Consensus Statement Paper

Data-Driven Medtech Development in Surgery
Panel Discussion in Munich, GER

caresyntax®

Medtech market landscape challenges and opportunities

Surgery ranks as the second largest healthcare spending after pharma in terms of therapy. Spending for surgery accounts for approximately $1.7 billion annually between the US (United States) and Europe. It is a major factor in hospital revenues with approximately one-third going to the supply chain. Medtech—medical device, robotics, software, and technology companies—represents almost $500 billion per year top line for these groups. Medtech vendors are constantly working toward developing novel solutions to improve care, efficiency, improve total cost of care, and on supporting existing solutions to make sure they are compliant, adopted well, and delivering the results. It takes significant time and effort to bring innovation to market.

Regulatory pathway

Bringing medical innovations to market is both complex and time consuming. This journey reflects a broader industry pattern of extended research and development timelines and the many hurdles companies face.

The challenges include:

- Limited access to comprehensive medtech data sets and high-fidelity data across various therapeutic areas, a stark contrast to the data-rich environments of the Pharmaceutical and Biotechnology industries.
- The medtech sector's utilization of real-world evidence as a cornerstone for value-based care is in its preliminary stages, particularly when considering the traditional reliance on randomized clinical trials. Such evidence is crucial for demonstrating the efficacy and safety of new medical technologies and for navigating the intricate regulatory pathways that ensure patient safety and product reliability.
- The regulatory landscape presents both challenges and opportunities, with the potential for expedited device approvals if there is sufficient clinical validation and adherence to rigorous regulatory standards. This environment could serve as a template for how regulatory pathways can become more agile and can facilitate innovation while maintaining stringent safety standards.

Importance of Real-World Data and Evidence

Real-world data (RWD) and real-world evidence (RWE) have emerged as crucial pillars in driving advancements in surgery and medtech. The reliance on traditional clinical trial data alone is no longer sufficient to meet the demands of a rapidly evolving healthcare landscape. Data-driven AI-enabled surgical intelligence platform eliminates silos and enables RWD and RWE. RWD, gathered by a vendor neutral surgical intelligence platform provides a comprehensive understanding of patient outcomes and treatment effectiveness in real-world settings.

Obtaining relevant data points can improve adoption of medtech innovation by highlighting increased clinical effectiveness, perioperative efficiency, and reducing the total cost of care. This shift towards a more holistic data-driven approach—including patient reported outcomes— is instrumental in expediting the development and validation of innovative medical technologies.

Pre-market regulatory

Clinical trials can use RWE to supplement and influence regulatory filings (FDA (Food and Drug Administration), MDR (Medical Device Regulation), etc.). It can also be used to supplement randomized clinical trial data.

Post-market surveillance

Post-market surveillance enables quality management by leveraging RWE to document ongoing efficiency and effectiveness. RWE can be used to identify leading indicators of adverse events.

Importance of Real-World Data and Evidence

Expanding RWD datasets enables data-driven innovation by collecting data from various sources:

- Patient reported outcomes
- Clinical data collection
- Video-based assessment
- Telepresence and remote monitoring
- Analytics and benchmarking

This data spans the entire surgical care continuum pre-, intra-, and post-operative. The data can then be used to identify trends, assess clinical effectiveness, increase quality and safety, inform the next generation of product development, and support commercial product launches.

Surgical Ecosystem and Strategic Partnerships

Developing a comprehensive ecosystem that encapsulates a strategic partnership network is essential. This includes collaboration with government entities, healthcare providers, research organizations, universities, medtech companies, AI (Artificial Intelligence) innovators, and investors. Central to this ecosystem is the facilitation of partnerships that drive surgical innovation and the identification of surgical use cases and priorities, alongside establishing key performance indicators (KPIs).

Caresyntax's Role

Caresyntax is set to play a transformative role in the use of medtech data driven surgical care. By harnessing the power of RWD and RWE, Caresyntax will be instrumental in driving medtech innovation and accelerating the development and market adoption of innovative technologies.

Through the deployment of Caresyntax's platform and its partners' solutions within operating rooms, there will be an unprecedented opportunity to improve clinical proficiency, patient safety, and the economics of surgery. The ability to capture structured, clinically curated data sets will not only optimize surgical procedures but will also be invaluable to medtech Device Manufacturers who currently face challenges in obtaining such data.

Differentiated Data

Differentiated data sets offer both contextual and longitudinal insights that can be speciality and procedure specific. Capturing real-world use offers access to unique data that drives real, actionable insights.

Lower Regulatory Hurdles

A faster, cheaper process for capturing the data that leads to more value can decrease development and clinical costs and limit institutional review board time and cost.

Speed to Action

Data-driven medtech development delivers faster results than can be quickly implemented with data delivery in months, not years. It creates outputs that are ready for immediate commercial application and use.

The integration of this type of surgical intelligence into the healthcare ecosystem, supported by innovative regulatory initiatives, will facilitate well-governed surgical data flows that are essential for medtech product life cycles. This will enhance medtech companies' ability to conduct clinical trials and launch innovative technologies, contributing to a thriving research environment and attracting top-tier clinical talent.

Conclusion

The utilization of real-world data and evidence streamlines the development process of medtech innovations, fostering a faster and more efficient pathway from concept to market. This approach enables researchers, developers, and regulatory bodies to gain insights into the performance and safety of medical technologies in diverse patient populations and real-world scenarios. By harnessing the power of RWD and RWE, the medtech sector can overcome traditional barriers, ultimately reducing time-to-market, and enhancing the overall agility of the industry.

The value of a data-driven approach in medtech extends beyond stakeholders to patients, ensuring personalized and evidence-based treatments that enhance overall care outcomes, fostering a patient-centric healthcare paradigm.

As the medtech industry navigates through challenges and capitalizes on opportunities, the commitment to a data-driven approach emerges as a cornerstone for progress. By leveraging the transformative potential of data, stakeholders can collectively contribute to advancing surgical -outcomes, driving innovation, and optimizing the vast investment in the medtech sector.

- **Prof Alexander Kaltenborn, MD, MHBA** Hannover Medical School, CEO and Founder, KAMIQ Institute (moderator)
- **Prof. Hanno Matthaei, MD** University Hospital Bonn
- **Detlef Loppow, MD** and CEO Martini-Klinik Hamburg
- **Prof. Nasir Navab, MD,** Director of the Laboratory for Computer Aided Medical Procedures, Technical University of Munich, and Johns Hopkins University
- **Bruce Ramshaw, MD,** CMIO (Chief Medical Informatics Officer) Caresyntax