# NOOPUR MODI

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- Dynamic and result-oriented Clinical Research Professional with M.S. in Natural and Biomedical Sciences currently managing and driving various Clinical Projects at a biomedical research organization devoted to Huntington's Disease - a neurodegenerative disease
- Highly dedicated and enthusiastic professional with hands-on experience managing and supporting multiple clinical studies/trials, simultaneously

## AREA OF EXPERTISE/TECHNICAL SKILLS

Project Management| Strategic Planning| Vendor Management| Project Cost & Integration Management| Task Management & Delegation| Clinical Study Coordination| Safety & Quality Control| Document Management| Clinical Operations| Regulatory Compliance| GCP| Study Site Management| Site Performance Monitoring| Repository Management| Data Analysis| Risk Assessment/ Management| Study Budget Planning & Contracts| Process Improvement| Neuroscience| MRI Analysis| Oncology| Clinical Immunology | Molecular & Cellular Biology

## RELEVANT PROFESSIONAL EXPERIENCE

**CHDI MANAGEMENT INC.| PLATFORM TEAM, CLINICAL RESEARCH** **Oct'18 – Present**

**Regional Manager, Global Registry Study**

- In charge of 70+ sites across North America and Australasia (a total of 40% of active study sites); oversight of regional site management and monitoring– including study clinical operations, site recruitment, performance, ethics submission, and enhancing sponsor-investigator relationship for other platform studies in the region
- Initiated the site performance evaluation project and developed a training plan for the underperforming sites
- Devised staff training plans and bridged the gap to enhance engagement between the internal Site Managers and CRO Monitors; Prepared site assignments, implemented transition plans and task delegation workflows
- Enhanced existing risk mitigation strategies at various study sites and suggested process improvements by implementing CAPA plan under the direct supervision of COO
- Support company sponsored clinical study/projects; collaborate cross-functionally for clinical study start to finish planning and management (including site feasibility/selection, logistics, budgeting, ICF development and negotiations, data clean-up and biorepository management)
- Deliver high-level recommendations to the core global team with strategies to improve efficiency and streamline processes
- Collaborate with external partnerships team to identify and develop accelerated strategies for clinical programs along with providing project and budget planning for multiple clinical projects
- Work with science directors, offices of CLO and CFO for MRO, CRO, and third-party vendor budgets/contracts
- As an SME, oversee purchasing and management of licenses/contracts for assessment and coding dictionaries; support study teams in obtaining global life sciences insurance coverage along with admitted local country specific policies
- Independently, handled negotiations with license vendors and introduced a new licensing policy for studies in start-up, and saved 30% of annual expenses related to licensing (clinical assessments and coding dictionaries)

**CHDI MANAGEMENT INC.| PLATFORM TEAM, CLINICAL RESEARCH** **Apr'16 – Oct'18**

**Clinical Research Program Manager**

- Served as a Site Manager and supported study sites remotely; coordinated with sites to ensure that studies are conducted in accordance with existing CTAs; monitored in-house EDC activity, payments and clinical workflows
- Designed and implemented SOPs and study process guidelines in accordance with GCP guidelines
- Managed licensor/vendor and executed clinical site contracts, including drafting SOW, supplement execution, amendments, renewals, and tracking of licenses; managed consultant contracts and service agreement for CRO
- Tracked consultant and vendor activities, including billing, invoicing, analyzing price proposals, progress reports, reconciliations, and process payment workflows
- Amended process documents including protocols, CRFs, study manuals, ICFs/translations, monitoring plans, communication plans, tracking tools, and other project tools
- Achieved 5-star rating during the annual performance review cycle, usually awarded to top 5% company employees

**ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI| GENOMICS CORE FACILITY** **Nov'15 – Apr'16**
**Clinical Associate Researcher**

- Worked in a high-throughput setting in genomics and assisted with method development on NGS platforms
- Gained hands-on experience in working with clinical and research samples in CLIA lab setting; library preparation and sequencing
- Assumed project manager responsibilities for four months to fill in the void and oversaw documentation and managed the progress of experiments using LIMS & JIRA (including workflow and issue management)

**UNIVERSITY NEUROLOGY, INC.| BUFFALO NEUROIMAGING ANALYSIS CENTER** **Sep'14 – Oct'15**
**Clinical Trial Project Coordinator/Investigator Initiated Study Trial Manager**

- Coordinated Multiple Sclerosis (MS) post-market drugs based medical research and investigator-initiated trials funded by various pharmaceutical companies
- Designed and developed key clinical trial documents, operational SOPs, and guidelines for trials
- Liaised sponsor/investigator obligations and ensured compliance with local, FDA and ICH guidelines
- Managed overall study conduct and regulatory/IRB submissions (initial approval, continuing review, amendments), event reporting, along with obtaining informed consents & HIPAA authorization
- Supported study feasibility activities and maintenance of investigator site file and trial master file
- Independently, managed MRI scheduling, biosample shipping and clinical data entry
- Maintained source documentation and regulatory documentation

**UNIVERSITY NEUROLOGY, INC.| BUFFALO NEUROIMAGING ANALYSIS CENTER** **Sep'14 – Aug'15**
**Research Assistant**

**Thesis:** *Interaction effect between physical activity and groups of BDNF genotypes on brain atrophy in multiple sclerosis*

- Analyzed 3D High Resolution (HIRES) T1-WI using fast spoiled gradient echo (FSPGR) with magnetization-prepared inversion recovery (IR) pulse scan using FreeSurfer imaging software
- Completed statistical analysis for test data from the images to look for correlation with physical activity data

**ROSWELL PARK CANCER INSTITUTE| DEPARTMENT OF MOLECULAR & CELLULAR BIOLOGY** **Aug'13 – Sep'14**
**Research Assistant**

- Analyzed effect of f-PSA internalization and immobilized f-PSA on angiogenic factors signifying the presence of PSA specific ligand on the cell surface
- Executed *in vitro* assays showing PSA mediated inhibition of endothelial cell proliferation, migration, invasion

**ROSWELL PARK CANCER INSTITUTE| DEPARTMENT OF IMMUNOLOGY** **Jan'12 – May'13**
**Research Assistant Nov'12 – May'13| Research Intern Jan'12 – May'12**

Rotation Project: Effects of housing temperature on immunosuppression in tumor microenvironment

- Conducted experiments on lab mice to examine tumor growth at thermoneutral temperatures while using breast cancer-4T1 murine model and validated slower tumor growth supporting the hypothesis

Research Internship: Performed isolation of mouse bone marrow along with RNA isolation, RT-PCR/qPCR analysis, and flow cytometry for a project to illustrate down-regulation of IRF-8 by tumor-derived GM-CSF

**TRINITY BIOTECH USA INC., JAMESTOWN, NY| RESEARCH & DEVELOPMENT DEPARTMENT** **May'11 – Aug'11**
**Product Development Intern**

Project*: ELISA for detection of HSV-2 specific IgM antibodies to glycoprotein G (gG-2)*

- Orchestrated a joint effort with internal product development and bioprocessing departments for the production of Enzyme Immunoassay (EIA) products/kits

## EDUCATION

**University at Buffalo, State University of New York| Roswell Park Cancer Institute** **Sep 2015**
Master of Science – Interdisciplinary in Natural Sciences: Natural & Biomedical Sciences

**University at Buffalo, State University of New York| School of Medicine and Biomedical Sciences** **Jun 2012**
Bachelor of Science – Biotechnology