SHANE JUSTIN SMALL M.S.

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Professional Summary

Clinical Research professional with a cumulative twelve years of experience managing and monitoring clinical trials, procuring vendors, leading study start-up activities, communicating study progress to stakeholders, and ensuring regulatory requirements are met. Experienced and adept in working with rescue and high enrolling studies along with and Dependable and flexible with the ability to communicate effectively and efficiently. Values building relationships with employees across all levels of the organization.

Therapeutic Area

- Oncology
- Neurology
- Hematology
- Psychiatry
- Dermatology
- Endocrinology

Professional Experience

Pancreatic Cancer Network (IQVIA Biotech); Arlington Heights, IL
Senior Clinical Research Associate (Contract) **January 2023 –March 2024**

- Successfully monitored 87 patient site that was a part of a platform rescue study.
- Identified and resolved issues and deviations through effective communication with site staff and study team members resulting in on-time study database lock.
- Leveraged in-depth therapeutic area knowledge to guide trial protocols and ensure compliance with GCP, ICH guidelines, and SOPs, reinforcing the reliability and quality of trial outcomes.
- Managed and mentored CRA team in carrying out site management in collaboration with the project managers.
- Therapeutic Area/Phase: Oncology/Phase 2

Biomea Fusion (IQVIA Biotech); Arlington Heights, IL
Senior Clinical Research Associate (Contract) **January 2023 –January 2024**

- Leveraged in-depth therapeutic area knowledge to guide trial protocols and ensure compliance with GCP, ICH guidelines, and SOPs, reinforcing the reliability and quality of trial outcomes.
- Monitored 6 sites of a platform study.
- Ensure all data remains consistent with source documents.
- Collaborate with clinical study site and sponsor to troubleshoot and provide solutions to study-related issues.
- Conducted the following types of monitoring visits: Pre-study, Site initiation, interim, and closeout.
- Therapeutic Area/Phase: Hematology/Phase 1

Monopar Therapeutics, Inc.; Wilmette, IL
Senior Clinical Research Associate (Contract) **February 2023 – August 2023**
Senior Clinical Research Associate (Permanent) **April 2022 – January 2023**

- Mentored and trained contract monitors on protocol, monitoring, and company strategy
- Managed and implemented monitoring strategy for a team of 7 contract monitors
- Managed each monitor's deliverables to ensure company goals are met
- Reviewed monitoring reports to ensure site activities and compliance is being reported clearly and accurately
- Conducted the following types of monitoring visits: Pre-study, Site initiation, interim, and closeout
- Therapeutic Area/Phase: Oncology/Phase 2b/3 and 1b

Exicure, Inc.; Chicago, IL
Senior Clinical Research Associate (Permanent) **September 2020 – March 2022**

- Provided sponsor oversight for: site selection, monitoring, site issue mitigation, development and continuing review of project plans, site start-up, executive steering committee development, attend study specific meetings, and contract execution.
- Reviewed monitoring reports for assurance that CRO staff is monitoring and documenting site activities clearly and accurately.
- Liaison between vendors, CRO, and Exicure's management team.
- Co-managed vendor selection for expanding the current studies.
- Therapeutic Area/Phase: Oncology/1b/2 and 3; and Rare Disease (Neurology)/2

Xeris Pharmacueticals, Inc.; Chicago, IL
Clinical Research Associate (Permanent) **January 2020 – August 2020**

- Conducted routine and close-out monitoring visits

- Trained and mentored colleagues on monitoring practices
- Developed, implemented, and managed end of trial monitoring strategies to achieve study timelines and objectives
- Created a more robust monitoring program
- Ensured trial master files were inspection ready
- Acted as the main contact for investigational sites
- Therapeutic Area: Endocrine/1 and 3

Aptinyx, Inc (Previously Naurex Inc.); Evanston, IL
Senior Clinical Research Associate (Permanent) **March 2019 – November 2019**
Clinical Research Associate – Internal (Permanent) **June 2016 – March 2019**

- Administered clinical study plans and monitored progress to revise as necessary
- Oversaw study progress according to internal and vendor quality standards, SOPs, GCP, and ICH guidelines to fulfill all federal and local regulations
- Collaborated with study team to achieve successful execution and completion of clinical studies
- Coordinated cross-functional teams and worked with major functional area leads to identify, mitigate, and escalate project issues
- Ensured solutions to clinical study issues were implemented in a timely and efficient fashion
- Evaluated progress across teams to ensure over 85% of milestone achievements were met
- Developed clinical study protocols and study designs
- Created and maintained trial master files for assigned projects through collaboration with investigative site and field monitoring personnel to ensure audit readiness
- Conducted Pre-Study, Site Initiation, Routine Monitoring, and Study Close-Out visits, including the development of report templates and monitoring tools for site visits
- Finalized and negotiated project contracts across financial, legal, and clinical teams
- Trained and continuously mentored new team members
- Curated vendor and site selection
- Introduced company SOPs, Work Instructions, and Flow Charts
- Therapeutic Area/Phase: Mental Health/1 and 2; and Neurology/1 and 2

Quality Assurance Technical Specialist, Clinical (Permanent) **February 2015 – June 2016**

- Edited standard operating procedures, change control requests, and training materials as directed by Quality Management for quality impact to GCPs
- Oversaw employee training records
- Synchronized efforts between functional groups to ensure compliance and overall clinical objectives
- Orchestrated internal/external due diligence, compliance, and CRO/Vendor qualification audits against regulatory authorities
- Facilitated employee training through collaboration with multiple training vendors and consultants
- Audited sites and vendors through individualized custom plans

Advanced Clinical; Deerfield, IL
In-House Clinical Research Associate (Permanent) **July 2014 – February 2015**

- Conducted in-house clinical monitoring tasks for Phase I, II, and III clinical trials
- Spearheaded processes that provided a more effective review of study documents
- Co-led the creation of a clinical monitoring application system
- Produced a manual to navigate through the clinical monitoring application for current and new employees
- Functioned as a liaison between different departments - including data management, regulatory, clinical monitoring, and project management
- Aggregated study start-up documents for clinical trials
- Conducted routine monitoring visits
- Reconciled data sets between the Master Project Workbook, Document Reconciliation Workbook, Clinical Monitoring Reports, and the Electronic Data Capturing System
- Therapeutic Area/Phase: Dermatology/2; Reproductive/3

The University of Chicago; Hyde Park, IL
Clinical Research Associate 1 (Study Coordinator) (Permanent) **February 2013 – July 2014**

- Managed, maintained, and coordinated clinical oncology trials with research teams, outside institutions, and sponsors to standards of all applicable regulatory agencies

- Assured data entered into EDC systems meet ALCOA-plus framework
- Created a Clinical Research Associate training manual
- Resolved queries administered from doctors, research staff, CRAs, and medical monitors
- Scheduled and ordered tests by coordinating with inside and outside departments and institutions mandated by research protocols required at specified time points
- Created source documents through utilization of study protocols and EDC systems
- Setup and lead meetings including site initiation visits, monitoring visits, close-out visits, and data safety monitoring with multiple departments at the institution
- Conducted a gap analysis between institution's SOPs and the actual procedures and practices required by study protocols
- Therapeutic Area/Phase: Oncology/1, 2, and 3

Hoffman-Barrington Internal Medicine Specialist; Hoffman Estates, IL
Administrative Assistant (Permanent) **September 2011-May 2013**

- Scheduled patients for appointments
- Liaison between nurses, doctor, and patients
- Prepared patient charts for upcoming appointments
- Collected and prepared data inquired by third party organizations for case studies
- Performed document audits on policies and procedures in regards to patient administration

EDUCATION & CREDENTIALS

Barnett International
Monitoring Clinical Drug Studies: Beginner **August 2018**
30-Hour Clinical Research Auditing Certification Program **May 2016**
American Society for Quality
Certified Quality Auditor **December 2015 – August 2018**
Project Management Institute
Certified Associate in Project Management (CAPM) **April 2014 – April 2019**
Rush University; Chicago, Illinois
Master of Science*, Biotechnology* **June 2012**
Bradley University, Peoria, Illinois
Bachelor of Science, *Construction* **December 2010**