COLIN McGREGOR

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PROFILE

Certified oncology clinical research coordinator managing an extensive portfolio of Phase 1 cancer drug trials. Detail-oriented, excellent under pressure, and knowledgeable about multiple disease sites (thoracic, neurology, sarcoma, melanoma). Experienced in implementing complex pharmacokinetic timelines, maintaining organized and complete source documentation, and managing multiple collaborating departments. Looking to further my career in the sponsor-side clinical research industry.

SKILLS AND CERTIFICATIONS

- ◆ Certified Clinical Research Coordinator (ACRP)
- March 2024
- ◆ ICH/GCP guidelines and federal/local research regulations
- ◆ AE/SAE reporting
- ◆ PKs with multiple reference drugs
- ◆ Solid tumor response criteria (RECIST 1.1; iRECIST)
- ◆ Delegating work appropriately and training new hires

- Use of clinical project management tools (EDC, IVRS, CTMS, various EMRs)
- ◆ Experience working in phase I, II, and III clinical trials
- ◆ Informed consent/subject eligibility
- ◆ Source data verification
- Analytical and critical thinking, active listening, and empathy
- ◆ Dose escalation/expansion/backfill cohorts; associated DLTs

WORK HISTORY

LEAD CLINICAL ONCOLOGY RESEARCH COORDINATOR ROSWELL PARK COMPREHENSIVE CANCER CENTER – 2022-PRESENT

- Supervisor and primary support for 15 solid-tumor protocols; combined 20-30 active patients and 60-70 on follow-up
 - Successfully opened 4 pharmaceutical-sponsored trials and ran 7 others, including 4 phase 1 trials with PKs for as many as 3 simultaneous reference drugs
 - Assessed protocols for efficacy, feasibility, and subject safety; reviewed inclusion/exclusion criteria; facilitated open discussions between sponsor and investigator
 - Managed high-accruing, multi-phase IIT w/initial dose escalation
 - Ran two National Cooperative Group studies on site level
- Completed in-house monitoring SDV tasks for an investigator-initiated trial (total of 21 patients over roughly 1 year) and shadowed in-house CRAs
- Assists in updating and rewriting existing standard operating procedures to adapt to evolving IRB, FDA, and NIH regulations, as well as FDA audit findings

- Maintains open communication between sponsor, CRO, investigator, processing labs, treatment center, site data management, and home clinic
- Provides oversight and training of new clinical research coordinators, assistants, and laboratory employees
- Ensured timely and consistent long-term follow-up of 60-70 patients while consistently recruiting at high-accruing site
- Manages 4 data-entry employees and delegated tasks appropriately
- Worked in multiple EDC databases (including REDCap, iMedidata RAVE, Advarra, Veeva) and electronic medical records (Epic, Allscripts EHR)
- Obtains informed consent, demographics, medical history, concomitant medications, and documented appropriately in source
 - Maintains accurate case report forms, source binders, and electronic source
- Serves as point-of-contact during 6 site initiation visits and hundreds of investigator meetings
- Ensured compliance with 1572 and DOA
- Coordinates sponsor-supplied equipment approval and testing
- Completed and compiled continuing review documentation
- Reports, documents, and communicates routine AEs, SAEs, AESIs, and DLTs as applicable and ensures subject safety in accordance with IRB guidelines
- Verifies compliance with GCP, FDA, ICH, and any local regulations
- Documents protocol deviations and reportable problems; assisted sponsors with study startup/ closeout
- Provides timely, efficient, and friendly assistance to monitors

CLINICAL NEUROLOGY RESEARCH COORDINATOR

JOHNS HOPKINS MEDICAL INSTITUTE 2020-2022 (RESEARCH ASSISTANT 2017-2020)

- Coordinator of 55 patients on treatment or follow-up
- Served as coordinator on 6 protocols involving neurodegenerative movement disorder patients
- Designed and built pilot study aiming to test investigational walking device (see Publications)
- Attended and participated in investigator/staff meetings. Provided guidance on progress and participant timelines
- Obtained informed consent, baseline information, financial disclosure statements
- Ensured compliance with ICH, GCP, FDA, and local guidelines
- Coordinated meetings and data reviews with sister sites and maintained rapport with colleagues across the world
- Administered tests and questionnaires including the MoCA, Purdue Pegboard Assessment, Box and Blocks Test, Hopkins Verbal Learning Assessment, Trail-Making Tests, and Stroop Tests
- Completed and compiled continuing review documentation
- Actively attended several physicians' clinic days to distribute IRB-approved recruitment materials to prospective patients
- Participated in journal club meetings and suggested papers for discussion

PUBLICATIONS

- Bastepe-Gray S, Wainwright L, Lanham DC, Gomez G, Kim JS, Forshee Z, Kaas B, McCoy A, McGregor C, Moukheiber E, Rajan S, Suarez-Cedeno G, Wang J, Brennan S, Coughlin S, Kang K, Pantelyat A. GuitarPD: A Randomized Pilot Study on the Impact of Nontraditional Guitar Instruction on Functional Movement and Well-Being in Parkinson's Disease. Parkinsons Dis. 2022 Jun 25;2022:1061045. doi: 10.1155/2022/1061045. PMID: 35795456; PMCID: PMC9252755.
- Zajac JA, Porciuncula F, Cavanaugh JT, McGregor C, Harris BA, Smayda KE, Awad LN, Pantelyat A, Ellis TD. Feasibility and Proof-of-Concept of Delivering an Autonomous Music-Based Digital Walking Intervention to Persons with Parkinson's Disease in a Naturalistic Setting. J Parkinsons Dis. 2023;13(7):1253-1265. doi: 10.3233/JPD-230169. PMID: 37840504; PMCID: PMC10657706.

LEADERSHIP

BOARD OF DIRECTORS - STEINWAY SERIES AT SILO HILL (2018-PRESENT)

- Youngest member ever elected to board; one-year volunteer before being elected
- Liaison for Parkinson's disease research and funding opportunities
- ♦ Sought out studies across the United States that led to a combined ~\$20,000 in research funding
- Assisted in organizing 22 classical music performances, each of which raises around
- \$3000-4000 to fund Parkinson's Disease research

EDUCATION

JOHNS HOPKINS UNIVERSITY - BACHELOR OF ARTS: COGNITIVE SCIENCE (2020)

OTHER INTERESTS/SKILLS

- Skills: WordPress, basic HTML/CSS/web management, public relations, public speaking, writing (scientific and creative)
- Music:
 - Graduate of Juilliard School Pre-College Program (2016, Violin Performance)
 - Winner of Hopkins Symphony Orchestra bi-annual concerto competition performed Mendelssohn's Violin Concerto in E Minor, Op. 64, in its entirety as a soloist
 - ◆ 19 years' experience playing violin; 5 years' experience playing guitar
 - Knowledgeable in advanced music theory and counterpoint
- Interests: music theory of popular songs, license plate collecting/archiving, interior design, houseplant care (notably rare Hoyas), songwriting, and road-tripping in rural Michigan and Colorado