

Jameson Zimmerman

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SUMMARY

Clinical Research Leader with nine years of medical device and neurovascular trial experience across global study execution, **evidence generation**, clinical safety, and product development. Leads trials from feasibility and **site selection** through monitoring, closeout, data review, registration, publication support, and post market follow up. Authors protocols, **informed consents**, CRFs, **monitoring plans**, study manuals, investigator brochure content, annual reports, and safety plans. Partners with investigators, CRAs, sites, IRBs and ECs, vendors, Regulatory Affairs, Medical Affairs, R&D, data management, and biostatistics. Applies ICH GCP, ISO 14155, MDR, MEDDEV, SOPs, and global regulations while protecting participants, controlling budgets, and meeting milestones. Brings practical judgment, clear technical writing, and steady cross functional leadership that supports safe evidence generation and sound clinical decisions.

EXPERIENCE

Clinical Research Leader, Neurovascular Trials

April 2023 - Present

Cerevia Medical Devices

Durham, NC

Leads two multinational neurovascular device trials from feasibility through closeout, directing study resources, evidence plans, safety coordination, and cross functional delivery within approved budgets and regulatory commitments.

- Led two multinational **neurovascular** trials through feasibility, execution, closeout, budgets, and regulatory milestones.
- Authored protocols, consent forms, CRFs, monitoring plans, manuals, brochures, and **annual reports**.
- Resolved site, enrollment, data quality, and device accountability issues through risk based oversight.
- Directed **clinical data review** with **data management** and biostatistics before analyses and publications.
- Maintained **ClinicalTrials.gov** records while coordinating evidence input for **product development** and life cycle planning.
- Coordinated safety plans, adverse event reviews, authority reporting, ethics reporting, and adjudication activities.

Senior Clinical Research Manager, Device Studies

January 2021 - March 2023

Arcstone Neurotech

Charlotte, NC

Managed pivotal and post market interventional neurology studies, aligning sites, vendors, monitoring plans, budgets, evidence packages, and clinical resources across concurrent projects.

- Managed pivotal and post market device studies using country, site, vendor, and monitoring plans.
- Controlled investigator **agreements**, site payments, vendor scopes, inventories, budgets, and milestone recovery actions.
- Led qualification, initiation, interim, and **closeout** visits under ICH GCP, **ISO 14155**, and SOPs.
- Developed PMCF Plan content and Evaluation Report summaries using literature, complaint, and study evidence.
- Supported regulatory and **notified body discussions** with safety findings and benefit risk evidence packages.
- Mentored clinical staff on **monitoring** quality, site communication, **technical writing**, and project escalation.

Clinical Research Manager, Vascular Devices

July 2018 - December 2020

Blue Ridge Vascular Innovations

Greensboro, NC

Managed vascular device operations and evidence activities, connecting investigators, IRBs, CRO staff, engineers, and medical stakeholders with study timelines and product review needs.

- Managed vascular device operations with **investigators**, **IRBs**, CRO staff, engineers, and medical stakeholders.
- Built **feasibility** assessments around investigator capability, patient populations, procedures, and operational readiness.
- Maintained registrations, essential documents, safety correspondence, monitoring files, and device accountability records.
- Reviewed data listings and source queries with **CRAs** and data management before analysis milestones.
- Prepared literature assessments and evidence summaries for **clinical evaluations**, presentations, and product reviews.
- Tracked **budgets**, vendor deliverables, and timelines, then proposed recovery actions for emerging constraints.

Clinical Research Associate, Medical Devices

October 2017 - June 2018

Piedmont Clinical Research Collaborative

Winston Salem, NC

Monitored medical device and surgical research sites, supporting compliant execution, participant protection, source review, safety escalation, device accountability, and investigator communication.

- Monitored medical device **sites**, verifying consent, source records, eligibility, adherence, and essential files.
- Conducted qualification, initiation, interim, and **closeout** visits with documented findings and follow up.
- Reviewed adverse event documentation and routed safety information according to approved study procedures.
- Reconciled device receipt, use, return, and disposition records against site documentation.
- Supported **investigators** with **CRFs**, query resolution, manual interpretation, and audit preparation.
- Managed visit schedules, reports, and follow up while maintaining trusted site relationships.

PROJECTS

Global Neurovascular Evidence Program 📅 2024

Coordinated clinical, safety, regulatory, and data partners around a global evidence plan for neurovascular devices. Clear ownership helped teams resolve open questions and keep decisions grounded in participant safety and clinical evidence.

Post Market Clinical Follow Up Framework 📅 2022

Connected literature review, complaint information, clinical findings, and regulatory input into PMCF planning. Cross functional review gave colleagues a shared view of evidence gaps and practical next steps.

LEADERSHIP & AWARDS

- Clinical Research Leadership Recognition, Cerevia Medical Devices, 2025
- Clinical Operations Excellence Award, Arcstone Neurotech, 2022
- Study Team Mentor Recognition, Arcstone Neurotech, 2021

EDUCATION

Master of Science in Clinical Research

2017

Duke University GPA: 4.0

Durham, NC

Coursework: Clinical trial design, biostatistics, clinical data management, regulatory affairs

Bachelor of Science in Biological Sciences

2015

North Carolina State University GPA: 4.0

Raleigh, NC

Coursework: Human biology, physiology, research methods, biological statistics

CERTIFICATIONS

- Certified Clinical Research Professional 📅 2019
- Good Clinical Practice Training 📅 2026

TECHNICAL SKILLS

- **Clinical Trial Operations:** Feasibility, site selection, monitoring
- **Clinical Documents:** Protocols, informed consents, CRFs
- **Study Oversight:** Study manuals, monitoring plans, annual reports
- **Medical Device Standards:** ISO 14155, MDR, MEDDEV
- **Good Clinical Practice:** ICH GCP, SOPs, global regulations
- **Safety Management:** Safety plans, adverse events, adjudication
- **Clinical Data Systems:** ClinicalTrials.gov, data review, data listings
- **Post Market Evidence:** PMCF Plans, PMCF Evaluation Reports, literature assessment
- **Regulatory Submissions:** Regulatory affairs, notified body discussions, authority reporting
- **Project Controls:** Budgets, milestones, vendor scopes
- **Stakeholder Platforms:** IRBs, ECs, investigator sites
- **Product Development:** New Product Development, Life Cycle Management, benefit risk

SKILLS

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|-----------------------------|-----------------------|----------------------------|----------------------|
| • Clinical research science | • MDR | • ClinicalTrials.gov | • Regulatory affairs |
| • Medical devices | • MEDDEV | • Safety management | • Technical writing |
| • ICH GCP | • Trial management | • Adverse event reporting | • Project budgets |
| • ISO 14155 | • Evidence generation | • Clinical data management | |

PROFESSIONAL AFFILIATIONS

- Association of Clinical Research Professionals, member since 2019
- Regulatory Affairs Professionals Society, clinical research participant
- Medical Device Clinical Research Network, professional member

LANGUAGES

- English (Native)
- Spanish (Intermediate)

ADDITIONAL INFORMATION

Work Status : Authorized to work in United States. No sponsorship required.

REFERENCES

AVAILABLE ON REQUEST