Shawna Marie Brown

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Work Experience:

Medpace - *Maastricht , Netherlands*

Present — **Clinical Trial Manager**

Lead clinical team in all aspects of trial activities, providing daily work direction to support needs of clinical site and work to meet goals and timelines of sponsor, including determining study objectives, strategy, scope and procedures to meet sponsor's needs:

- Coordinate and manage planning and execution of global clinical research trials from start-up through maintenance to close-out
- Develop study management tools, study-specific plans and materials
- Provide input on study protocol, data analysis plan, data clean-up results, analysis and final study report
- Assure Good Clinical Practice standards in line with medical device regulations and local regulations in each country involved
- Identify and anticipate potential issues and challenges, develop solutions
- Oversee cross-functional team and act as primary contact for sponsor and study team members for project specific issues
- Provide management oversight of Clinical Trial Assistants, Clinical Research Associates and other clinical study team members
- Review and approve monitoring visit reports, data reports and safety reports
- Monitor and report key project indicators, task order and monthly budget units

Project Coordinator

- Engage in clinical trial management on a day-to-day level
- Create and maintain project timelines and project-specific status reports
- Coordinate site feasibility, activation, and progress assessments
- Educate the study team on study-specific protocols and procedures
- Provide oversight of electronic Trial Master File (TMF), including creation of project-specific TMF Specifications and management of TMF quality reviews

Feb 2017

Medical College of Wisconsin - *Milwaukee, WI*

May 2016 — **Research Program Manager**

- Managed departmental research of up to 30 simultaneous studies
- Maintained up-to-date understanding and compliance with medical research standards of FDA and local Institutional Review Board (IRB)
- Developed and audited department processes and strategy including workflow, lab standards, and compliance training
- Wrote, edited and contributed to abstracts, manuscripts and publications
- Oversaw regulatory maintenance, recruitment, data and sample collection
- Reviewed and recommended funding opportunities and assisted investigators in development of grant budgets for proposed projects
- Managed budgets for active funding proposals
- Reported to sponsors and boards regarding study deviations, progress, findings and financial status
- Provided basic statistical analysis on study data and presented results at conferences
- Developed, built and supported study databases
- Communicated with vendors and other academic departments to complete studies and publications

Aug 2014

Clinical Research Coordinator

- Collected project data and enrolled participants
- Compiled and maintained regulatory and subject files
- Assured compliance with regulatory, institutional and agency policies
- Collaborated on the development of program materials and marketing materials including website development
- Maintained reporting timelines and provided reports to department administration and funding agencies
- Coordinated outreach to community organizations and outside programs and organized site visits and special events

Nov 2010

Additional Information:

Location: Born, Limburg, Netherlands (residence permit holder since 2016)
Nationality: Canadian

Education:

University of Wisconsin - Parkside
Bachelor of Science in Psychology
Minor in Computer Science
Web Development Certification

Skills and Languages:

English (native)
Dutch (CFER B2 certified)
Technical expertise in data analysis programs, Excel, MS Project and all Microsoft Office products
Public speaking
Writing and editing
Organized
Detail oriented
Problem solving and analytics

Professional Affiliations:

PHACE Syndrome Community,
Board Member (2015 - 2016)

Pediatric Dermatology Research Alliance (PeDRA),
Member (2014 - 2016)