Curtis L. Wilson, Jr.
[redacted]

Professional Summary

A clinical trials research professional with extensive experience in the clinical setting, and within the contract research organization and sponsor environments. Proven record of increasing responsibility, based on a versatile and transferable skill set. An advanced understanding of the importance of improving clinical/research site staffers' experiences in clinical trials. A passionate and trusted professional with a desire to serve clients, and ultimately patients, through the reliable and competent monitoring of clinical trials.

Core Competencies

- Adaptability
- Engaged leadership
- Collaborative communicator
- Detail-oriented
- Results-driven
- Problem-solving
- Teamwork-Focused
- Relationship builder
- Integrity
- Ambitious learner
- Commitment to excellence
- Efficient and Reliable

Employment Experience

Independent Contractor ***Mar 2020 - Present***

Senior Clinical Research Associate on assignment for various Sponsors/CROs

Bayer US | Whippany, New Jersey ***Jan 2017 – Mar 2020***

Senior Manager, Country Lead Monitor (CLM), Recruitment

- Exemplified the Bayer LIFE values--- Leadership, Integrity, Flexibility, Efficiency.

- Developed strategic patient recruitment and retention plans per clinical research trial, in collaboration with the local study team, other local stakeholders, as well as with global clinical trial management.
  - Supported local/global trial teams through the recruitment period/maintenance phases
  - Detected anomalies and areas of immediate concern, by offering solutions via root-cause analysis
  - Identified and measured targets for determining success for different recruitment and retention strategies, and through process innovation feedback loops, refined strategies and tactics as needed

- Led protocol and site feasibility for the US site management team once a new global trial was announced.
  - Identified and recruited target sites for participation into Bayer clinical trials, specific to a therapeutic area (i.e. cardiovascular, cardiorenal, cerebrovascular, oncology, hemophilia)
  - Assessed protocol data to identify key challenges for the US, specific to the inclusion and exclusion criteria, availability of the required patient population, and the trial procedures in the test schedule
  - Coordinated with Medical Affairs, Study-Start-Up, Contracts, Legal, and Regulatory to gain their insights into key deliverables

- Provided a comprehensive US country assessment report for executive leadership that outlined key challenges, the medical landscape in the US specific to the trial indication, projected US country enrollment forecasts (i.e. pre-screening, screening numbers, screen failures, and randomizations), and the US/global regulatory environment

- Established relationships with patient advocacy groups that served trial populations specific to the Bayer pipeline of clinical trials, with the purpose of increasing awareness of Bayer clinical trials within these organizations and the patients they served.

- Built therapeutic area expertise based on insights from previous feasibilities, competitive intelligence, and the use of databases (e.g. IMPACT & other internal data sources, Citeline [Trialtrove and Sitetrove], clinicaltrials.gov, self-assigned independent study).

Pharmaceutical Research Associates, Inc.* | *Raleigh, North Carolina July 2015 - Jan 2017

Clinical Trial Liaison I (on assignment for Bayer US)

- Exemplified the Bayer LIFE values--- Leadership, Integrity, Flexibility, Efficiency.
- Identified and implemented recruitment and retention strategies for each clinical trial assigned.
- Fostered and grew long-term relationships with sites that Bayer identified as a high-value/strategic site.
- Provided detailed reports when interacting with Principal Investigators during site engagement visits.
- Assisted clinical research associates and local project managers with resolving complex site-based issues.
- Created internally-facing and externally-facing educational material to provide clear and meaningful data regarding the science, trial design and scope, and important enrollment caps/potential barriers.

Clintel Services, Inc.* | *Germantown, Maryland April 2013 – July 2015

Contract Senior Oncology Clinical Research Associate (on assignment for Bayer US)

- Exemplified the Bayer LIFE values--- Leadership, Integrity, Flexibility, Efficiency.
- Performed study Site Manager activities, including, but not limited to oversight of investigator clinical trial sites' conduct to ensure adherence to the study protocol, US Federal regulations, International Conference on Harmonization's Good Clinical Practice (ICH-GCP) guidelines, and Bayer standard operating procedures (SOPs).
    - Performed 100% source document verification
    - Maintained site regulatory files and the sponsor site files
    - Verified investigational product shipment, storage, dispensing and disposal requirements were met
    - Prepared written, detailed reports for each site visit type (i.e. site initiation visits, routine monitoring visits, closeout visits, site engagement visits/site motivational visits, audits)
- Served as the primary contact for clinical trial site staff.
    - Assisted site staff with requests of varying complexity and urgency
    - Collaborated with clinical staff to increase staff satisfaction and increase compliance within their clinical trial program
- Contributed to the US site and investigator selection process for cardiovascular/cardiorenal clinical trials.
- Conducted clinical site staff training throughout the life of the clinical trials.
- Trained and mentored junior clinical research associates.

Randstad Pharma | Woburn, Massachusetts ***Aug 2012 – Mar 2013***

Contract Senior Oncology Clinical Research Associate

- Monitored an expanded access oncology clinical trial according to US Federal regulations, ICH-GCP guidelines, and the Sponsor's SOPs.
- Assisted with special tasks at the Sponsor's request (e.g. co-monitoring visits, drug accountability support, and complex investigational new drug report reconciliation).
- Performed clinical site staff training.

Pharmanet, Inc.| Princeton, New Jersey ***Nov 2007 – Mar 2011***

Oncology Clinical Research Associate II

- Conducted pre-study, site initiation, routine and closeout visits at investigative clinical sites.
- Performed site staff oversight to confirm compliance with US Federal regulations, ICH-GCP compliance and Sponsor SOPs.
- Obtained essential documents and administrative documents from investigative clinical sites, and reviewed the documents for appropriateness and completeness.
- Prepared and processed serious adverse event reports.
- Reviewed and verified case report forms (CRFs) and other clinical data for accuracy and completeness, and generated queries as needed.
- Resolved queries of CRF data with investigative clinical site personnel.

Carle Clinic Association - Cancer Center * | Urbana, Illinois ***Oct 2003 – Aug 2007***

Clinical Research Associate I

- Exemplified the Carle Clinic Association mission statement--- "Provide Superior Healthcare".
- Partnered with medical oncologists and radiation oncologists to identify potential patients for participation in an oncology clinical trial, in a fast-paced and highly technical environment.
- Conducted patient clinical trial education visits (i.e. informed consent), as well as re-consent visits.
- Coordinated and drafted orders for oncologist visits, laboratory blood work, imaging visits, and chemotherapy infusions for patients participating in a clinical trial.
- Responsible for assessing and documenting toxicities (side effects) experienced by clinical trial participants.
- Managed key trial activities including: maintaining required patient case report from, regulatory documents, patient medical records, patient trial folders, and performing quality control checks (i.e. audits).
- Communicated with physicians, nurses, social workers, and research staff regarding all aspects of a patient's clinical trial participation and care.

Education

- University of Illinois @ Urbana-Champaign
  Degree: Biology

Significant Contributions (2015 -present)

Cardiovascular

- Lead sponsor of the Bayer and Veterans Administration (VA)--- Cooperative Research and Development Agreement (CRADA)
    - Fully executed in 2020.

- Pharma 2030 US core member (2018 - 2020)
    - Internal Bayer pilot initiative designed to position Bayer to conduct trials in the growing digital age, and to make trials more patient-centric.

- US Decentralized Clinical Trial pilot initiative contributor (2018 - 2020)
    - Selected to attend Drug Information Associates 2019 Conference in San Diego--- met with vendors specializing in DCT conduct and associated processes (June 2019).
    - Conducted a vendor assessment visit with a potential DCT partner (MRN) on behalf of the US DCT team.

- US site outreach lead for the FXIa inhibitor program- 3 studies (2019).
- Executed the most Bayer Framework CDAs of any Bayer US employee (2019).
- Performed most US site outreach contacts among the US MCR team (2019).

- Global Patient Retention Panel inaugural core member (Diabetic Kidney Disease program-DKD) 2017-2020
    - Only non-global team colleague throughout the world invited to be a member.
    - Author of the US country level patient retention action plan.
    - Organized with the National Kidney Foundation (NKF), to have a Patient speaker at the US patient retention summit meeting (June 2018).

    - Creator of the US FUSION-DKD initiative (2018)
        - Designed the site staff application/intake form used by country teams globally.
        - Within the US, prior attempts resulted in only 2 interested sites; with my initiative and re-branding, 50+ applications were received.
        - Interviewed approximately 30 US site staff coordinators to function as US country representatives under the global retention initiative; selected 7 and awarded them contracts.

    - US host for December 2017, in-person, patient retention core team meeting--- attendees included site staff and colleagues from around the world
        - Oversaw entire meeting planning and coordination, obtained approval authorizations from the various international compliance attorneys, and obtained visas for international attendees as needed.

- DKD Global Vendor Management Team (2016-2020)
    - Only non-global team colleague throughout the world invited to be a member.
    - Supported the two largest, internally managed clinical trials in Bayer history.

- Aided in the design, approval and implementation of the:
  - Recruitment outreach printed materials and patient support items which included printed materials (12 unique items), and 3 patient support items (pedometer, diabetic socks, tote bag),
  - US recruitment outreach media campaign (17 tactics), including a website, call center, and TV commercial,
  - Retention and site engagement text messaging, and app/push notifications resource.

- US DKD recruitment strategy site management team lead (2017-2018)
  - Achieved outreach to 10 external patient advocacy groups.
  - DKD commercial aired on CCTV in US Bayer buildings.
  - Coordinated with Bayer US Communications/Media team, and with Bayer US Medical Affairs to select key Principal Investigators to be interviewed by local journalists to increase awareness of the DKD program at local levels.
  - DKD information published in Bayer's internal newsletter (East Coast Daily News).
  - DKD print add featured in "Heartbeat" magazine; a publication of Mended Hearts.
  - DKD program listed on the NKF's website, NKF social media blasts, and emails sent to NKF's subscriber database.

- US DKD cross-functional team workstream coordinator---- included US Medical Affairs, US New Product Commercialization, US Communications, US Media Relations, US Advocacy, US Launch Cardiorenal, US Social Media (2017-2018).

- Global site engagement and customer centricity initiative - US representative (2016-2017)
  - A global pilot initiative aimed at improving clinical sites' experiences when conducting a Bayer clinical trial.
  - Participated in the screening and beta testing of proposed new technologies for clinical development (e.g. Investigator portal).
  - Provided strategic feedback to the initiative's team leads on ways to impact the customer experience.

- June 2015--- most named US CRA by site staff in the Health Care Professional Site Staff Satisfaction Survey.

Oncology

- Creator of a country recruitment and engagement plan template used in a Bayer oncology trial.

- Specifically requested by a global feasibility strategist colleague to lead a new US feasibility project that he was overseeing based on our prior interactions on a feasibility deliverable.

- First Operational Point of Contact (OPOC), under a new Bayer initiative in Oncology, to visit their assigned high-value site--- Memorial Sloan Kettering Cancer Center (Dec 2019).

- First OPOC to create an engagement and communication plan under new initiative (Feb 2020).

Hemophilia

- Supported the development of pediatric patient and family educational and recruitment material.

- Recruitment challenge engagement and issue resolution.
  - Identified a core issue that was perhaps contributing to the lack of enrollment for over a year at the only remaining US site.
  - The site was not listed as "recruiting" on www.clinicaltrials.gov

- Consulted with the global trial registry team to confirm that they misunderstood the clinicaltrials.gov terminology and that in order for this specific site to be listed as “open”, they needed to change the designation.