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SPEED DEVICE DESIGN TO BOTTOM-LINE VALUE WITH LIVE, REAL-WORLD DATA

All medical device manufacturers face the same challenge – how to speed innovation and commercialization without sacrificing quality, breaking the bank, or harming patients. Rising cost pressures; intense competition; and demands for greater value among healthcare regulators, providers and payers keep the C-suite up at night.

Data is power: manufacturers that gather actionable data early in the product lifecycle can gain a competitive edge in market adoption and payer reimbursement.

Imagine the impact of providing research and development (R&D) team members with real-time, virtual access to live procedures so they can gather end-user feedback firsthand to inform new product design. With this approach, R&D can quickly identify opportunities to build greater value into the product – and act on them.

Additionally, this access can be extended to other stakeholders to facilitate live case observation and remote proctoring for medical education teams; support peer-to-peer clinical training; connect marketing/product managers with providers; and force multiply sales team training, education, and case coverage.

THE POWER OF DATA TO DRIVE INNOVATION AND COMMERCIALIZATION

Some of the world's leading device manufacturers are leveraging digital case support that goes beyond remote connectivity. This digital-first strategy can provide product development teams with customized intraprocedural data capture and reporting, two-way communication with key opinion leaders (KOLs) and clinical end-users, and a digital playbook to define step-by-step best practice procedural workflows customized by user role.

Here's how R&D teams are utilizing digital case support at each phase of development, with commentary from Tessa Heydinger, Director of Product for Explorer, a GHX Company, who has played a central role in developing and bringing complex medical devices to market.

Defining the clinical need

At device conceptualization, the R&D team must understand the unmet clinical need it's intended to address, but in most cases, they don't have access to the clinical setting or end-users at this early stage.

"As an engineer, it's incredibly challenging to develop a device when you lack direct exposure to see how it will be used and are unable to communicate with end-users," said Heydinger. "You can get insights secondhand from medical

device sales reps, but their role is surgeon support, not product development. To ensure companies are innovating products that deliver value, interoperative information gathering and decision-making should be in the power of the people developing the devices – the R&D team."

With digital case support, R&D teams – and other medical device stakeholders such as regulatory and quality teams – can observe cases remotely without the burden of traveling, collaborate directly in real-time with surgeons, and see the patient's needs firsthand.

Designing workflows

At the concepting and prototyping stage of developing a product, the R&D team will also begin to generate test methodologies. Whether the device in development has a standard procedural protocol in place or requires protocol design/redesign, the team can leverage the digital playbook for workflow documentation, review, revision and approval.

"The R&D team can build out a workflow in the digital playbook and then use it to mimic the procedural scenario during product development work in their office or lab environment," Heydinger explained. "If it's a new or redesigned protocol, the team can use the Delphi Method within the playbook for KOL review and to facilitate various workflows in voting rounds and come to a consensus in an unbiased way."

Testing prototypes

"Once the procedural steps are defined in the playbook, development and testing teams can utilize it during the testing phase of a project. A clean workflow with role-specific instructions can help teams perform more accurate testing in-house before final surgeon validation," Heydinger explained.

Real-time remote connectivity helps secure faster feedback from KOLs on prototyping instead of waiting for KOLs to be available to join a lab in-person. Additionally, digital data capture in the validation lab helps support seamless regulatory submissions for device approvals.

Gathering Alpha launch insights

Once the product enters the field, the product development team can work with KOLs to live-stream cases, gather real-time feedback, provide direct support, and fix issues.

"We enable R&D teams to remotely observe more cases to get direct surgeon feedback on what is working well and not working well with the device,"

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Tessa Heydinger,
Director of Product for Explorer, a GHX Company

Heydinger commented. "This reduces the travel and time involved in gathering accurate post-market surveillance."

The team can also leverage digital data and image capture to gather information required to support claims and messaging for marketing around the product's commercial launch.

Supporting successful commercialization

Teams gain transparency into real-time data during live procedures to help track provider performance, isolate training opportunities, monitor user-level usage and procedural steps completed, minimize inconsistencies, and annotate the screen during a live stream for real-time collaboration – all remotely.

Teleflex, a medical device manufacturer operating in 40 countries, leverages the Explorer Live digital case support platform when providing device site of service, as Marc Bolton, Sr. Clinical Affairs Manager, Interventional Urology, NeoTract, explains:

> *"It tells us a great deal. The person who is there in-person or watching remotely can record what steps are done – and when they're done – in real-time so that provides metrics right away and that's a valuable tool. If you can begin to recognize where a surgeon may or may not be proficient, [Explorer] can provide a lot of valuable feedback."*
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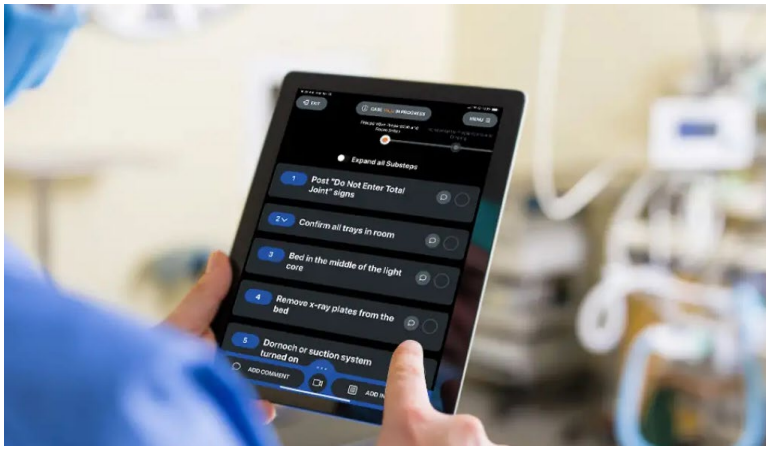

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LEVERAGING DIGITAL INSIGHTS TO SUPPORT VALUE-BASED CARE/PRICING

Healthcare providers, regulators and payers demand real-world evidence (RWE) from manufacturers to prove device impact on outcomes, quality, and costs. Digital case support with intraoperative data capture has the potential to help device manufacturers gather and centralize data across multiple live cases.

"Hospital administrators will ask, 'will this technology drive better care and align with current reimbursement models for our unique patient population?' before they approve a product in value analysis committees," said Rachel Armstrong Bowers, MHA, Head of Market Access and Healthcare Economics for Tulavi Therapeutics, a company focused on developing intuitive, proactive nerve care solutions built to improve the standard of care and in doing so, reduce and prevent chronic pain, costly reoperations, and lead to financial savings for the hospital.

"They look at their data to see, 'how much are we spending on this patient population, what's our disease burden, and how is using your product favorable from a reimbursement perspective?' If you

go into hospitals armed with data that addresses those questions, they're more likely to take your meeting and you're more likely to garner service line and executive level support for approval."

Data from live cases employing digital case support can help shorten the time to create and publish real-world clinical studies, reduce the technical burden of mining data files, and increase the speed of gathering RWE to support pass-through payments, which Armstrong Bowers says are the "holy grail" of the device world, stating:

"You need RWE to support pass-through payments, and presenting this data to the medical professional societies and payers will lead to faster product adoption by demonstrating the 'proof' that your device works."

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CONCLUSION

Medical device companies need faster access to actionable insights derived from device usage when innovating new products or revising existing ones – and remote digital case support offers a solution. With access to this data at the very start of the development lifecycle through commercialization, manufacturers can speed up innovation of high-quality devices and gain insights to demonstrate their value, to ultimately drive market adoption and reimbursement.

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