# Panel Discussion Report

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

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A Surgical Innovation Hub Roundtable was held in Munich, Germany to facilitate a discussion with relevant healthcare ecosystem players and key opinion leaders regarding data-driven medical technology (medtech) development in surgery. The event was hosted by **Bjoern von Siemens**, Co-Founder and CFO (Chief Financial Officer) of Caresyntax, together with members of its management team.

The esteemed panel of participants included:

- **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

# Medtech market landscape challenges and opportunities

Surgery ranks as the second largest healthcare spend (behind pharmaceutical therapy). Spending for surgery accounts for approximately $1.7 billion annually between the US (United States) and Europe. Medtech —medical device, robotics, software, and technology companies—represents almost $500 billion for these groups. Medtech vendors work to develop novel solutions to improve care, efficiency, and total cost of care. It takes significant time and effort to bring innovation to market.

## Regulatory pathway challenges

Bringing medical innovations to market is both complex and time consuming. This journey, ranging on average three to eight years for Class II or III devices reflects a broader industry pattern of extended research and development (R&D) timelines and multifaceted hurdles.

# Real-World Data and Evidence

## Access to quality, real-world data

The panel discussed the importance of real-world data (RWD) and real-world evidence (RWE) in surgery and medtech and the relevance of both to advance medtech innovations in a faster and more efficient manner. This represents a tremendous opportunity for improvement, given that medtech companies do not have systematic access to excellent quality real-world evidence. Data is needed, not only for scientific reasons, but to prove that you have treated your patients in the best manner possible. Data is also needed for medtech insights and innovation.

"The current state of surgery (and innovation) is basically the same as it was conducted 50, even 100 years ago--basically human-led study design, human-led data collection, human-led understanding of context, and so on," said Dr. Kaltenborn.

"We have an ambition to automate data collection in a way that creates massive value for medical device companies' product development. If you want to understand how to make a new product or to improve your product, it is very valuable to see how it is used [in the real world]: to see performance data, data beyond the initial clinical trials, data for quality management, and beyond the regulatory pathway," said Bjoern von Siemens, Co-Founder and CFO (Chief Financial Officer) of Caresyntax.

## Medtech innovation and development: covering all stakeholders

In general, the panel aligned on 5 primary stakeholders that must be addressed in order to drive meaningful adoption and uptake of any new medical devices:

1. the patient;
2. the users of the device (the surgeon and/or support staff);
3. the hospital that purchases the device;
4. the medtech company; and last but not least,
5. the overall health system.

Medtech innovation could leverage RWE and RWD data to increase adoption, ensure market segmentation/patient selection, and ensure that all stakeholder (surgeons, surgical team, hospital system) needs are met.

## Benefits of collecting RWD for the healthcare system

Providers and surgeons benefit in multiple ways by collecting robust RWD and RWE. Hospitals can improve quality, margins, and overall revenue from surgery. For example, the ability to reduce surgical site infection (SSI) could lead to quicker discharge and reduce readmissions. In terms of staffing and workflow efficiency, data can be used to optimize operating room throughput, improve clinical decision support, enhance workforce management decisions, and support the long-term survival of health systems. Therapy adoption and selection could be bolstered significantly with a deep data understanding of selection criteria and risk stratification.

"The systematic collection of data around our more than 2.5 thousand surgical procedures a year allows us to deliver better service for the patient," said Dr. Loppow of Martini-Klinik.

In addition to near-term quality benefits, research and innovation can also thrive in a data-rich environment. Collecting data from multiple modalities including video and audio, in the context of the complete patient surgical episode, can drive novel discovery and data analysis for clinical research and scientific publications.

### Data collection focused on value (outcomes), not volume or averages

"The principles of data science and the benefit of using technology that offers Real World Data is that users can now use predictive algorithms to help identify subpopulations at risk, said Dr. Ramshaw. "It helps move away from a one-size-fits-all approach, and instead identifies subpopulations that can be matched to the best value treatment, diagnostic tools, or drugs to treat their unique needs."

### Collecting and aggregating data across the ecosystem is essential

There is a need to have the patient reported outcomes integrated in EMR (Electronic Medical Records) data, but the data in electronic medical records is not easily accessible because much of the data is siloed or exists in separate EMR systems . The average US hospital has 16 disparate EMR vendors in use.

Some hospital systems collect data for clinical, administrative, and research use. However, out of petabytes of data, rarely are outcomes included in that collection, but as a result, decisions and treatments are based on traditional data averages from EMRs. Therefore, it is particularly important to integrate patient-reported outcome measures in EMR data to be able to focus on the best 10 percent of outcomes and to set a goal to achieve the best 10 percent of results.

In addition, it is important for every system to determine what is necessary in terms of infrastructure in the hospital to be able to gather the data . "Medtech innovation requires cost-benefit analysis," said von Siemens, "government and the health insurers are already doing this, so we must provide the corresponding real-world data or significant economic health technological assessments to prove that the technologies we are putting into the market are giving a benefit. It is in the interest of all of us as payers of health. The evidence we need to give to new therapies is fundamental."

### Reduce barriers to entry

There is a need to reduce barriers to entry and the costs associated with it. Academic surgeons lack large budgets. Medtech companies have the budget, but most of the budget is spent on acquiring users, rather than research. Vendor neutral, data aggregation can offer a win-win solution for all parties: surgeons can get real-time decision support, which drives better outcomes to the patient, medtech companies receive the data to improve product development.

### We must maintain a long-term vision for the potential of technology to improve care

While most clinicians focus on clinical evidence to improve quality outcomes today, there is a need within the academic and innovation community to maintain long-term vision. The key factor," says Dr. Loppow, "is the long-term perspective. The DaVinci robot has not created enough compelling outcomes-based evidence yet, but it is important for the technology (and the company) to survive because in the long run, the robotic system will be autonomous, be better with evidence, and humanity will have a truly valuable product."

To achieve this long-term vision, there is a need to automate the collection of data every day throughout the entire system and surgical procedures . "Short term thinking," says Dr. Loppow, "is that you cannot afford high-end systems because it does not make our medicine better right now. What is important is to be able to judge what is good development for the healthcare system and what treatment might lead to better patient outcomes."

# Potential use cases in tech-led, data-driven healthcare

### Use case: Surgical training

A data-driven approach to medtech development for surgery includes the ability to support training and benchmarking of surgical performance. If benchmarks are available, patients can use that data to choose hospitals with better outcomes for their specific surgery. Hospitals with strong benchmark performance will benefit by increasing procedure volumes. Surgeons can use video of their procedures to learn from mistakes or to identify steps in the procedure that can be done more quickly, all in the name of continuous learning and quality improvement.

"The less experienced surgeons in our hospital really appreciate that they can see their results and that they are getting closer to the outcomes of more experienced surgeons," said Dr. Loppow. "Even for the learning curve (customary to robotic surgery approaches), it's a very good instrument to have for regular benchmarking of your surgeons in your hospital."

Currently there are millions of surgical videos recorded and saved by hospital IT systems, but they are rarely used to benchmark outcomes or performance. Video-based assessment technologies offer significant value for patient safety and efficiency. Caresyntax uses this type of data in TKA (Total Knee Arthroplasty) to drive research and clinical publications. The platform has supported hospitals across the world to add video-based assessment as a new dimension to curricula and training.

Video can also be used for clinical validation. When medtech companies deliver a new camera or gauze, for example, the video can provide clinical validation for its efficacy and serve as a prospective medtech evaluation database.

"In this digital transformation of surgery, we are now in a phase where we can collect videos in a more standardized fashion and develop various use cases for them," said Dr. Hanno Matthei. Video-based assessment can support training purposes to ensure sufficient proficiency when the newly learned procedure is performed in a real-life setting on a patient. "What we now want in surgical education is a progression-based model where operations are trained through simulation (dry lab) in advance and then the OR itself becomes the concert hall, where we must not practice any longer, but where we are ready to perform the perfect concert." VBA gives the opportunity to film within the risk-associated learning curve of first real operations after a training and then determine whether the surgeon has performed properly or requires additional training.

### Use case: Distilling complex case video

The Caresyntax platform can be used to snip crucial episodes within the video to collect smaller references for clipping, extraction, etc., that can be exported without having to save the full-length procedure video. This saves storage space for the hospital system and enables more efficient surgical training.

### Use case: Convenient reporting

The panelists highlighted a tremendous opportunity to automate and collect operational notes through technology. For some surgeries, procedures can last up to 4-5 hours. Instead of normal dictation and reporting that can take hours of post-operative time, technology could automate the entire post-op note and surgical record. This streamlines the process for the surgeon, staff, and hospital, enables consistent reports for patients, and also presents a tremendous data flow for medtech partners.

### Use case: Surgical assistant/co-pilot

The use of a chat system in surgery allows the surgeon to ask questions, understand options, and deliver optimal care, while also outputting a post-op report. This "surgical co-pilot" creates immediate clinical and time benefits, and in the long run, also provides medtech partners with tremendous insight into current pain points and needs, direct from the operating theater.

## Data-collection platforms and the need for multi-modal data

In order to gather full context about patient care, it is essential to collect data longitudinally (before, during, and after surgery), as well as vertically across multiple modalities (surgical videos, tower feeds, in-room video, EMR data, imaging records, medical devices). Furthermore, unstructured data like handwritten progress notes contain valuable information and context from each patient interaction. In the effort to drive toward meaningful data-driven decision making, players in the healthcare ecosystem must find ways to distill and collate the huge variety and volume of data across a patient interaction. Surgical Intelligence systems like the Caresyntax platform can serve as centralized data aggregators for health systems and for medtech partners alike.

Furthermore, data must be collected and used appropriately to drive quality improvement. From the long history of medical legal reform, video data is often viewed as a tool to be potentially used against clinicians and hospitals. This is most evident in the US, where tort law accounts for a heavy portion of healthcare process and activity. However, when surgical video is used for scientific, development, or quality control purposes, it should be viewed not as part of the electronic medical record but rather, as part of a scientific database. In the US, the concept of patient safety organizations (PSOs) protects organizations that collect video data for the purpose of safety and quality improvement, protecting them from legal discovery and punitive action. By reframing the healthcare culture from "blame" to "improvement," the entire system can start to view data as an ally for constant iterative evolution. In the Netherlands, it is obligatory to store videos of robotic and open surgery in the EMR.

# Conclusion

In conclusion, the convergence of real-world data, real-world evidence, and innovative platforms like Caresyntax's surgical intelligence platform signifies a paradigm shift in Data-Driven Medtech Development in Surgery. As 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 care, driving innovation, and optimizing vast investment in the broad healthcare industry.

Caresyntax is set to play a transformative role in the use of medtech data driven surgical care. By providing clinicians, support staff, hospital leaders, healthcare administrators, and medtech partners the power of RWD and RWE, Caresyntax will be instrumental in driving medtech innovation and accelerating the development and market adoption of innovative technologies.

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.

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.

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

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[i] Social determinants of health and the $1.7 billion opportunity to slash spending Healthcare IT News. 9 Oct 2017.

[ii] Why EHR data interoperability is such a mess in 3 charts. Healthcare IT News. 16 May 2018.

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caresyntax®

**caresyntax.com**

**BERLIN**
Komturstraße 18A
12099 Berlin
Tel: +49 (0)30 71302970
caresyntax@caresyntax.com

**SAN FRANCISCO**
900 Larkspur Landing, Suite 120
Larkspur, CA 94939
info@caresyntax.com

**MILWAUKEE**
1035 W Glen Oaks Lane, Suite 200
Meguon, WI 53092
Tel: +1262 478 0763
info@caresyntax.com