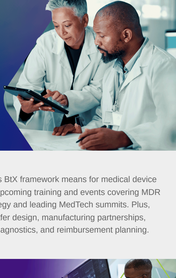
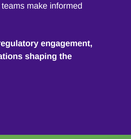
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NOVEMBER '26

Insights from the Cutting Edge of MedTech

This November, explore what the EU's BtX framework means for medical device and IVD evidence planning. Discover upcoming training and events covering MDR certification, clinical evaluation strategy and leading MedTech summits. Plus, explore insights on device trials, safer design, manufacturing partnerships, preclinical challenges, AI-enabled diagnostics, and reimbursement planning.



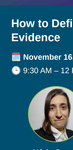
Inside MDCG 2025-9 and BtX Designation

Veranex Experts on What Manufacturers Need to Know

MDCG 2025-9 introduces new considerations for manufacturers developing breakthrough medical devices and IVDs. Understanding the framework, its requirements, and potential implications can help teams make informed regulatory and evidence-planning decisions.

Get practical insight into BtX eligibility, early regulatory engagement, lifecycle evidence planning, and the considerations shaping the framework as it moves into practice.

Explore Our BtX White Paper



TRAINING

MDR Expert Training

Learn how to implement EU MDR requirements across quality systems, clinical and post-market processes, UDI, EUDAMED, and PRRC responsibilities and prepare for the TÜV SÜD Academy MDR Expert exam.

🗓 **November 30 – December 11, 2026**
🕗 8 AM – 12:30 PM EST | 2 PM – 6:30 PM UTC+1
Exam Date: December 18, 2026

Register Now



TRAINING

Clinical Evaluation Strategy Under MDR

How to Define and Justify the Appropriate Level of Clinical Evidence

🗓 **November 16, 2026**
🕗 9:30 AM – 12 PM EST | 3:30 PM – 6:00 PM CET



Núria Gresa, Ph.D.
Scientific Affairs Manager, Veranex

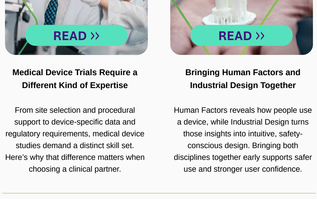


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Veranex is a proud Diamond Sponsor of Mayo Clinic's 2026 Beahrs Surgical Innovation Summit, where surgeons, innovators, and MedTech leaders come together to advance the future of surgical care.

🗓 **November 17, 2026**
📍 Rochester, MN

PCR London VALVES

The Heart Team Course focuses on transcatheter therapies for structural heart disease.

🗓 **November 22-24, 2026**
📍 London, UK

2026 Bohemian Medical Device Summit

Veranex is a proud sponsor of the 21st Annual Bohemian Medical Device Summit, which brings together senior MedTech leaders to discuss the current and future trends of the industry.

🗓 **December 2-4, 2026**
📍 London, UK

Meet with Veranex

INDUSTRY INSIGHTS FROM OUR EXPERTS



Medical Device Trials Require a Different Kind of Expertise

From site selection and procedural support to device-specific data and regulatory requirements, medical device studies demand a distinct skill set. Here's why that difference matters when choosing a clinical partner.



Bringing Human Factors and Industrial Design Together

Human Factors reveals how people use a device, while Industrial Design turns those insights into intuitive, safety-conscious design. Bringing both disciplines together early supports safer use and stronger user confidence.



Choosing a Medical Device Manufacturer? Ask This One Question.

Novel devices bring unexpected challenges. Learn the question that can reveal whether a potential manufacturing partner has the expertise and collaborative approach to solve problems with you.

When a Device Doesn't Behave, Surgical Expertise Matters

In cardiovascular preclinical studies, unexpected challenges can put usable data at risk. Read how experienced surgical teams can adapt in the moment, troubleshoot device issues, and help keep a study on course.

Beyond Clearance: Plan AI Diagnostics for Market Adoption

Regulatory approval is one milestone; reimbursement, clinical adoption, and lifecycle readiness help determine whether an AI/ML-enabled diagnostic reaches patients at scale. Read the article for five ways to bring these priorities into planning early.

Reimbursement Is Moving Into Pivotal Trial Design

CMS's proposed RAPID pathway could bring Medicare coverage evidence needs into the investigational stage, raising the stakes for trial design and future revenue. Explore key evidence-planning considerations.

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