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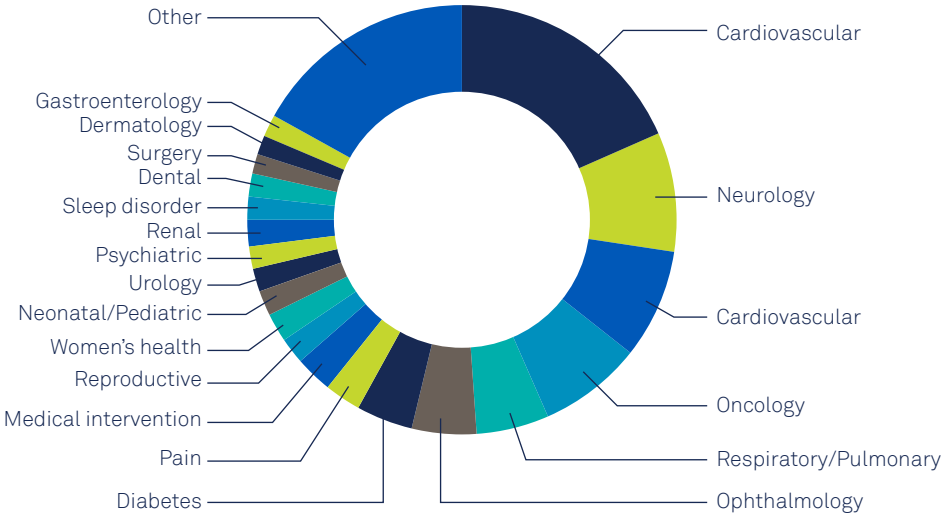
Technology and Expertise Add Operational Value to Medical Device Trials

The medical device industry generates $350 billion yearly as it creates life-saving and sustaining innovations in healthcare, bringing new treatments across the range of therapeutic areas (Figure 1).

Device manufacturers face an array of challenges as they invent, test and commercialize their products, which include some of the most effective treatment and diagnostic products available. These innovators are navigating a bumpy landscape, that includes requirements for individual UDIs, an uncertain tax situation, scrutiny of physician relationships and reimbursement / payer hurdles.

Figure 1: Medical Device Trials Started in 2014



Source: clinicaltrial.gov, May 2015; Medidata

As the industry faces its new and existing requirements, the most innovative companies are looking to all tools – processes, organization and technology – to create commercial value and, most importantly, bring therapeutic and preventive breakthroughs to the public.

Medidata Solutions, the leading global provider of clinical trial technology, supports over 570 life sciences organizations conducting the testing needed to bring new treatments to waiting patients. Our scalable cloud platform is used by all of the top 25 global biopharmaceutical companies[1] as well as more than 350 development stage, mid-sized, small and specialty medical device, diagnostic, pharma and biotech companies.

Medidata is used in cardiovascular studies across the globe, from large, multiple country studies to one site studies. Medidata's customers span the globe (Figure 2), representing local, regional and multinational organizations

Figure 2: Top 15 Global Medical Device Companies, Medidata Customers v. Others

Source: Top 40 Medical Device Companies, Medical Device Business, 21 Nov 2014; Medidata

[1] By branded drug sales, from: Pharmaceutical Executive, "Pharm Exec's Pharma 50 2015," June x, 2015

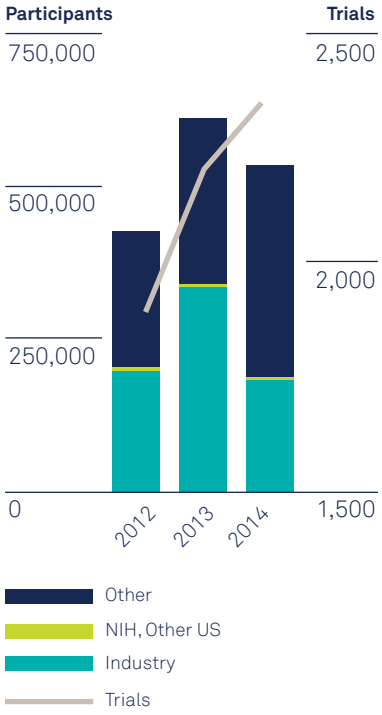
The Unique Challenges of Medical Device Trials

Medical device clinical trials in today's world, whether in support of premarket approval (PMA) or premarket notification 510(k), require management of safety, regulatory, design, operational and resource issues. Skillfully and efficiently navigating this environment determines whether new innovations generate positive returns, and often whether they can be launched at all.

The more numerous pharmaceutical clinical trials are frequently the focus of available trial designs, third-party support and expert advice. However, device trials, which have numbered almost 6,500 studies with over 1.5 million patient volunteers from 2012 to 2014 (Figure 3), present unique challenges. Compared to drug and biologic trials, they frequently involve smaller sizes; difficulties or impossibility of blinding (single or double); issues with recruiting appropriate physicians; requirements for clinician training; and longer trial time lines required to meet statistical goals. Device firms and device subsidiaries of pharmaceutical companies are organized for innovation and device manufacturing, and often lack the large development staffs of pharmaceutical companies.

Medidata's cloud-based technology and data analytics platform is optimally suited to help device innovators meet their critical trial goals. Medidata's scalable technology has been used for trials across the range of devices — implantables, inhalers, orthopedics, neuromuscular stimulators, surgical and emergency interventions — all benefiting from the transparency, design configurability and ease of use of the platform and the insight and experience of Medidata's expert service teams.

Figure 3: Medical Device Trials 2012-14, Participants and Number of Trials Started by year



The Medidata Approach

Operational Value for Your Trials

Medidata's cloud-based platform has supported hundreds of device trials with its comprehensive, configurable set of applications that support the research team throughout the trial process, from planning through administration and execution.

The Medidata platform enables productivity across the multiple activities of the clinical study lifecycle, from study planning and setup, site management and patient engagement, to study execution and reporting. With Medidata's fully scalable platform, customers can contract for a single capability, including the industry-leading Medidata Rave® EDC/CDMS, and add randomization, trial supply, coding and safety reporting integration as their organizations grow and needs evolve. The Medidata platform also provides the basis for industry analytics reporting across studies and trials, with benchmarks to industry norms and best practices, for enhanced decision-making.

Secure, Accessible Cloud Infrastructure — In it for the Long Haul

Medidata's cloud-based infrastructure offers the scalability, configurability and sustainability required by device trials. Long-term trials, many with modified amendments, additional sites and even adaptable designs, can rely on Medidata's platform and capabilities for the trial's lifecycle.

Medidata's cloud-based platform gives immediate accessibility to members of the research team, including physicians at sites worldwide with an Internet connection. Trial applications run in the secure Medidata cloud infrastructure, freeing the device company from burdensome IT requirements and validations. With industry-leading technology, Medidata provides the highest level of security in its clinical research infrastructure.

Helping Design the Right Trials, Right from the Start

The Medidata platform approaches the device trial as a comprehensive whole, from developing the protocol to producing final data sets. Medidata technology can simplify front end planning and protocol development, providing the tools to build a trial right from the start.

With optimal setup, trial administration, management and quality are maximized throughout the trial, eliminating interference with scientific, manufacturing and other key functions. Medidata technology is designed to support multiple work streams, provide timely and comprehensive reports and support real-time adjustments as needed, leaving the company's innovation experts free to focus on producing value-driven commercial pathways.

Hundreds of device trials have been supported by Medidata's secure, accessible cloud infrastructure.

Feature-rich, Operationally Simple Applications

- **Configurable EDC/CDMS** — Medidata's data collection and management tool automates secure data input from patient sites, providing immediate data cleansing and audit trails and reducing data reconciliations, redundancies, batch uploading, and ex post facto patient data collation, key contributors to trial errors and delays. Data from other sources, such as labs and legacy systems, can be easily merged through Medidata's standards-based APIs, creating a unique transactional database for anonymized patient data.
- **Integrated EDC and randomization** — Medidata's ground-breaking technology for randomization simplifies planning, setup and implementation with a choice of sophisticated allocation methodologies, including support for adaptive trial designs. Automatically integrating with Rave EDC/CDMS, it provides a single sign-on, integrated experience for investigative sites, eliminating the need for separate web or telephone-based systems.
- **Integrated medical coding** — Integrated, on-demand, centralized coding capability supports internal and outsourced clinical researchers in a secure cloud environment.
- **Safety reporting system integration** — Providing a bridge from the EDC/CDMS system to an organization's E2B/E2B+ safety reporting system, this capability eliminates redundant paper collection and minimizes reconciliation processes.
- **Full range of risk-based monitoring (RBM) support** — For companies looking to implement RBM to streamline and improve data quality reviews, Medidata offers the broadest set of capabilities in the industry, from initial decision making and planning, to setup and implementation, as well as change management consulting.
- **Operational support for payments, site compliance reporting** — Medidata Payments® automates the critical tasks of clinical site payment setup, calculation, approval and reporting, helping to maintain high satisfaction with clinical partners. Medidata Payments also provides documentation for compliance with Sunshine Act and international transparency reporting requirements using Medidata's proprietary database of global procedure costs as benchmarks.
- **Flexible, scalable clinical trial management system** — Medidata's clinical trial management system (CTMS) enables effect tracking and deployment of critical resources, helping device manufacturers address performance issues and streamline operational workflows before trials run aground. Medidata CTMS's is a modular SaaS system, and companies can start with one functionality and scale to others as operations evolve. Helping monitors deliver visit reports more efficiently or streamlining investigator site payments, Medidata CTMS® provides easy-to-use focused deployment that is more cost effective and rapidly deployed than legacy or installed products.

Expert and Experienced Service Teams

Device customers implement Medidata's technology with the expert help of Medidata's professional services team. Using proven methodology crafted for medical device trials, medical experts configure the study, work with sites to prepare and assist in managing the trial through its lifecycle. Medidata professionals can also work with sponsor researchers during the trial to build in-house proficiency.

Device developers preferring to implement trials through a contract research organization (CRO) can choose from over 70 Medidata accredited partners that have been trained in building and implementing Medidata studies.

Patient Engagement

Medidata is helping life sciences companies evolve toward a patient-centered approach, from putting electronic patient-reported outcomes (ePRO) on consumer devices to an ongoing commitment to "patients as partners."

Medidata set out to build a new model for PROs—one as simple to use and deploy as paper, already unified with EDC and with a compelling ROI, whether for many or a few assessments. The result is Medidata Patient Cloud®, a mobile app that runs on smart devices (smart phone, tablet, etc.), delivers fully validated instruments to the patient and feeds completed assessments directly to EDC. There are no separate ePRO databases to integrate or reconcile, reducing operational risk and speeding trial timelines.

Medidata is pioneering a number of mobile health (mHealth) initiatives to bring digital, personalized medical devices into the rigorous regulatory and safety environment of clinical research. By working through the rigorous data, technology and regulatory issues with our customers, we are helping them take advantage of real-time biometric measurement through integrations with Apple® ResearchKit™, Fitbit® and Garmin®, among others.

About Medidata

Medidata Solutions is the leading global provider of cloud-based solutions for clinical research in life sciences, transforming clinical development through its advanced applications and intelligent data analytics. The Medidata Clinical Cloud® brings new levels of productivity and quality to the clinical testing of promising medical treatments, from study design and planning through execution, management and reporting. We are committed to advancing the competitive and scientific goals of global customers, which include over 90% of the top 25 global pharmaceutical companies; innovative biotech, diagnostic and device firms; leading academic medical centers; and contract research organizations.

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