

Luna Olson

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SUMMARY

Senior pharmacovigilance professional with 11 years of experience supporting **multinational pharmaceutical** studies through accurate clinical trial **case management**, regulatory reporting, vendor oversight, and GxP compliance. Leads SAE, AESI, and pregnancy case operations, **Safety Reporting Plans**, ICSR compliance reviews, safety coding, case consistency, and **expedited reporting** activities. Partners with clinical, safety, quality, technology, and external service teams to resolve issues, deliver study specific training, and maintain inspection ready records. Uses KPIs, KQIs, CAPAs, SOP development, complex data review, privacy requirements, and drug safety database improvements to strengthen operational control. Experience includes regulatory inspections, vendor governance, regulatory agency submissions, and durable process improvements that support timely, accurate safety decisions.

EXPERIENCE

Senior Clinical Safety Case Manager January 2022 - Present
Meridian Therapeutics *Princeton, NJ*

Leads **clinical trial safety case management** across assigned studies, coordinating vendors, safety operations, quality partners, and study teams. Owns operational records, reporting controls, issue resolution, and process improvements that support compliant delivery.

- Directed **SAE, AESI**, and pregnancy case workflows, preserving timely reporting across multinational clinical studies.
- Maintained **Safety Reporting Plans** and responsibility records, giving study teams clear ownership and escalation paths.
- Reviewed vendor ICSR compliance, CAPAs, coding, and **case consistency** before **regulatory reporting** milestones.
- Established KPI and KQI reviews, exposing bottlenecks and guiding focused corrective actions across active studies.
- Trained vendors and pharmacovigilance colleagues on study requirements, improving alignment during case management handoffs.

Clinical Trial Safety Lead July 2018 - December 2021
Helix Pharmaceutical Sciences *Cambridge, MA*

Led **clinical trial safety** operations for multinational programs, serving as an operational contact for vendors and cross functional partners. Guided reporting analysis, procedure development, data quality, and inspection preparation across evolving study portfolios.

- Oversaw vendor processing for SAE, AESI, and **pregnancy cases**, resolving study questions through documented guidance.
- Prepared SUSAR reporting packages for **regulatory agencies**, supporting accurate and timely expedited clinical trial submissions.
- Analyzed complex safety datasets for **inter case consistency, intra case consistency**, and accurate event coding.
- Supported GxP inspections and audits with organized evidence, issue logs, and **inspection readiness** activities.
- Developed SOP updates from recurring case issues, giving teams clearer steps for consistent safety execution.

Pharmacovigilance Specialist March 2015 - June 2018
Arbor Life Sciences *Raleigh, NC*

Supported **clinical trial pharmacovigilance** delivery through case processing, safety data review, regulatory documentation, and vendor coordination. Contributed practical insight for compliant workflows, quality monitoring, and drug safety database improvements.

- Processed SAE and **AESI** information with controlled review steps, strengthening completeness before case submission.
- Applied medical coding checks to event and **drug terms**, reducing avoidable clarification cycles during quality review.
- Tracked vendor reporting performance through KPI summaries, helping senior staff target recurring operational gaps.
- Maintained privacy compliant case records and study documentation for cross functional safety team review.
- Contributed user feedback for **drug safety database enhancements**, improving fit between workflows and system functions.

Drug Safety Associate July 2012 - February 2015
Beacon Drug Safety Services *Durham, NC*

Handled foundational drug safety operations for clinical and post market work, supporting case intake, documentation, coding, quality review, and client communication. Built disciplined records management habits that supported progression into **clinical trial safety** leadership.

- Entered clinical safety cases into controlled systems, preserving complete source details for downstream assessment.
- Reviewed case narratives for missing information, prompting focused follow up with clinical operations contacts.
- Applied event and drug coding conventions under supervision, supporting consistent safety database records.
- Organized reporting documentation for client review, helping teams meet scheduled **case management** milestones.
- Recorded recurring processing questions for team guidance, contributing to smoother training and daily handoffs.

PROJECTS

Clinical Safety Database Upgrade 📅 2024

Partnered with safety, quality, and technology colleagues on workflow requirements for a drug safety database upgrade. Mapped case controls, review points, and reporting needs so system changes supported consistent clinical trial operations.

Vendor ICSR Compliance Review 📅 2021

Led a cross functional review of vendor ICSR reporting controls, connecting performance findings with CAPA actions, training needs, and inspection readiness. Shared practical findings that helped teams close gaps with clear ownership.

LEADERSHIP & AWARDS

- Selected Study Operations Lead, Pharmacovigilance Process Improvement Working Group
- Recognized Senior Contributor, Clinical Safety Vendor Governance Forum
- Commended for inspection ready clinical safety documentation and vendor collaboration

EDUCATION

Master of Science in Pharmaceutical Sciences
University of North Carolina at Chapel Hill GPA: 4.0
Coursework: Pharmacovigilance, Clinical Research, Drug Safety, Regulatory Affairs

2012
Chapel Hill, NC

Bachelor of Science in Biological Sciences
North Carolina State University GPA: 4.0
Coursework: Biology, Human Physiology, Microbiology, Biochemistry

2010
Raleigh, NC

CERTIFICATIONS

- Drug Safety and Pharmacovigilance Continuing Education 📅 2024
- GxP and Clinical Safety Compliance Training 📅 2026

TECHNICAL SKILLS

- **Case Management:** SAE, AESI, Pregnancy cases
- **Safety Reporting:** ICSR, SUSAR, Expedited reporting
- **Pharmacovigilance:** Clinical trials, Drug safety, Case processing
- **Regulatory Compliance:** GxP, Pharmacovigilance regulations, Legislation
- **Quality Management:** CAPA, SOPs, Quality systems
- **Safety Data Quality:** Event coding, Drug coding, Case consistency
- **Performance Metrics:** KPIs, KQIs, Vendor metrics
- **Vendor Operations:** Vendor oversight, Vendor training, Service providers
- **Inspection Readiness:** Regulatory inspections, Audits, Inspection support
- **Safety Databases:** Drug safety databases, Database upgrades, Data governance
- **Data Analysis:** Complex datasets, Safety analysis, Data review
- **Privacy Controls:** Privacy protection, Confidentiality, Data privacy

SKILLS

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|----------------------------------|--------------------------|--------------------------|-------------------|
| • Pharmacovigilance | • Pregnancy cases | • Expedited reporting | • SOP development |
| • Clinical trial case management | • ICSR reporting | • GxP compliance | • KPIs |
| • SAE | • SUSAR reporting | • Regulatory inspections | • KQIs |
| • AESI | • Safety Reporting Plans | • CAPA | |

PROFESSIONAL AFFILIATIONS

- Pharmacovigilance Process Improvement Working Group
- Clinical Safety Vendor Governance Forum
- Pharmaceutical Safety Operations Community

LANGUAGES

- English (Native)
- Spanish (Intermediate)

ADDITIONAL INFORMATION

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

REFERENCES

AVAILABLE ON REQUEST