SHAHERAH YANCY

FOUNDER AND CEO, RCI GLOBAL PARTNERS

REGULATORY & CLINICAL COMMERCIALIZATION ARCHITECT

Helping Innovators Turn Medical Innovations into Commercial Success.

50-Word Speaker Bio

Shaherah Yancy, **MBA**, **MS**, **ACRP-CP®**, **PMP®**, is Founder & CEO of **RCI Global Partners**, where she helps MedTech, biotech, and digital health companies transform regulatory strategy into commercial success. With more than 20 years of global leadership experience, she equips innovators to accelerate market access, strengthen clinical evidence, and build products that achieve lasting market adoption.

200-Word Speaker Bio

Shaherah Yancy, **MBA**, **MS**, **ACRP-CP®**, **PMP®**, is the Founder and CEO of **RCI Global Partners**, a regulatory and clinical commercialization strategy firm helping MedTech, biotech, pharmaceutical, and digital health innovators bring products to market—and ensure they succeed once they get there.

With more than two decades of executive leadership spanning hospitals, academia, MedTech, and the pharmaceutical industry, Shaherah has guided global regulatory and clinical strategies for hundreds of products across the United States and international markets. Her experience includes leadership roles with industry organizations such as Medtronic, Smith & Nephew, Stryker, and St. Jude Children's Research Hospital, where she led multidisciplinary teams, strategic growth initiatives, and product commercialization programs.

Known for challenging conventional thinking, Shaherah believes regulatory strategy should never exist in isolation—it is the blueprint for commercialization. Through her proprietary Commercialization Intelligence System™, powered by The ACCESS™ Code and The ADOPT™ Pathway, she teaches organizations how to align regulatory, clinical, and commercial strategy to accelerate market adoption, attract investment, and drive sustainable revenue.

A sought-after keynote speaker, advisor, and mentor, Shaherah regularly speaks to founders, investors, accelerators, and healthcare leaders on FDA strategy, clinical evidence, commercialization, and the future of healthcare innovation.

SIGNATURE TALKS

The Commercialization Intelligence System™

Powered by The ACCESS™ Code and the ADOPT™ Pathway

Brining an innovative healthcare product to market required more than regulatory clearance—it requires a strategy for commercial success. In this signature keynote, Shaherah introduces her proprietary Commercialization Intelligence System™, a practical approach that helps innovators bridge the gap between product development and market adoption.

Built on two proprietary frameworks—The ACCESS™ Code, which positions products to earn market attention, and The ADOPT™ Pathway, which transforms attention into sustained adoption and revenue—this keynote provides leaders with a roadmap for building products that regulators clear, clinicians embrace, payers support, and markets reward.

Best for: MedTech and Biotech founders, commercialization leaders, investors, accelerators, innovation programs, healthcare executives, and research institutions.

Audience walks away with:

- A practical approach to aligning regulatory, clinical, and commercial strategy from the earliest stages of development.
- How to build evidence and value propositions that resonate with regulators, providers, payers, investors, and customers.
- A commercialization roadmap that accelerates market attention, drives adoption, and creates long-term revenue growth.

How to Win With Regulatory

Regulatory strategy isn't a compliance cost — it's the highest-leverage business decision an innovation company makes. This talk reframes the FDA pathway as architecture: how classification and sequencing decisions determine valuation, clinical burden, and time to market.

Best for: Founder audiences, accelerators, investor forums

Audience walks away with: A decision framework for pathway selection, the most expensive sequencing mistakes and how to avoid them, and what FDA engagement looks like when you control the narrative.

Success Beyond the Technology: The Critical Role of Strategic Commercialization

Brilliant science fails for non-science reasons. Drawing on 200+ product launches, this talk maps why innovations stall between approval and adoption — and how to build commercialization into the strategy from day one instead of bolting it on after clearance.

Best for: Innovation summits, university tech-transfer programs, corporate innovation teams

Audience walks away with: The commercialization decisions that must be made pre-submission, and how evidence planning serves regulators, payers, and customers simultaneously.

Get It Right the First Time: Smarter Clinical Trial Design

A clinical study is the most expensive sentence a startup ever writes. This talk covers designing studies that satisfy FDA, support claims, and convince investors — the first time — rather than generating data that answers the wrong question.

Best for: Clinical and scientific audiences, biotech programs, research institutions

Audience walks away with: How to scope evidence to the actual regulatory question, where trials over-build and under-build, and design choices that compress timelines without compressing rigor.