



ISAAC WATANABE

Clinical Trial Assistant

CONTACT INFORMATION



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Meadville, PA 12345

KEY SKILLS

- Electronic Data Capture (EDC)
- Medidata
- Trial Master File (TMF)
- CTMS
- ICH Guidelines
- FDA Regulations
- HIPAA Compliance
- GCP
- Microsoft Office
- Query Resolution

ABOUT ME

Clinical trial support professional with 3 years of experience in EDC data analysis, TMF management, and regulatory document coordination across Phase I and Phase II studies. Improved participant retention from 80.9% to 92.6% over 8 months by coordinating reminder calls and visit scheduling for 74 enrolled subjects, while maintaining ICH compliance during sponsor-requested reviews.

PROFESSIONAL EXPERIENCE

Clinical Trial Assistant

Allegheny Creek Research Group, Meadville, PA | 2024 - Present

- Analyzed 247 data points monthly in EDC across 2 Phase II cardiovascular studies, reconciling query responses within 48 hours of issuance.
- Accelerated the study timeline for a Phase I metabolic trial by 16 days by reorganizing document collection workflows and pre-staging IRB submission materials.
- Improved participant retention rate from 80.9% to 92.6% over 8 months by coordinating reminder calls and visit scheduling for 74 enrolled subjects.
- Filed and indexed 318 essential documents in the TMF, maintaining compliance with ICH guidelines during 2 sponsor-requested reviews.
- Assisted with informed consent processes for 39 new participants, confirming eligibility criteria against protocol requirements before screening visits.

Clinical Research Intern

French Creek Biomedical Partners, Erie, PA | 2023 - 2024

- Entered and verified 143 data points monthly in Medidata for a Phase I dermatology study, resolving 11 open queries per week.
- Shortened the study timeline for the final data lock by 13 days by tracking outstanding case report forms and escalating overdue entries to site coordinators.
- Organized regulatory binders for 4 active protocols, scanning and uploading 261 source documents to the electronic TMF within 5 business days of receipt.

EDUCATION

BS Biology

