



Ms. Shelly T. Reid

Shelly Reid was born into her family as the first maternal grandchild and great grandchild in a small, rural community on the outskirts of Georgetown, SC.

She began her college career at the University of North Carolina located in Greensboro, NC in 2008 not only as a pre-nursing major but also as the first person in her immediate family to attend college. Her desire for nursing started when her maternal grandmother was diagnosed with breast cancer and her paternal grandmother, uterine cancer. As a pre-nursing major, she decided to take an introduction course to public health and this is where she discovered her love to not only treat as a medical professional but to prevent as a public health professional. She eventually graduated in May 2013 with a bachelor's degree in Public Health – Health Education.

She applied to nursing school in the summer of 2013 and was accepted however her heart was deeply yearning for the epidemiology research aspect of public health so while waiting to start nursing school in the Fall, she decided to make a life changing decision to decline their invitation. She would spend the next two years searching for a job in public health before deciding to further her education in the Master of Public Health – Health Promotion program at Liberty University located in Lynchburg, VA. Shortly after starting this journey, she was approached by a former classmate about a clinical research position with a company called Parexel. This was the beginning of her clinical research career.

EDUCATION

- Liberty University, Lynchburg, VA

Master of Public Health, Sep 2016

- University of North Carolina – Greensboro, Greensboro, NC

Bachelor of Science – Public Health, May 2013

PROFESSIONAL EXPERIENCE

PPD, CLAYTON, NORTH CAROLINA (HOMEBASED), USA

START-UP TEAM MANAGER, MAY 2021 - PRESENT

Leads, executes, and achieves site activation and amendment deliverables within a region or globally, within the assigned projects, by managing the scope of work to timelines, costs and quality. Ensures all project deliverables meet contracted and customer's expectations, providing accurate projections, reports and updates, as well as ongoing risk assessments. Develops and

maintains strategic relationships with customers in alignment with assigned projects, ensuring individual project targets are met and services are provided with the highest quality standards. Serves as the primary startup contact for the Project Lead and client.

PAREXEL INTERNATIONAL, DURHAM, NORTH CAROLINA, USA

INITIATION CLINICAL RESEARCH ASSOCIATE II, JUL 2020 – MAY 2021

INITIATION CLINICAL SITE MANAGER II, MAR 2020 – JUN 2020

Identified sites during feasibility along with the Feasibility Lead, Project Lead and client-based contacts on feasibility survey responses. Prepared, negotiated as well as facilitated the execution of confidentiality agreements (CDAs) before the Pre-Selection Visit. Collected and reviewed regulatory documents and informed consent forms from the site following client site selection. Attended client calls to provide start up updates/projections. Negotiated informed consent forms with the site and the client while ensuring country/state requirements are met. Submitted study level documents to the Central Institutional Review Board (IRB) assigned. Served as direct contact with assigned clinical sites until site activation has been obtained. Provided mentorship to level II and senior Initiation Clinical Research Associates.

CLINICAL SITE MANAGER I (CLINICAL RESEARCH ASSOCIATE I), OCT 2017 – MAY 2018

Conducted Pre-Selection Visits, Initiation Visits, Monitoring Visits and Close-Out Visits on-site as well as remote. Wrote monitoring visit reports that met internal and client compliance. Performed Source Data Verification reviews as well as ensured the electronic data capture system was in compliance with internal and client expectations. Identified queries and worked with the site to achieve resolution. Assessed and managed test article/study supply including supply accountability and destruction/return status. Maintained the electronic Trial Master File as well as the on-site Investigator/Pharmacy Site File binders. Served as direct contact with assigned clinical sites. Assisted site with any initial and subsequent Institutional Review Board (IRB) submissions. Reviewed site recruitment plans and drove recruitment with the site staff on an ongoing basis. Reviewed site contracts and followed up on pending investigator site payments. Trained or retrained site staff on study processes.

CLINICAL MONITORING ASSOCIATE I, JAN 2016 – JAN 2018

Conducted Pre-Selection Visits and Site Management Calls remotely. Assisted site with any initial and subsequent IRB submissions. Collected and reviewed required essential regulatory documents from the site to ensure first time quality. Supported collection and minor negotiation of informed consent forms while working closely with the Clinical Trials Specialist. Created start – up projections based on site discussions and informed Project Management of any reprojection rationales. Reviewed site recruitment plans and drove recruitment with the site staff on an ongoing basis. Reviewed site contracts and followed up on pending investigator site payments. Assessed and managed test article/study supply including supply accountability and destruction/return status. Maintained the electronic Trial Master File. Served as direct contact with assigned clinical sites. Participated on the Clinical Monitoring Associate (CMA) Training Committee to provide monthly/quarterly training sessions as needed to CMAs.

SYNEOS HEALTH, MORRISVILLE, NORTH CAROLINA, USA

SSU AND REGULATORY SPECIALIST II (ACTING SSU LEAD – USA ONLY STUDIES), JUN 2018 – FEB 2020

Created study level templates and guidelines. Distributed and collected as well as reviewed and/or approved high quality country and site specific essential regulatory documents. Completed study and site level IRB submissions and notifications. Customized, reviewed and negotiated informed consent forms directly with the site, IRB or client. Created projections based on site discussions and timelines. Communicated projections to the client and provided rationales for all reprojections. Updated and maintained appropriate CTMS as well as the electronic TMF. Conducted new hire training sessions to educate on the Essential Document Review, Soft Skills and System/Software portions. Provided mentorship to level I and level II SSU and Regulatory Specialist.

SSU AND PROJECT DELIVERY LEAD TRAINEE, SEP 2019 – FEB 2020

Oversaw SSU timelines to site activation. Collaborated with major functional area leads to identify and evaluate fundamental issues pertaining to SSU. Ensured all project deliverables met the internal and customers' expectations as per contracted deliverables, provided accurate projections, reports and updates as well as any risk assessments. Oversaw delivery of executed Clinical Trial Agreements (CTAs) and investigator budgets. Reviewed the project SSU budget with functional leads against project milestones. Established essential document collection leading to site activation. Assisted in development of informed consent forms in collaboration with the Project Manager or medical department as well as other core submission documents. Developed plans in accordance with Standard Operating Procedures (SOPs) and/or client-scoped processes.

CLINICAL TRIAL EXPERIENCE

- Arthritis: A Multicenter, Open-label (Part A) Followed by a Randomized, Double-blind, Parallel-group, Placebo Controlled Study (Part B) to Evaluate Maintenance of Remission in Subjects With Active Axial Spondyloarthritis (axSpA) Receiving Either XXX 200 mg Q2W or 200 mg Q4W as Compared to Placebo
- Cardiology: A Phase Ia/b Randomized, Single-blinded, Placebo-controlled Study to Evaluate the Safety, Tolerability, Immunogenicity, and Pharmacokinetics of Single Ascending Doses of XXX in Healthy Volunteers and Multiple Ascending Doses of AZD3427 in Patients With Heart Failure (HFrEF and HFpEF)
- Gastrointestinal: A Randomized, Open-label, Phase 2 Study to Evaluate Safety and Efficacy of XXX in Subjects With Primary Sclerosing Cholangitis (PSC)
- Lung Cancer: A Phase 2 Multicenter Study of XXX in Patients with Metastatic Non-Small-Cell Lung Cancer

- Lung Cancer: A Randomized Phase 3 Multicenter Open-label Study to Compare the Efficacy of XXX Versus Docetaxel in Non-Small Cell Lung Cancer Patients With EGFR Exon 20 Insertion Mutations Who Have Received Platinum-Based Chemotherapy
- Lymphoma: XXX: A Platform Protocol for the Treatment of Relapsed/Refractory Aggressive Non-Hodgkin's Lymphoma
- Ocular: XXX Versus Trabeculectomy in Open-angle Glaucoma
- Ocular: A Multicenter, Double-Masked, Randomized, Dose-Ranging Trial to Evaluate the Efficacy and Safety of XXX in Subjects With Neovascular Age-Related Macular Degeneration (AMD) (PANDA-1)
- Ocular: A Multicenter, Double-Masked, Randomized, Dose-Ranging Trial to Evaluate the Efficacy and Safety of XXX in Subjects With Neovascular Age-Related Macular Degeneration (AMD) (PANDA-2)
- Osteoarthritis: A Randomized, Double-Blind, Placebo-Controlled, Multi-Center, Phase 3 Study to Determine the Efficacy of XXX in Subjects With Kellgren and Lawrence Grade (KLG) 2 or 3 Osteoarthritis of the Knee
- Ovarian Cancer: An Open Label Randomized Active Controlled Phase II Clinical Study to Assess the Efficacy and Safety of XXX Plus Paclitaxel Versus Paclitaxel in Patients With Platinum-Resistant Ovarian Cancer
- Parkinson's Disease: A Multicenter, Randomized, Active-controlled, Double-blind, Double-dummy, Parallel Group Clinical Trial, Investigating the Efficacy, Safety, and Tolerability of Continuous Subcutaneous XXX Infusion in Comparison to Oral IR-LD/CD in Subjects With Parkinson's Disease Experiencing Motor Fluctuations (BouNDless)
- Psoriasis: A Phase 3, Multicenter, Randomized, Double-Blind, Placebo- and Active Comparator-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of XXX in Adult Subjects With Moderate to Severe Chronic Plaque Psoriasis
- Psychiatric: A Phase 3, Multicenter, Randomized, Double-blind Trial of Fixed-Dose XXX as Combination Therapy With Sertraline in the Treatment of Adults With Post-traumatic Stress Disorder
- Psychiatric: A Phase 3, Multicenter, Randomized, Double-blind Trial of XXX as Combination Therapy With Sertraline in the Treatment of Adults With Post-traumatic Stress Disorder
- Schizophrenia: A Long-term, Multicenter, Open-label Trial to Evaluate the Safety and Tolerability of Flexible-Dose XXX as Maintenance Treatment in Adolescents (13-17 Years Old) With Schizophrenia
- Schizophrenia: A Multicenter, Randomized, Double-blind, Placebo- and Active-controlled Trial to Evaluate the Efficacy of XXX Monotherapy for the Treatment in Adolescents (13-17 Years Old) With Schizophrenia

· Vaccine: Phase 3, Randomized, Placebo Controlled, Double-blind, Multicenter, Stratified Study of XXX Plus Standard of Care Versus Placebo Plus Standard of Care in Mild to Moderately Symptomatic Hospitalized Covid-19 Patients