed device history records

Tackle complexity with an agile IRT system

Medical device trials require that the IRT system you use is agile enough to handle trial complexities. You need an IRT system that can efficiently serve the special requirements of device trials

Real-time tracking

Medical devices are expensive and their high cost means they will most likely need to move from location to location frequently. If the device is sized incorrectly or patients don't qualify, for example, the device may need to go back to the depot for redistribution. Integration enables you to keep a close watch on all devices and track their movement, saving time and money

Dynamic distribution

Due to their expense and frequently limited supply, medical devices often require just-in-time labeling, so your IRT system must be a cost-conscious system that drives your supply chain to respond to distribution demands efficiently. IQVIA's supply chain expexpertise provides you with the capabilities to meet these unique needs

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