JEFFERY A. NIEVES

CHANDLER, AZ | (773) 495-7072 | JEFF@JEFFNIEVES.COM | JEFFERYNIEVES.COM

PHARM.D., CLINICAL OPERATIONS EXECUTIVE | ONCOLOGY & RARE DISEASE DRUG DEVELOPMENT

PROFESSIONAL SUMMARY

Clinical operations executive with a Pharm.D. and 20+ years running Phase I–IV programs across oncology, IO, and rare disease. **Administered $180M+ in program budgets, directed 20+ simultaneous studies,** and co-authored 10+ peer-reviewed presentations at ASCO, SITC, and AACR — bringing a level of scientific authority to operations that most organizations have never seen in a single person. Track record of building ops functions from scratch, solving rare disease enrollment problems, and delivering on timelines that others miss. Seeking VP/SVP Clinical Operations at a clinical-stage biotech.

KEY SKILLS

- ✓ Phase I–IV Global Execution
- ✓ IND / NDA/BLA / MAA Submissions
- ✓ Clinical Development Planning
- ✓ Site Feasibility & Enrollment
- ✓ CRO & Vendor Management
- ✓ Pharmacovigilance & GCP
- ✓ Cross-Functional Leadership
- ✓ Regulatory Strategy
- ✓ $180M+ Budget Oversight
- ✓ Oncology · IO · Rare Disease
- ✓ SOP Development & TMF
- ✓ Scientific Authorship

CAREER HIGHLIGHTS

$180M. 20 studies. 9 weeks.
At Celgene, administered $180M across 8 compounds and 20 simultaneous Hematology/Oncology studies — and opened 3 trials for patient accrual within 9 weeks of final protocol delivery. The industry benchmark is 4–6 months.

Rare disease. Blank-page enrollment strategy.
At Ayala, led global ops for a precision oncology program targeting adenoid cystic carcinoma — a rare cancer with no approved treatments and a narrow biomarker-selected patient pool. Engineered the site feasibility and recruitment strategy that made multinational accrual viable at all.

Built the function. Ran the trial. Published the data.
At Indaptus, joined as the first clinical ops hire and built the entire infrastructure from scratch — SOPs, CRO framework, TMF — while simultaneously running a Phase I/II IO program and co-authoring 10+ peer-reviewed publications at ASCO, SITC, and AACR. Most ops executives do one of these things.

PROFESSIONAL EXPERIENCE

Vice President, Clinical Operations, Indaptus Therapeutics, Inc. | *2022 – 2026*

- **Pharm.D. Scientific Operator:** Built the full clinical ops function from scratch while co-authoring 10+ peer-reviewed abstracts at ASCO, SITC, and AACR (2023–2024) — an unusual combination that elevated program credibility with global KOLs and demonstrated Pharm.D.-level scientific depth.
- **Infrastructure Buildout:** Established SOPs, CRO vendor framework, and TMF architecture enabling rapid site activation for a first-in-class immuno-oncology asset; chaired cross-functional oversight committee spanning Clinical Development, Preclinical, CMC, and Regulatory.
- **Budget & Vendor Oversight:** Directed CRO selection and performance management; oversaw clinical trial material forecasting and full study budget across multi-year execution in a resource-constrained biotech environment.

Executive Director, Clinical Operations, Ayala Pharmaceuticals, Inc. | *2021 – 2022*

- **Rare Disease Enrollment Strategy:** Engineered site feasibility and biomarker-selected recruitment for adenoid cystic carcinoma — a rare cancer with no approved treatments — navigating a narrow global specialist-center landscape to make multinational patient accrual viable.
- **Risk & Execution:** Maintained deliverables and cost targets through proactive identification and resolution of CRO, supply chain, and regulatory risks; aligned Regulatory Affairs, CMC, and PM around a unified execution roadmap in a resource-constrained environment.
- **Cross-Functional Partnership:** Drove inter-departmental alignment across Regulatory, CMC, and Project Management — improving handoff efficiency and reducing cycle time on key study deliverables.

Senior Director, Clinical Development & Operations, Horizon Therapeutics | *2015 – 2020*

- **Multi-Indication Portfolio:** Directed simultaneous programs across immuno-oncology, orphan disease, and rheumatology — one of the broadest multi-indication portfolios managed by a single ops leader at the company — ensuring all programs met ICH/GCP standards over a five-year tenure.
- **Regulatory Authorship:** Contributed to IND, NDA/BLA, and MAA submissions — authoring protocols, Investigator Brochures, and interim study reports that advanced multiple assets toward approval.
- **Vendor & Contract Execution:** Negotiated all CRO and vendor contracts; administered trial budgets in partnership with legal — consistently on scope and cost across a multi-year, multi-program portfolio.

Director, Global Study Management, Astellas Pharma | *2014 – 2015*

- **Portfolio Priority:** Led lifecycle strategy for the #1 and #2 oncology compounds in Astellas' global R&D pipeline; directly managed 14 clinical study staff across cross-regional teams.

Associate Director, Clinical Operations, Celgene Corporation | *2012 – 2014*

- **Portfolio Scale:** Administered $180M across 8 compounds and 20 simultaneous studies; mentored 8 Senior Study Managers across 3 regional offices globally.
- **Speed to Activation:** Opened 3 studies for accrual within 9 weeks of final protocol delivery — compressing a milestone that typically requires 4–6 months.

EDUCATION & CREDENTIALS

Doctor of Pharmacy (Pharm.D.) · University of Illinois, Chicago, IL
Bachelor of Science (B.S.) · Indiana University, Bloomington, IN

Memberships: ASCO · DIA · ASHP · HOPA

Publications: 10+ peer-reviewed abstracts and posters at ASCO, SITC, and AACR — including Phase 1 immuno-oncology preliminary results (2023–2024).

Earlier: TGen (Divisional Deputy Director) · Baxter Healthcare (Assoc. Director, Clinical Dev) · US Oncology (Director, Translational Oncology) · NeoPharm / Pharmacia (Sr. Director & Clinical Research Manager)