Marislena Amezquita
Clinical Operations Professional

+1 (508) 735–7530 | marislena.amezquita@gmail.com | Millbury, MA. USA | www.linkedin.com/in/marislena-amezquita

INDEPENDENT CONSULTING

Amez Clinical Consulting, Greater Boston, MA. Present Day

Founder and Owner, amezclinicalconsulting.com Established February 18, 2026

Clinical operations consultant supporting early-phase biotechnology programs in oncology and rare disease. Experienced in cross-functional study execution, patient operations, CRO/vendor coordination, and clinical trial startup activities within GCP-aligned, SOP-driven environments.

- Manage day-to-day clinical operations across CROs, vendors, study sites, and sponsor stakeholders to support protocol execution, study timelines, and operational deliverables for early-phase oncology and rare disease programs.
- Coordinate cross-functional collaboration across Clinical Operations, Regulatory, Clinical Development, Quality, and external partners to drive alignment on study priorities, timelines, and execution.
- Drove clinical trial execution through enrollment tracking, data collection activities, protocol compliance, and operational issue resolution in lean biotech environments.
- Contribute to the review of trial-related documentation including protocols, Investigator's Brochures (IBs), clinical study materials, and regulatory submissions to support IND-enabling activities.
- Partner with CROs and external vendors to coordinate study logistics, operational deliverables, and communication while working within ICH-GCP principles and SOP-driven processes.
- Maintenance of essential study documentation and trial records to ensure inspection readiness and compliance with study and regulatory requirements.

PROFESSIONAL EXPERIENCE

Clinical Operations Professional – Palliative Care, NKore Biotherapeutics April 2025 – May 2026

Clinical operations professional supporting the advancement of NK cell therapy within a lean biotechnology environment. Experienced in patient operations, site coordination, vendor management, and cross-functional execution to support scalable clinical operations and protocol-aligned patient care.

- Lead Clinical Advisory Meetings, including agenda development, stakeholder coordination, documentation, and action-item tracking to drive alignment on study priorities, timelines, and operational deliverables.
- Serve as the primary point of contact for clinical site coordination, partnering closely with investigator sites to support patient screening and enrollment workflows, support protocol compliance, and maintain operational readiness.
- Manage patient scheduling, treatment logistics, and day-to-day clinical workflows to support timely study execution and continuity of care.
- Oversee blood kit assembly, shipment, and exploratory biomarker sample logistics in collaboration with external laboratory partners, including UCLA, to ensure accurate tracking, timely processing, and data return.
- Manage study-related logistics and vendor coordination, including procurement of clinical supplies and operational resources to support uninterrupted study activities.
- Identify operational risks and workflow inefficiencies, implementing process improvements to enhance execution and organizational efficiency while operating within SOP-driven, GCP-aligned practices.

Project Coordinator, Boston Medical Center, Boston, MA. August 2021 – August 2024

Coordinated day-to-day operations for an NIH-funded community research study focused on improving health outcomes in underserved populations. Managed study logistics, participant engagement, regulatory coordination, and cross-functional activities to support successful study execution and program delivery.

- Managed day-to-day operational execution of NIH-funded research activities, coordinating timelines, milestones, resources, and study deliverables across internal teams and external stakeholders.
- Coordinated regulatory and reporting activities, including Institutional Review Board (IRB) submissions and NIH Research Performance Progress Reports (RPPR), to support study compliance

Marislena Amezquita
Clinical Operations Professional

+1 (508) 735-7530 | marislena.amezquita@gmail.com | Millbury, MA. USA | www.linkedin.com/in/marislena-amezquita

and continuity.
- Contributed to study design and protocol development, including eligibility criteria, endpoints, and safety and efficacy assessments.
- Managed participant recruitment, enrollment tracking, and research databases while maintaining accurate study documentation and reporting.
- Conducted data management and analysis activities using REDCap to support study monitoring, reporting, and research outcomes.
- Oversaw project scope, schedules, resources, and budget adjustments to maintain operational efficiency and alignment with study objectives.
- Designed and implemented training materials for research staff and community health advocates to support consistent study execution and participant engagement.
- Operated within SOP-driven research environments while maintaining study compliance and research integrity.
- Key contributor to the development and ongoing management of a robust participant engagement phone program to support recruitment, retention, and study participation.

Translational Data Analyst, Decibel Therapeutics, Boston, MA. August 2018 – May 2021

Contributed to translational research and early clinical development activities for programs focused on hearing and balance disorders. Partnered cross-functionally across research and development teams on endpoint analysis, biomarker evaluation, and first-in-human clinical planning.

- Managed collaborative research activities with Mass Eye and Ear Hospital, focusing on the analysis of temporal bone audiograms and translational research initiatives.
- Collected and analyzed natural history data to inform endpoint evaluation and clinical trial design strategies for early-stage programs.
- Conducted biomarker and immunohistochemistry analyses in disease models to support dose selection and first-in-human clinical development efforts.
- Performed pharmacodynamic analysis of mouse hair cell data using FIJI, ImageJ, and Zeiss software to advance translational research objectives.
- Conducted competitive intelligence and literature reviews related to disease areas and therapeutic modalities to inform program strategy.
- Presented scientific findings and literature reviews in cross-functional program meetings, serving as a technical contributor to research discussions.

Community Coordinator, Worcester Healthy Baby Collaborative, Worcester, MA. January 2020 – May 2020

Supported community health initiatives focused on improving maternal and infant health outcomes through stakeholder engagement, program coordination, and community partnerships.

- Coordinated and implemented maternal and child health initiatives, including Baby Box distribution, preparation of City Council reports, and coordination of community planning meetings.
- Represented WHBC in Community Health Improvement Plan (CHIP) meetings, contributing to discussions on integrated assessment models and public health initiatives.
- Managed digital communications and community outreach efforts, including web content and educational resources related to infant mortality and maternal health.
- Developed partnerships with community organizations, including the March of Dimes, to expand collaboration across healthcare, housing, education, and government sectors.

Marislena Amezquita
Clinical Operations Professional

+1 (508) 735-7530 | marislena.amezquita@gmail.com | Millbury, MA. USA | www.linkedin.com/in/marislena-amezquita

EDUCATION

Bachelor of Science in Public Health | Worcester State University | Worcester, MA. May 2020

ADDITIONAL EXPERIENCE

Entrepreneur Founder and Owner | TABUTEE (E-Commerce Venture) August 2024 – February 2025

Blood-Transfusion Research Technician | ZATA Pharmaceuticals | Worcester, MA. May 2016 – August 2016

Volunteer | Soydoy Foundation | Bogotá, Colombia May 2018 – August 2018

Telemarketer | Worcester Academy Phonathon | Worcester, MA. September 2013 – May 2016

Volunteer | Worcester Academy Immersion Program | Costa Rica March 2016

CORE COMPETENCIES

Professional Skills Clinical Trial Operations | Clinical Development | Study Startup & Site Activation | Cross-Functional Collaboration | CRO & Vendor Coordination | Patient Recruitment & Enrollment | Clinical Logistics | Study Timeline & Deliverables Management | Protocol Compliance | GCP/ICH Guidelines | SOP-Driven Environments | Regulatory Documentation | IRB Coordination | Clinical Data Management | Biomarker & Sample Logistics | Data Analysis | Stakeholder Management | Rare Disease | Oncology | Translational Research | Trial Documentation Management (TMF) | Certified in Good Clinical Practice (GCP) and HIPAA Compliance | Bilingual: English & Spanish

Technical Skills Microsoft Office Suite (Excel, Word, PowerPoint) | RedCap | FIJI | ImageJ | Zeiss | Adobe Creative Suit | HTML | Teams | Outlook