



WEAKLEY
LIFE SCIENCES
CONSULTING LLC

Clinical Insight. Strategic Direction. Operational Results.

CAPABILITY STATEMENT

Fractional Clinical Operations Leadership for Emerging Biotech and Pharma

Alicia Weakley, MBA brings 25+ years of hands-on clinical operations experience across both sponsor and CRO environments. Weakley Life Sciences Consulting LLC provides fractional and interim clinical operations leadership, giving emerging companies the senior expertise of a VP Clinical Operations without the full-time overhead—exactly when a critical milestone demands it.



WHO I SUPPORT

Biotech startups and specialty pharmaceutical teams.



STRATEGIC PARTNERS

Venture capital firms and boards seeking independent clinical expertise or experienced leadership support.



CORE COMPETENCIES

- ✓ Clinical trial management and execution
- ✓ CRO selection, vendor oversight, and management
- ✓ IND preparation and regulatory submission support
- ✓ Clinical team buildout and leadership development
- ✓ Trial startup, Feasibility and Activation
- ✓ Pre-Inspection Compliance Reviews & Audit Support.
- ✓ Program management across Phase I through Phase IV



DIFFERENTIATORS

- 25+ years across BOTH sponsor and CRO sides—a rare combination that means fluency in how each side actually operates
- Fractional model: senior leadership without the cost or commitment of a full-time hire
- Direct, hands-on execution, not just strategic advisory
- Experience in different regulatory authority submissions (e.g. FDA, EMA, PMDA, MHRA)
- Lean Six Sigma Certified Facilitator, continuous process improvement

LEAN OPERATING MODEL, DELIVERY CAPACITY & ENGAGEMENT MODELS



LEAN OPERATING MODEL DESIGN

Design the team structure, FTE plan, budget, governance, sourcing, and vendor model required to move a program from strategy into execution, with knowledge of ICH GCP guidelines and other regulatory requirements.



DELIVERY CAPACITY

Assemble and lead the internal resources, specialized consultants, and partners a program needs, with WLSC retaining operating oversight and accountability.



FRACTIONAL / INTERIM VP CLINICAL OPERATIONS
3 to 12 month engagements



PROJECT-BASED SUPPORT

IND prep, CRO selection, trial startup, Feasibility and Activation, regulatory submission

A fit-for-purpose alternative when a full traditional CRO model is not yet the operating structure.

THERAPEUTIC AREAS



Women's Health



Immunology



Rare Disease



Cell & Gene Therapy



Neuroscience



Hematology / Sickle Cell Disease



Rheumatology

SELECTED SPONSOR / CLIENT EXPERIENCE

Eli Lilly • Regeneron • Grifols Therapeutics • Agios • GenSci
Caelum Biosciences • Visus Therapeutics • Aclaris Therapeutics • Spirovent

PROVEN IMPACT



\$500M+

Early- and late-stage trial program leadership



\$20M+

Revenue acceleration through process & performance optimization



25+

Years of clinical operations leadership



95%

On-schedule milestone delivery



Global

Reach across 50+ countries / 6 continents

ABOUT ALICIA WEAKLEY, MBA

Alicia helps clinical-stage biotech and small-to-mid pharmaceutical companies strengthen teams, accelerate ramp-up, and reduce execution risk through practical, cross-functional clinical operations expertise.

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I turn complexity into clarity, strategy into execution, and clinical plans into measurable results. ”