**LUKE SHAW**

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**SUMMARY**

Expertise developed as a Clinical Research Site Manager, a Clinician in the delivery of primary health care and a Research Manager in hospital, academic, and corporate settings with extensive experience collaborating with clinical healthcare and industry study teams.

**THERAPEUTIC AREAS**

* **NEUROLOGY**: Epilepsy, Huntington’s Disease, Parkinson's Disease, Dementia, Multiple Sclerosis, Alzheimer's Disease
* **CIRCULATORY:** Stroke, Hypertension, Cardiomyopathy, Heart Failure, Bypass Graft, Aneurysm
* **ONCOLOGY:**  Bladder Cancer, Hemophilia, Breast Cancer, Brain Cancer, Cachexia, Anemias.
* **ENDOCRINE:** Hypogonadism, Obesity, BPH, Bladder Disorders, Metabolic Disorders.

**EXPERIENCE**

**Senior Clinical Research Associate •PPD**

MAY 2016 – Present

* Implements and monitor clinical trials to ensure sponsor and investigator obligations were met and were compliant with applicable local regulatory requirements and ICH-GCP guidelines
* Assess the qualification of potential investigative sites, initiated clinical trials at investigative sites, instructed site personnel on the proper conduct of clinical trials at investigative sites
* Review and verify accuracy of clinical trial data collected
* Works closely with other clinical team members to facilitate timely resolution of trial and/or clinical issues
* Perform essential document site file reconciliation
* Perform source document verification and query resolution
* Provides coaching, counseling, and feedback, and identifies developmental opportunities for assigned staff
* Ensured adherence to study timeline and budget
* Assure ongoing compliance with all system, regulatory, federal regulations and department policies.
* Review eCRFs for protocol adherence, protocol violations/deviations and query resolution.

**Clinical Research Associate II •PPD**

NOV 2014 – MAY 2016

* Monitored sites in order to ensure that studies are carried out according to the study protocol, ICON SOPs/WPDs, applicable regulations and the principles of ICH-GCP
* Provided a benchmark of monitoring competence to inexperienced/less experienced colleagues
* Provided field training and guidance to new Clinical Specialists
* Assisted and conducted Clinical Monitoring activities
* Data review, safety reporting and complaint handling
* Monitored and conducted on-site qualification, study initiation, interim monitoring and close-out monitoring visits at investigator sites.
* Identified and resolved vendor and client issues.
* Completed and submitted monitor trip reports for review and finalization.
* Reviewed eCRFs for protocol adherence, protocol violations/deviations and query resolution.
* Verified data in source documents are in agreement with source, initiate data query resolution and confirm resolution in timely manner.

**Clinical Research Associate I •COVANCE**

MAR 2011– NOV 2014

* Implemented and monitored clinical trial to ensure sponsor/investigator obligations are met and are compliant with applicable local requirements and FDA and ICH guidelines.
* Identified site issues and initiates correction plans based on monitoring reports.
* Conduct monitoring visits to confirm protocol compliance, assess qualifications of study personnel, ensure "Good Clinical Practice", and conduct close-out visits
* Verified drug accountability logs and storage requirements.
* Ensured subject safety and adverse event reporting to sponsor and IRB/IEC
* Managed patient in follow up on treatment trials, patients on non-treatment, retrospective and repository trials (including screening, eligibility review, consenting and ensuring completion of all protocol-required assessments).
* Served as a resource liaison for investigators and other researchers involved in the day to day management of patients on clinical trials.
* Responds to requests from investigative sites in a timely fashion.

**Clinical Research Study Coordinator • BOSTON CLINICAL TRIALS**

MAY 2008– MAR 2011

* Maintained effective/ongoing communication with research participants/sponsors increasing customer satisfaction.
* Coordinated appropriate and timely payments to participants ensuring sustained enrollments.
* Implemented approved recommendations for audit findings reducing repeat discrepancies.
* Oversaw adherence to study protocol for radiographic and clinical patient evaluations, treatment administration, and collection, processing, and shipping of biological specimens.
* Screened subjects from the daily clinic schedule and confirm eligibility of potential study subjects.
* Managed regulatory documents and clinical trial manuals; designed patient tracking charts using spreadsheets and formulated source documents and data collection charts.
* Facilitated completion of clinical charts and case report forms.
* Controlled quality of data retrieved from patient records and reported research activities to team.
* Knowledge of ICH and local regulatory authority regulations regarding drug research and development.

**EDUCATION**

**BACHELOR OF SCIENCE,** AUBURN UNIVERSITY