NEWS RELEASE

Pittsburgh-Based Contract Research Organization, Clinical Research Strategies, LLC Launches New Tech Transfer Advisory Service Led by Julie Cramer, PhD

Pittsburgh, PA – February 4, 2026. Clinical Research Strategies, LLC ("CRS"), a Pittsburgh-area-based, US-owned and operated clinical contract research organization (CRO) and executive management consultancy for the life sciences industry announces the official launch of a new **Tech Transfer Advisory Service** led by Julie Cramer, PhD, Senior Director of Clinical and Regulatory Affairs.

Julie's experiences with driving commercial translation within an academic technology transfer office and in a university start-up company make her especially equipped to lead this service at CRS.

Photo by Jen Worley

Based on popular demand and increased requests by major universities across the United States, Julie and the CRS team are available to provide advisory services for:

- Regulatory Strategy
- Early FDA Interactions
- Clinical Strategy
- Investor Relations
- Partnering
- Gap Analysis, and
- Business Development

Universities are a rich source of innovative technologies for the life science ecosystem. However, not all universities are equipped to effectively transfer these technologies into the commercial realm. Even those that are equipped often need support addressing potential investor questions related to pathway to market, cost, timeline, and associated risks.

This new Tech Transfer Advisory Service helps university-based technologies avoid the "valley of death" by providing actionable assessments of the regulatory and clinical landscape, grounded in professional experience with funding, intellectual property, and contracting considerations unique to university settings.

The CRS team specializes in translating complex regulatory expectations into clear, actionable steps that enable research teams to sharpen development strategies and advance more efficiently toward clinical and commercial milestones.

Learn more about CRS' Tech Transfer Advisory Service at https://clinicalresearchstrategies.com/life-sciences-consulting/tech-transfer/.

Contact Julie for a free introductory 30-minute capabilities: julie@clinicalresearchstrategies.com.

Read what others are saying about Julie and the CRS team of experienced advisors:

"Clinical Research Strategies (CRS) has been an exceptional regulatory and clinical strategy partner for READE.ai's NOTIS™ program. Their team helped us shape a clear FDA engagement plan, refine our validation and ground-truth strategy, and professionally manage our Q-Submission process—including preparation for and documentation of FDA interactions—so we could move forward with confidence and alignment. CRS consistently delivers practical, high-quality guidance that accelerates decision-making and reduces regulatory risk."

-- READE.ai, University Startup Company

"For many early-stage innovators, navigating FDA pathways can slow momentum. Clinical Research Strategies removed that barrier by translating complex regulatory expectations into clear, actionable steps that enabled our research teams to sharpen their development strategy and advance more efficiently toward clinical and commercial milestones."

-- University Licensing and Commercialization Office

"As a team navigating the regulatory process for the first time, partnering with CRS early on has been instrumental for Accelowave. The CRS team was patient, highly responsive, and exceptionally clear in explaining our regulatory options, timelines, and responsibilities. Their detailed and collaborative regulatory path assessment helped us understand how our device fits within the FDA regulatory framework, clarify our overall FDA strategy, and know what to expect from early FDA interactions. The experience has given us confidence and clarity as we move forward, and we're grateful to have CRS as a long-term partner in our commercialization journey."

-- Accelowave, University Startup Company

"Our collaborative experience with Clinical Research Strategies (CRS) on the Short Regulatory Pathway Assessment (S RPA) for the NSAT prototype has been exceptional. CRS demonstrated outstanding professionalism, deep regulatory expertise, and a level of communication that made a complex process remarkably efficient and transparent. Their team quickly developed an accurate and actionable

assessment that clarified the regulatory landscape for our device and helped us align our commercialization strategy with current FDA expectations.

The guidance provided by CRS not only strengthened our understanding of the most appropriate regulatory pathway but also enhanced our team's confidence in navigating key decision points as we advance the NSAT technology. Their ability to meet our needs, respond quickly, and translate nuanced regulatory considerations into clear next steps has made them an invaluable partner.

As we move forward, our team plans to continue working with CRS to engage in early FDA interactions, refine our regulatory strategy, and coordinate clinical study design and execution. Their support will play an essential role as we progress the NSAT prototype through the FDA approval process and into the next phase of clinical validation. We look forward to building on this partnership as we bring the NSAT system closer to real-world clinical impact."

-- University of North Carolina, Wilmington & NSAT Team

About Clinical Research Strategies, LLC: CRS is a specialty clinical CRO and executive management consulting firm that fits-for-purpose veteran life sciences executives, regulatory scientists and strategists, clinical operations, project management, quality assurance engineers, and risk management teams to take on the biggest challenges for start-up, mid-sized, and large life sciences companies, many of whom are developing novel, first-in-class drugs, biologics, diagnostics and medical devices, or software as a medical device (SaMD). Service areas are clinical trials; regulatory compliance, strategy and submissions; QMS, product requirements, IFU; EU MDR and GDPR; rescue trials and trial master files; risk management, mitigation and remediation; Human Factors; training high-performing teams; staffing solutions; and, real-world evidence (RWE) and decentralized trials.

Therapeutic areas include Aging, Biosensors, Cannabis, Cardiovascular Disease, Central Nervous System, Critical Care Medicine, Gastroenterology, Genetics, Infectious Disease, Immunology, Men's Health, Metabolic Disorders, Microbiome, Neonates & Pediatrics, Neurology, Oncology, Ophthalmology, Opioid Abuse, Orthopedics, Pain, Precision Medicine, Rare Diseases, Radiology, Regenerative Medicine, Respiratory Diseases, Sleep, Women's Health, Wound-Healing, and many more.

CRS is an approved sub-contractor for the NIH, DoD, and DARPA. CRS is also affiliated with MTEC and is a Spoke Member of ARPA-H.

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