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The Rise of Integrated Data in Medical Devices

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Introduction

The generation and analysis of massive amounts of data have completely transformed several industries, and this trend will likely continue, revolutionizing almost every facet of the economy. Indeed, a recent analysis concluded that roughly 50% of the S&P 500 will be replaced over the next 10 years, which are "shaping up to be the most potentially turbulent in modern history" (Anthony, 2016). This analysis also showed that over the past 6 years, at least several companies that are heavily reliant on big data analytics entered the S&P 500 (e.g. Facebook, Netflix, and Trip Advisor) (Anthony, 2016). This revolution has largely been driven by ever-increasing computing power at less cost (as per Moore's Law), coupled with precipitous drops in data storage costs. Additionally, there has been a dramatic uptick in consumer-generated data, and the rise of the platform economy which is broadly characterized by services that act as an intermediary to bring together groups of users to facilitate economic or social exchange (Simon, 2013; Evans, 2016).

The prevalence of large datasets (i.e. *big data*) is providing a resurgence for the field of statistics. While much of the analyses being used today were discovered in the beginning to the middle of the 20th century, over the last decade, innovative artificial intelligence processes have emerged that are superior to the traditional statistical approaches. These advanced techniques are increasingly being used for data integration purposes, whereby heterogeneous data can be acquired, combined and incorporated into a structure that allows different data types. For instance, in the clinical trial industry, this approach can allow for traditional clinical trial data, electronic health records, imaging data, sensor data, and patient-provided data to be merged and utilized for a variety of purposes. We have only scratched the surface in terms of the impact that integrated data analyses will have for commercial purposes.

Google is one of the pioneers in leveraging integrated data to gain new commercial insights. For instance, Google's Nest is a product that is transforming the home heating and cooling market. Nest collects and aggregates sensor data to automate thermostat changes, with the goal of saving the end user money by optimizing these processes. On a larger scale, by comparing thermostat data from all users, Google has gained insights into energy use consumption across communities and cities that are not possible with manual thermostats, and these data may be valuable to governments or other companies.

In addition to Nest, there are a multitude of examples where integrated data has been successfully used to create a new product or monetize opportunities that would not have otherwise been possible. It is undisputed that integrated data, when used effectively, can offer insights that were not available in the recent past. However, the potential of integrated data can only be realized by having the proper infrastructure in place. The huge volume of information demands an infrastructure that can assure that the data are reliable and not siloed. In our experience, small- to mid-sized medical device companies are often overwhelmed by the volume and types of generated as part of their development and post-marketing programs because they fail to have the adequate infrastructure to enable the following effectively:

- ☑ Acquisition of data
- ☑ Extraction and cleaning of data
- ☑ Aggregation and integration of data
- ☑ Modeling, analysis, and interpretation of data

Utilizing big data in an efficient and meaningful manner requires up-front planning and investment. Once the appropriate infrastructure has been established, the struggles of dealing with huge volumes of information are minimized, and manufacturers can focus their efforts on bringing life-changing medical devices to market.

Current State Of The Medical Device Industry

The U.S. medical device industry has been estimated to be worth more than $140 billion, accounting for approximately 45% of the global market, which is valued at roughly $274 billion and expected to grow by an annual average of 4.6% (Lucintel, 2016). While the outlook for the medical device industry is certainly positive, the industry faces several well-documented challenges:

- **Pricing pressures and margin erosion.** Medical device markets are forecasted to grow, but unit prices are expected to erode, and operating margins are projected to continue declining (see Figure 1).

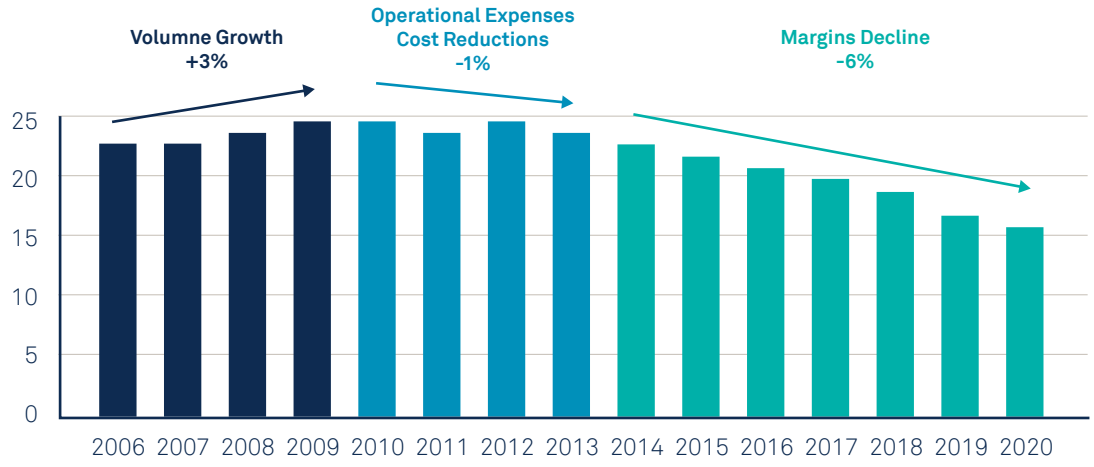

Figure 1: Medical device industry margins (% of sales, 2006 – 2020) (Redrawn from A.T. Kearney, 2014).

- **Dynamic and unpredictable regulatory path.** The medical device industry is heavily regulated, and the regulatory environment is dynamic and can change with emerging recalls and other unanticipated issues.
- **Product commoditization.** Differentiating medical device products in a competitive market is critical for minimizing commoditization, especially when supply chain purchasers view innovative medical devices as commodities and competitors from less developed markets can offer medical devices that are perceived as "good enough" for less cost. Substantiation of marketing claims using integrated data-driven approaches is one way to reduce medical device commoditization by focusing on clinical value in discussions with payers and providers.

These challenges are exacerbated when firms seek to integrate siloed and disparate datasets. It has been reported that more than 70% of healthcare-related data streams are from external sources (e.g., electronic health records for outcomes, electronic data capture [EDC] systems, healthcare providers, sensors, patient engagement solutions). Consequently, it is imperative that the appropriate infrastructure be established to utilize these data individually and in combination with internal data (Chen, 2015). Transitioning to an established cloud-based infrastructure can be an important first step. These types of systems foster increased access to the data, reduce costs (i.e., better hardware utilization and lower labor cost, among others), and enhance acquisition, integration, analysis, and reporting efficiencies. An important part of this effort is to manage and integrate datasets, which can be daunting and resource intensive for life sciences companies without a dedicated team of data scientists.

Beyond the pain points, there exist tremendous opportunities to establish new processes and a technical foundation to position medical device companies for a successful future. Some of the opportunities include the following:

- ☑ Leveraging data to support medical device positioning in the market as being state of the art
- ☑ Capturing a wider variety of non-traditional clinical data derived as close to the source as possible, including electronic health records, imaging data, sensor data, and patient-provided data
- ☑ Establishing the ability to aggregate data quickly based on standards and governed data management
- ☑ Serving analytical reports and dashboards to the broad audience for analysis and collaboration

In the next section, we describe in more detail how integrated data impact some of the challenges facing the medical device industry.

Integrated Data And The Impact On Industry Pain Points

In this section, we discuss how integrated data impact 1) product innovation, 2) regulatory pathways, and 3) access to data for commercialization.

Product Innovation

Integrated data can aid in product innovation by connecting and analyzing data in a manner that is superior to human analysis. This is made possible by collecting longitudinal data from disparate sources, which can be utilized to feed the product innovation engine. Digital biomarkers represent a stream of consumer-generated data from sensors embedded in a variety of devices, including wearables, implantables, and smartphones. While these digital biomarker data are key to supporting evidence-based outcomes (i.e., they allow for tracking efficacy and/or safety, monitoring and/or improving patient compliance, and monitoring clinical outcomes) (Wang, 2016), digital biomarkers can also provide novel insights into real-world use. When real-world use data are integrated with rigorous clinical trial data, breakthroughs can be achieved by gaining rare insights into previously uncharted territory.

Benefits

A major promise of using an integrated data approach is that new types of data streams will become available to medical device manufacturers. Examples of some of the available data streams are provided below:

Sensor data in clinical trials. As of August 2017, there were 69 active studies (not recruiting) listed in clinicaltrials.gov when the keyword "sensor" was searched. When searching all studies (completed, active, and recruiting) with this same keyword, 1,452 studies were identified (this is likely an underestimate of the true number of studies). The point to be emphasized is that sensors are being incorporated into wearables or implanted devices to remotely collect data to support safety and/or efficacy, as well as allowing for more frequent data collection, which can provide insights as to how to differentiate medical devices from competitors. Additionally, sensors may also help reduce the number of on-site clinical visits and clinical assessments during a clinical trial, reducing clinical trial cost and participant burden. As longitudinal data from sensors continue to be acquired, integrated, and analyzed, the full potential of these data to facilitate product innovation is seemingly limitless.

Clinical data monitoring. Clinical data monitoring devices can provide data about device performance, malfunctions, and patient alarm systems. For instance, it has been more than a decade since knee implants had the capability to measure twisting and bending as well as compressive and shearing loads. This has improved patient outcomes since surgeons have been able to make evidence-based decisions on implant position, for example (DesignNews, 2007). More recently, smart dressings have been shown to understand the wound state and suggest corrective action without having to be removed. This is expected to reduce the costs of wound care significantly (Tyndall National Institute, 2015). When the use of smart dressings is widespread, an effective integrated data strategy may provide novel insights about the healing process of different wounds as well as other important wound healing data that can foster additional product innovations.

Payer data to evaluate devices. Analysis of claims data has been suggested to provide a quicker and more accurate way to evaluate some categories of medical devices. For instance, Ibrahim et al. (2017) conducted a gastric band claims data study to evaluate the effectiveness of these devices. Briefly, using claims from the National Inpatient Sample estimate, it was determined that a total of 216,781 gastric band procedures were performed in the U.S. between 2006 and 2014. Investigators found that of the $2.1 billion spent on the gastric band during this period, $820 million was spent on operations to revise or remove the device. According to the authors, these data suggest that payers should reconsider

their coverage of the gastric band device (Ibrahim, 2017). Effective analysis of claims data can provide early detection of signals that can help minimize risk and better understand how existing products may need to be modified.

Devices that communicate with other devices and/or applications. Devices that communicate with other devices and/or applications provide an additional level of complexity relating to data acquisition and integration, but the payoff can be worth the effort. For instance, Medtronic markets the MiniMed Connect, which offers diabetics mobile access to their insulin pump and continuous glucose monitoring data (Medtronic, 2015). A recent study found that more than seven million patients are using remote monitoring, and the use of remote monitoring is expected to continue to expand, and opportunities abound for innovations, including general platforms that can be adapted to a wide variety of cases specific to therapeutic areas (mHealth Intelligence, 2017).

Challenges

There are several challenges when it comes to effectively leveraging integrated data to foster product innovation.

Integrated data are largely unstructured. Most data are unstructured, which means it must be converted into structured data (a very resource-intensive process) prior to aggregation, integration, and analysis. A commonly cited estimate is that 80% of company data are unstructured (Simon, 2013), and incomplete and inaccurate data is the number one data challenge for the life science industry, with 74% of surveyed companies encountering this issue (Reltio, 2015). Advances in statistical processes hold great promise to help clean and/or analyze unstructured data, but until these tools are more reliable, much of this work must be performed manually to some degree.

Combining multiple datasets. Integrating data from disparate datasets can provide novel insights. Managing data from different platforms and data streams can be overwhelming, extremely resource intensive, and costly. Errors and oversights can cause frustration, loss of valuable data, and even compliance issues. Even with available merging techniques, such as the Levenshtein algorithm,[1] there are often arbitrary decisions that exclude significant amounts of data due to the inherent difficulties in merging the datasets.

Data ownership and privacy issues. Major concerns have been raised over privacy, confidentiality, and control of patients' data once it is acquired. In general, individuals are increasingly concerned about data breaches, the implications of data analytics, and transparency over the control of data ownership (Kostkova, 2016). Furthermore, when it comes to acquisition of data from a variety of sources, there are additional vulnerabilities regarding data privacy since the data are often accessed and utilized by a multitude of data scientists, often via vulnerable open-source technologies. Overall, these risks must be managed at the level of the medical device company.

Solution

A central cloud-based data center for collection, aggregation, and analysis reduces complexities related to the challenges described in the previous section. Utilizing existing infrastructures and programs can circumvent the need to develop an entire program around the acquisition, aggregation, integration, and analysis of data. Prior to initiating data collection, careful consideration should be given to the infrastructure of the data center and how the data will be acquired, cleaned, aggregated, and integrated.

The frustration that comes from working with data from different platforms and sources can be alleviated through regulated content management (RCM). RCM is an integrated end-to-end system that delivers the required processes and ensures traceability, availability, high integrity, and confidentiality. The cloud-based data center provides enhanced privacy and security measures that are not otherwise offered by the traditional open-source platforms. Data security is particularly important in the medical device industry, since the potential consequences associated with misuse of data can be severe.

Regulatory Pathways

With rapid innovation in medical devices, it is essential that regulatory innovation follows. The FDA and other global regulatory agencies recognize the need for regulations to evolve and adapt, and these agencies are continually implementing new models to generate evidence and strengthen product quality while safely improving patient outcomes.

Benefits

Integrated data can help drive and clarify regulations that facilitate and foster innovation, in addition to rendering more precise categorizations of medical devices, decision support systems, and consumer devices.

Below are several regulatory initiatives that benefit from insights offered by integrated data:

National Evaluation System for Health Technology (NEST). The broad aim of this FDA initiative is to uncover novel approaches to harness the power of integrated data. NEST is in a mature state of development and coordinated by the Duke-Robert J. Margolis, MD, Center for Health Policy. NEST is a collaborative evaluation system that will link and synthesize data from different sources across the medical device landscape, including clinical registries, electronic health records, and medical billing claims. The FDA will provide funding grants to support the development and implementation of NEST, issue guidance to clarify how real-world evidence may be used to support pre- and post-market regulatory decisions, increase access to and use of real-world evidence to support regulatory decisions, and work closely with manufacturers, payers, patients, and healthcare systems to build NEST (FDA, 2017a).

Case for Quality. This FDA initiative seeks to address the gap between compliance and quality by shifting focus from meeting the minimum requirements to quality throughout the life cycle of a device. In short, the FDA recognized that compliance with FDA regulations does not always mean that a device will be high quality. What does this mean for the industry? The FDA's Center for Devices and Radiological Health (CDRH) will implement new metrics for evaluating the quality of a device and how the device is monitored and controlled. This may also include an additional burden on companies to focus on new, innovative post-market surveillance activities and accessing more data across disparate streams and sources. Providing higher-quality devices to the marketplace should, in theory, reduce the number of adverse events and product recalls. This may result in a higher return on investment, increased consumer confidence, and superior patient outcomes (FDA, 2017b).

European regulations. New regulations in the European Union (E.U.) would consolidate authority for medical device review and approval while adding additional requirements for post-marketing analysis and reporting. Indeed, as mentioned later, two new E.U. regulations were passed in April 2017. Overall, the E.U. is moving toward greater rigor on safety and protection of products, and to do this adequately, it is adapting to the significant technological and scientific progress that fuels the medical device sector. This may provide opportunities for manufacturers and other stakeholders to collaborate with the regulatory authorities to enable new regulatory processes.

Challenges

Adhering to evolving regulatory requirements. The dynamic and unpredictable nature of regulations means that manufacturers must stay abreast of the latest regulatory initiatives. This can be difficult for small to medium companies that do not have a dedicated regulatory staff. For instance, a recent U.S. congressional investigation on safety monitoring of medical devices identified several shortcomings in the current post-marketing scenario (Murray, 2016). Following this investigation, the Medical Device Safety Monitoring Act[2] was introduced in the U.S. Senate in early 2017; if it becomes law, this could require new Unique Device Identifiers (UDIs), among other requirements. Furthermore, the European Parliament adopted two new regulations in April 2017 that were aimed at modernizing the previous legislation. The new rules will apply three years after publication for medical devices and five years after publication for vitro diagnostics.[3]

Development of an integrated data plan at the outset can help efficiently address additional clinical study and post-marketing requirements. These data can also help support the quality of devices, which is an evolving area under increased scrutiny by the regulatory agencies.

Changing definition of device equivalence. Stricter E.U. requirements regarding device equivalence mean that companies will no longer be able to claim equivalence to products manufactured by other companies. The revised MEDDEV 2.7.1/Rev 4 and the new E.U. Medical Device Regulation (MDR) require clinical evaluation and post-market clinical follow-up for assessment of product safety and performance commensurate with product risk. Manufacturers will have to generate more clinical data for their specific products while facing an increased burden regarding post-market surveillance data. There will be no grandfathering provisions, so all marketed products will need to recertify to the new standards, including increased safety and performance reporting requirements on an annual basis.

Solution

Novel data streams obtained from sensors and other external sources can provide a valuable trove of data. However, it is important that the data are clean, and easily accessible. This will allow for efficient integration, analysis, and reporting that can help meet evolving regulatory requirements. As noted previously, sensors have been incorporated into more than 1,400 clinical trials listed on clinicaltrials.gov, and this trend is expected to continue to rise. Building a quality data program up front and having the capacity to efficiently analyze data intermittently is key to minimizing risk early in clinical trials. Furthermore, this demonstrates to regulators that quality is being ensured proactively rather than as an afterthought and that quality activities can be linked to post-market surveillance, post-market clinical follow-up (PMCF), and clinical evaluation reporting (CER). The FDA's NEST initiative is also intended to increase the use of real-world data as an alternative to randomized clinical trials (RCTs). Again, a carefully prepared data plan prior to initiating data acquisition can potentially facilitate analysis of real-world data by considering what needs to be measured and what actions will be taken from the data.

Access To Data For Commercialization

Integrated data can foster commercialization of medical devices by providing empirical data to support value-based claims, as well as increasing efficiencies related to post-marketing activities and potentially driving new models for product adoption and reimbursement. While there exist some challenges in using integrated data to maximize commercialization opportunities, these challenges can be managed with some upfront planning.

Benefits

Integrated data can be leveraged for commercialization purposes in two ways: 1) minimizing commoditization, 2) improving post-marketing surveillance and global market access, and 3) new models for product adoption and payment.

Minimizing commoditization. As indicated earlier in this paper, medical device commoditization is a main pain point for the industry. While current market trends suggest that price is increasingly becoming a competitive differentiator, integrated data have the potential to substantiate value-based claims for devices and empirically demonstrate product superiority (Greener, 2016). A study of healthcare buyers in the U.S., U.K., Germany, and Spain showed that 77% considered price to be the top factor for purchasing decisions (MPO, 2014). However, it was also noted that healthcare reform initiatives, such as value-based purchasing and pay-for-performance, are expected to surge, and so purchasers will be less influenced by cost reductions alone (MPO, 2014).

In the medical device environment, there are increasingly strict regulations and guidelines on claims that can be made regarding product benefits. Explicitly or implicitly making claims beyond the approved language can be devastating to a product and company. Increasingly, clinical trials are collecting data from a wider variety of sources that present unique opportunities to supplement the effectiveness of a clinical study. For instance, medical images, X-rays, CT scans, and MRIs offer greater insights into the overall patient profile, but they are often stored and managed separately from systems capturing traditional clinical data.

Improving post-market surveillance and global market access. Efficient access to clean data can aid with post-market surveillance and market access activities on an ongoing and global scale. This contrasts with siloed data for different countries, which can be an enormous burden when it comes to meeting requirements mandated by different countries and regulatory agencies. EDC is an example of a process that can streamline data acquisition and reporting, ultimately improving post-market surveillance and global market access.

New models for product adoption and payment. An optimal integrated data strategy can help negotiate new models for product adoption and payment. A recent example highlights this opportunity. Medtronic's Tyrx™ products are implantable antibacterial medical devices designed to encapsulate cardiac and neurostimulatory devices. Replacing heart devices that have become infected is estimated to add more than $1 billion per year in expenses to the U.S. healthcare system. Based on positive data from several studies using the Tyrx™ envelope (e.g., Henrikson, 2017), Medtronic has signed "risk sharing" agreements with healthcare providers in which the company will pay a substantial rebate toward the $50,000 cost of removing an infected Medtronic device and implanting a new one if a Tyrx™ envelope was used in the original surgery (Parmar, 2017).[4]

Challenges

While an integrated data approach can certainly facilitate access to data to enable commercialization, there are challenges that need to be overcome:

Different reporting standards. Different countries and regulatory agencies have different regulatory reporting standards. Access to clean, integrated data that can be easily analyzed and reported is a solid first step in easing the burden of meeting the many different reporting standards that exist globally.

Massive amounts of data from post-market surveillance. Failure to adhere to best practices in acquiring and storing huge volumes of global post-market surveillance data can quickly overwhelm companies and data centers. Furthermore, there are costs associated with managing the surveillance activities and data, and without an up-front plan, these costs can balloon and quickly become unmanageable.

Going beyond traditional in-clinic data. As clinical trials continue to increase the types of data that go beyond traditional in-clinic data, such as medical images, X-rays, CT scans, and MRIs, a strategy is necessary to store, manage, and integrate these data with the traditional clinical data. These integrated data can offer insights that can supplement the effectiveness of a clinical study.

Solution

Leveraging a unified platform enables data to be readily accessible across different systems. This reduces the resources required in a normally very resource-intensive activity. Deriving knowledge and insights from sensor data can help minimize the eroding effects of commoditization and improve post-market surveillance activities and market access on a global scale. In addition to enabling easier data configuration for different country reporting requirements, surveillance data can also provide valuable insights that so manufacturers can adjust their technology for optimal performance over longer periods. Medidata RaveX[5] represents an example of an integrated solution that allows for easy access to verified data that can be reported as required.

Clinical Study Technology

The creation and availability of many more data points in clinical trials enables novel insights that were not possible even a few years ago. Historically, clinical trial data arose from a single source: a patient visiting a clinic, whose information would be entered into an EDC system. Clinical trials are now accommodating more diverse sources of data, including high-resolution images, genomics, sensor data, investigator files, and consent forms. A powerful way to aggregate data acquired from different sources is an EDC system. The most advanced EDCs in clinical development have evolved beyond simply capturing traditional in-clinic data to incorporating data from multiple sources while simultaneously cleaning, standardizing, and verifying it.

Today, the most advanced clinical development technology providers offer data discovery and data science capabilities as a service. These capabilities can reduce the future development burden on clinical development companies and the technology organizations that support them. Data discovery tools such as dashboards and benchmarks provide ease, agility, and flexibility in data analysis to a wide range of stakeholders, including those who do not have specialized skills in data science or statistical modeling. In clinical trials, data discovery is very important, as it allows users to identify the relevant data to support decision-making around a specific use case, such as patient engagement, site feasibility, or site monitoring. Furthermore, ensuring cross-study reporting and ad hoc reports that target specific study parameters can enable a multitude of small study adjustments, with a large impact on feasibility or performance. Data science and the analytical capabilities it can support offer several opportunities to transform clinical development. These include advancements in site selection, risk-based monitoring, and even synthetic control arms for certain studies. More importantly, the extent to which data science can enhance clinical trials is directly proportional to the robustness of the dataset. Leveraging these capabilities can help power the clinical trials of the future, including intelligent risk-based monitoring and adaptive trials.

Use Case: Enhancing Late Phase Clinical Development

Different uses of clinical study technologies can help unlock the value of data and content in late phase clinical development. Utilizing an intelligent, integrated, and intuitive platform can help sponsors maximize the chance of success of their clinical program. The first step to using these technologies to facilitate late phase development is to have a clear understanding how data can inform each step of the process. In this Use Case, we provide a high-level overview of how data can inform some of the key steps of late phase clinical development.

Beginning with the study plan, sponsors can leverage vast repositories of past study protocols to help optimize logistics during operational planning stages. Additionally, utilizing a study design optimizer can help strike the right balance between protocol vs. operational efficiency.

Clinical study technologies can also aid in better site planning, monitoring and operations to help achieve maximal site engagement during the study. This can help enhance transparency into patient data and enable access to real-time insights into site performance. These insights can help with early error detection and mitigate the risk of delays and study failure. Further, human effort associated with global late phase trials can be minimized by efficient risk-based monitoring strategies that rely upon integrated data and analytics.

Improved patient recruitment and retention is another key benefit. Using eConsent capabilities, easy to use questionnaires across many local languages, and email alerts to remind patients to take assessments or complete questionnaires can have a significant positive impact on recruiting and retaining your study population.

Efficient operation of late phase clinical studies requires an integrated, flexible, and multi-language platform. Utilizing a configurable randomization and clinical trial supply management solution can accelerate late phase clinical trial execution through logistics efficiency. Continual refinements to existing platforms are further enabling these technologies to unify clinical, operational, financial, and regulated content. Applying data and analytics can improve operational efficiency while minimizing cost, reducing human effort, and maintaining data quality. Machine learning and outlier detection techniques can help improve quality across clinical data, and operational performance analytics can help optimize site selection and identify systematic inefficiencies.

Overall, vast volumes of clinical data bring new and transformative opportunities in facilitating product innovation, regulatory pathways, and commercialization. While there are challenges that must be considered and addressed, consultation with an experienced provider can help save time, money, and resources and allow manufacturers to bring new medical devices to market both safely and efficiently.

Conclusion

The creation and analysis of vast amounts of data is will continue to transform many industries over the coming years. Major opportunities exist for those businesses that can efficiently integrate data from disparate sources to gain insights that are not possible from siloed data. Like many other industries, the medical device industry is facing some specific challenges, but having a solid integrated data plan at the outset of a development program can help alleviate some of these pain points by enabling innovation, guiding regulatory pathways, and maximizing commercialization opportunities.

By engaging in early discussions with experienced partners or collaborators, it is possible to leverage the new opportunities that an integrated data approach offers and enhance the success of a medical device program.

About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,400 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

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