

# HOW TO ACHIEVE COMMERCIAL VIABILITY FOR THE U.S. MEDICAL MARKET

*From Proof-of Concept to Acquisition – What you Need to Know*

## CONFERENCE OVERVIEW

The United States is the largest healthcare market in the world. With only four percent of the world's population, it represents roughly half of the \$8 trillion worldwide health care economy. But how does an international founder untap this market? Led by a team from RQR Advisors, we will explore the answers to this question with a focus on USA commercial viability and its many interrelated workstreams.

Founders and their investors must answer many questions related to commercial viability, including whether there is a market need for the technology and the various layers of the competitive landscape. Questions include: Who is the customer? Is it the patient, physician, outpatient clinic, regional hospital, hospital supercenter, a network of hospitals and their Value Analysis Committees, or an insurance company (or some combination of the above)? Will healthcare companies and consumers believe they need the technology (in other words, is the technology a “nice to have” or a “need to have”)? Is there a pathway for coding, coverage, and payment? How does a founder align the marketing claims with the regulatory claims and then choose the correct regulatory pathway? Are there Key Opinion Leaders who will champion the product? Will medical societies adopt the new technology as the new standard of care? Is there a strategic buyer that has an unmet need for the product in its existing portfolio? In short, even if product functionality is likely strong and supportable with data, will anyone buy it?

Of course, with early-stage healthcare technologies, there will rarely be definitive answers to all the necessary questions about commercial viability. But by understanding and addressing these questions at an earlier stage in the development pipeline, founders and investors can **decrease the risk** of failure and **increase the likelihood** of success.

### About RQR Advisors, B.V.

RQR Advisors LLC is a global medical technology advisement firm, based in Minneapolis, Minnesota with a strong presence in the Netherlands, operating through RQR Advisors B.V. RQR Advisors specializes in the evaluation and achievement of commercial viability for early-stage healthcare innovations. RQR advises founders, investors and government partners using its Commercial Quotient® and Commercial Viability Map® platforms to guide milestone-based investment decisions, with a pre-commercial, defined exit as the goal.



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### PRESENTERS

**Mike  
Phalen**



Mike is the retired EVP for Boston Scientific, where he was Group President for a \$4B+ business group and successfully managed over \$2B in M&A transactions, including numerous early-stage assets that are now an integral part of Boston Scientific's portfolio. He has extensive C-Suite network throughout the healthcare industry, having served as the board chair for MassMEDIC and board member for Advanced Medical Technology Association.

**Jim  
Sargent**



Jim is an experienced global healthcare executive, consultant, and trusted advisor to an extensive network of entrepreneurs, government leaders, physicians, and investors across the globe. He has led numerous sales, commercialization, and cross-functional leadership teams within Boston Scientific over 20+ year career. He has led workshops throughout Northern Europe and Asia during his extensive post-Boston Scientific consulting career.

**Laurie  
Lewandowski**



Laurie has over 25 years of experience in regulatory affairs and quality assurance with global companies, including Guidant, Medtronic, and Wright Medical and with numerous start-ups. She has successfully obtained dozens of FDA approvals on behalf of her clients and has considerable experience with all aspects of USA regulatory approvals. In addition, she has significant expertise managing design, development, manufacturing, and quality systems.

**Kevin  
Hensler,  
MD**



Kevin is a private practice radiologist, specializing in interventional radiology in Minnesota. As a board member for one of the largest private radiology groups in the USA, Kevin brings a fundamental understanding of healthcare business as it pertains to clinicians and physicians. He serves on the Medical Advisory Board for a major USA medical device company and has served as the CMO for several startup companies.



**Jay Stracke**



Jay is a healthcare financing specialist with expertise in establishing new and improved reimbursement policies, generating clinical and economic evidence, and executing payer relations strategies for innovative medical devices. He has held senior leadership positions with Smiths Medical, Zimmer, and Boston Scientific, among others.

**London Krueger**



London is a marketing expert with a long career in medical devices. She has worked in the orthopedic spine, cardiology, oncology, and diabetes markets and consulted on numerous marketing projects in the healthcare industry, including portfolio strategy, new product launch, evaluation, market development and tactical implementation.

**Rudiger Mees**



Rudiger is based in Belgium and is a Director for RQR Advisors B.V. He has extensive experience as a founder, fund raiser, and healthcare leader. In addition, he previously managed the life sciences business of one of the largest IT companies in Europe, with over 8,000 employees.

**James Joslin**



Jim is a legal and strategy expert with extensive experience with starts-ups, private capital raises, life-sciences, intellectual property, venture capital, and cross-border transactions. He previously worked as a partner at Kirkland & Ellis LLP, in executive legal leadership roles at Honeywell International, and in the legal department at Abbott Labs.



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## AGENDA (Day 1)

8:15 – 8:45 a.m.	<b>Registration</b>
9:00 – 9:15 a.m.	<b>Welcome &amp; Overview</b> <i>Rudiger Mees</i>
9:15 - 10:30 a.m.	<b>USA Commercial Viability: <i>What is it and how do I achieve It?</i></b> <i>James Sargent</i>
10:30 – 10:45 a.m.	<b>Break</b>
10:45 a.m. – 12:00 p.m.	<b>Perspectives from the C-Suite: <i>How do I get the attention of a strategic buyer?</i></b> <i>Mike Phalen</i>
12:00 – 1:00 p.m.	<b>Lunch</b>
1:00 – 2:15 p.m.	<b>The Physician's Perspective: <i>Improving quality of life in a profit-driven healthcare system</i></b> <i>Kevin Henseler, M.D.</i>
2:15 – 2:30 p.m.	<b>Break</b>
2:30 – 4:30 p.m.	<b>Marketing &amp; Regulatory Claims: <i>Aligning the FDA Strategy with Commercial Opportunity</i></b> <i>Laurie Lewandowski &amp; London Krueger</i>



**RQR ADVISORS**

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### **AGENDA (Day 2)**

<b>9:00 - 10:30 a.m.</b>	<b>How Do I Get Paid? <i>Unlocking the coding, coverage, and reimbursement mystery</i></b> <i>Jay Stracke</i>
<b>10:30 – 10:45 a.m.</b>	<b>Break</b>
<b>10:45 a.m. -12:00 p.m.</b>	<b>Founder Economics: <i>Cap tables, funding rounds, and value creation</i></b> <i>James Joslin</i>
<b>12:00 – 1:00 p.m.</b>	<b>Lunch</b>
<b>1:00 – 4:00 p.m.</b>	<b>Case Studies: <i>Working through 3 founder fact patterns**</i></b> <i>RQR Team and Attendees</i>  <i>(**case studies selected from questionnaires completed by attendees at conclusion of Day 1)</i>
<b>4:00 – 5:00 p.m.</b>	<b>Networking</b>

