Nadia M. Bracken

nadiambracken@gmail.com
415-580-2564 ▪ Redwood City, California

SUMMARY

Experienced Clinical Trial Manager leading Phase I-III global studies in oncology, cardiovascular, CNS, infectious diseases, and vaccines. Skilled in CRO and vendor oversight. Proven ability to identify risks, optimize study processes, and leverage analytics to enhance trial efficiency and decision-making.

PROFESSIONAL EXPERIENCE

Clinical Trial Manager *Biomea Fusion (Oncology)* | 2023 - 2025

- Directed CRO, vendors, and site activation in Phase I First-in-Human oral dose-escalation.
- Developed study plans with Clinical Science, Quality, Biometrics, Safety and Regulatory.
- Optimized clinical trial budget allocation and accruals across selected institutions.
- Prepared trial documentation, dose-level review committee materials, and contributed to deviation review and conference presentations (ASCO, ASH, Acute Leukemia Forum).

Clinical Operations Consultant | 2018 - 2022
Adjuvance (Vaccines), Alector (CNS), Clovis Oncology, Medidata/Moderna, Tizona Oncology

- Clinical Operations Advisor – Medidata Strategic Consulting:
    - Enabled Risk-Based Quality Management professional services for Enterprise and CRO clients, presenting operational risk visuals, metrics, and safety signals.
- Phase I Pertussis vaccine adjuvant First-in-Human:
    - Project Management reporting to CEO supporting preclinical, CMC, and CMO.
- Phase II Antibody in Advanced Cancers & Phase III Ovarian Cancer:
    - Tracked biopsies, scans, and discrepancies.
    - Facilitated risk assessment for first-line 1000 patient study utilizing Cluepoints.
    - Developed dashboards (SharePoint, Smartsheet) for CRO and vendor performance.

Sr. Clinical Trial Manager *Nektar Therapeutics* | 2017 - 2018

- CRA line manager responsible for coordinating tasks and setting performance objectives.
- Managed vendors and regional sites for Phase II solid-tumor immuno-oncology trial.
- Supported data readiness (Eliminate, Smartsheet) for ASCO and SITC.
- Delivered Phase III 600 patient chronic pain study closeout 4 months ahead of schedule.

Clinical Trial Manager *Gilead Sciences* | 2014 - 2017

- Collaborated with global cross-functional study teams for Phase IIIb and Phase II HIV trials in adolescent and special populations.
- Conducted data reviews, supporting EDC, Biometrics, IDMC, and interim snapshots.
- Contributed to initiatives (eSignature, Compassionate Use).

Sr. Clinical Research Associate *Biotie Therapies* | 2011 - 2014

- Program oversight for Phase I & II CNS trials (Parkinson's, Alzheimer's) site startup, initiation, recruitment support, and patient profile generation for accelerated trial closeout.
- Managed 3 CROs (6 countries) and 3 biostatistics vendors to deliver Clinical Study Reports.

Clinical Research Associate & Data Manager | 2006 - 2011
CV Therapeutics, Fibrogen, i3 Research/Pfizer, Kendle/Abbott/Takeda

- Monitoring early-phase, rescue, and complex advanced disease-state programs (Anemia, Cardiovascular, CNS, Transplant, Surgery).
- Oversaw top-enrolling sites Phase II/III and led Phase I pulmonary/cardiovascular trials.
- Performed global inspection readiness activities and provided CRA training/mentorship.

EDUCATION

Bachelor of Science in Business Marketing, 2002
North Carolina State University, Raleigh, NC