

Five lessons from biopharmaceutical trials for MedTech companies

How to use a wider range of data, in more creative and flexible ways, to cut costs and speed time to market.

Demand for medical devices is rising, driven by an aging population, the increased prevalence of chronic diseases, and the ability of robotic assisted, connected devices to perform minimally invasive procedures that speed recovery and reduce discomfort. The global medical device market is expected to grow to approximately \$799.6 billion in 2030, growing at a CAGR of 5.9% from 2023 to 2030.¹ But MedTech manufacturers are struggling with declining discretionary healthcare spending that limits their revenue, as well as supply chain disruptions that snarl production and the need to meet increasingly complex regulations.

To address these pressures, MedTech manufacturers must reprioritize their product portfolios and reduce costs wherever possible. Conducting clinical trials more quickly and efficiently is among the critical pieces of that puzzle. It's also an area where MedTech can look to the biopharmaceutical industry for inspiration.

Biopharma and medical device trials may vary in complexity, length, and sample size along with endpoints. Their regulatory paths may be different as well. And while biopharma trials focus on clinical outcomes such as disease progression, survival rate, symptom improvement and more, medical device trials assess endpoints related to technical performance and functional outcomes.

Despite these differences, there are still lessons to be learned from biopharma when it comes to the more efficient collection and use of data to speed insights into the safety and efficacy of products. In our work with clients across the globe, we have identified five best practices in this area that the MedTech industry can adopt from biopharmaceutical clinical trials.

1. Tap existing real-world data

One of the biggest challenges in biopharmaceutical trials is recruiting enough subjects, in part because many subjects fear they will be assigned a placebo rather than the treatment being studied. Biopharmaceutical providers are tackling this challenge with the use of synthetic control arms.

This strategy incorporates existing real-world data (RWD) from sources such as electronic health records, disease registries and medical claims to model the outcomes for a control group that would otherwise have received a placebo. The same data points, such as changes in symptoms or biomarkers, are collected for both the synthetic arm and the experimental device arm. Utilizing both allows valid comparisons without administering a placebo to some subjects.

MedTech can address challenges of comparison group creation for conventional control arms and can reduce sample size during clinical trials by using the historical information from RWD to simulate the outcome of the control groups.

Successful use of such synthetic control arms, however, requires excellent data management skills to ensure the quality of, or to correct issues with, patient data gathered from multiple RWD sources so it can meet regulatory standards.

2. Leverage observational studies

Observational studies of devices once they are approved can further test their safety and effectiveness and identify additional issues that may have been missed in premarket clinical trials. These studies play a pivotal role in biopharma to detect any rare or long-term adverse effect that may have been missed in pre-approval clinical trials. They can also be used to compare different treatment options and identify potential safety signals or unexpected adverse events. The insights gained can enhance patient care, help with informed regulatory decisions and guide healthcare practices.

3. Expand your range of data

Biopharmaceutical companies are increasingly using biomarkers (medical signals such as blood pressure, heart rate or input from wearable medical sensors) to both identify potential trial subjects and the effect of a MedTech device on their condition.

Medical devices can use biomarkers for patient selection by selecting participants who have specific disease characteristics that align with the intended use of the device. They can also be used to establish a baseline assessment of the patient's conditions before usage of the medical device as a point of reference.

Biomarkers also assist with safety evaluation. For example, changes in biomarker levels can indicate safety concerns. They can also be used in efficacy assessment to indicate the effectiveness of the medical device by analyzing biomarker data. Finally, they can be used for long-term monitoring to evaluate the device's durability, stability and continued impact on the patient's health. By making more data available more quickly, the use of such biomarkers can reduce the cost and time required for such trials.

4. Use the right technology platform

In the past few years, numerous biotechnology firms have employed technology based on genetic information to create "biomolecular platforms." These platforms intervene in distinct steps of the data cycle to alter the biomolecular actions associated with various diseases. Next, researchers identify a spectrum of illnesses within multiple therapeutic fields or linked clusters of basic science that could be treated with the method and prioritize it for drug design and advancement.

Biomolecular platforms can be used in MedTech for patient stratification based on biomarkers, safety assessment, efficacy evaluation and, in some cases where medical devices may release drugs, pharmacokinetic analysis. The use of such platforms may vary depending on the nature of the devices and their respective intended use. This along with the efficient use of proper data, document and process management platforms can not only reduce the cost and time required for the trial process but improve the efficiency and quality of the product itself.

Improved access to data about a device's reliability, safety and efficacy, as well as about issues providers or patients faced using it, can be fed back into the design and manufacturing processes for continual improvement.

Use of the proper document management platforms can ease the process of generating and categorizing the records required to meet regulatory requirements, and to more easily share feedback with design and manufacturing staff.

5. Build in flexibility

To increase flexibility, biopharma has increasingly implemented adaptive designs for clinical trials, utilizing collected information to make predetermined modifications to the trial. Adaptive designs are frequently more cost-effective, productive and ethical than fixed designs as they maximize the use of resources like money and time while decreasing the need for participants.

The need for flexibility in medical device clinical trials is greater than in biopharma, as medical devices often undergo iterative development and may require adjustment or modification during the trial process. The patients in medical device trials are often from a broader range of the patient population, and additionally may face device-specific challenges such as variation in device implantation techniques.

All this increases the possibility that the trial endpoints may change. Adaptive clinical trials allow for flexibility in the design of the study, the sample size and other variables during the study. Drawing even preliminary conclusions from interim analysis of trial results allows for early correction of errors and redesign of the device to increase retention rates for the study and/or subject adherence to its protocols.

The digital future

The increasing digitization of healthcare and advances in medical technology will provide even more opportunities to adopt biopharmaceutical technologies for MedTech trials. These include advanced imaging techniques, advanced analytical techniques, cell and gene tracking, advanced modeling and simulation, and advanced health delivery systems.

Careful adoption of best practices from biopharmaceutical clinical trials, along with an increased emphasis on rigorous data management, can help medical technology providers meet strict regulatory standards and bring new devices to market most cost-effectively.

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