

Capability Statement



**Clinical Research Consulting
Regulatory Strategy
Medical Devices & In-Vitro Diagnostics**

Lucent Clinical Consulting LLC (Lucent Clinical) has a mission to improve global healthcare by helping companies commercialize novel medical devices and diagnostics. Lucent Clinical provides strategic consulting services for clinical research and regulatory strategy to accelerate the commercial launch of new medical technologies, ensure regulatory compliance, and realize quality improvement goals.

Lucent Clinical brings more than 30 years of executive experience from Fortune 200 companies (Medtronic, Danaher Corp) in overseeing more than 500 clinical trials, built high-performing research organizations and clinical infrastructure.

As a certified Minority, Woman-Owned Small Business, Lucent Clinical is committed to excellence and creating innovative and flexible solutions for State and Federal clients.

What sets Lucent Clinical apart from the competition?

- Proven Hands-on Expertise
- Performance-Based Processes
- Integrated Tools to Promote Regulatory Compliance
- Client Relationship Management
- Strategic Balance of Technology and Business

Core Capabilities

Lucent Clinical will work with clients to understand their business priorities and research goals to deliver the following capabilities:

- Regulatory Strategy
- Risk-based Clinical Trial Methods
- Cross-functional Collaboration

Consulting

Our Consulting Services cover the full medical product development lifecycle. By incorporating industry's Good Clinical Practices into your business processes and management strategies, we can help you stay ahead of the competition and better serve your customers. Our services cover the following medical product phases:

- Business Case (due diligence, regulatory pre-submission planning)
- Feasibility & Design (regulatory standard selection, risk management plan, post-market surveillance strategy, benefit/risk assessment)
- Design Verification (clinical protocol design, risk-based monitoring plan)
- Clinical Validation (clinical trial execution)
- Commercial Release (post-market performance follow-up, evidence generation)

State Certifications

Minnesota

- *CERT - Women-Owned, Small and Minority-owned Business Enterprise (WBE/SBE/MBE)*

Sample – Major Clients

Commercial
Bristol Meyers Squibb
LabCorp
MyoKardia
MedTech Bridge (Europe)
YourEncore / Advarra

North American Industry Classification System (NAICS)

NAICS 541715: LIFE SCIENCES RESEARCH AND DEVELOPMENT
LABORATORIES OR SERVICES (EXCEPT BIOTECHNOLOGY AND
NANOTECHNOLOGY RESEARCH AND DEVELOPMENT)

General Information

Registered Company Name: Lucent Clinical Consulting LLC

DBA: Lucent Clinical Consulting

Year Incorporated: January 2020

State of Incorporation: Minnesota

Corporation Type: LLC

D-U-N-S Number: 117434702

CAGE Code: 8HRK5

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