# EDUCATION

**Duke University** - Durham, NC December 2015

Master of Engineering in Biomedical Engineering *Cardiac and Neuroengineering*

**University of Rochester** - Rochester, NY May 2014

Bachelor of Science in Biomedical Engineering *Biosignal and Control Systems*

# SKILLS

**Research and Development:**

Real-World Evidence, Clinical Research, Preclinical Research, Experienced in cardiovascular diseases, chronic pain, movement disorders, neurological disorders, and oncology, Competitive Landscape Analysis, Market Assessments, Patentability Research, Design of Experiments, Delivering Class I to Class III products, IP disclosure, Literature Review, DRM, FMEA, Systems Engineering, Technical Reports, Publications and Presentations, Translational Research, Design Verification and Validation, ICH-GCP, FDA guidelines, EMEA Regulations

**Analysis & Modeling**:

Big Data Analysis, Monte Carlo Analysis, Physiological Signal Acquisition and Processing, Computational Modeling (physiological), Finite Element Modeling, Circuitry Modeling

**Software Knowledge**:

Python, MATLAB, Power BI, MS Office Suite, Prism, Minitab, Stata, R, Crystal Ball, Excel, PowerLab, NEURON, PSPICE, ImageJ, LabView, OrCAD PSpice, Mathematica, Simulink, WorkBench, COMSOL, ANSYS

# PROFESSIONAL EXPERIENCE

**AtriCure Hybrid, United States**

**Manager, Real-World Evidence** Aug 2021 - Present

* + Leading a portfolio of studies that supplies real-world data (RWD)/evidence (RWE) for regulatory submissions, health economic and outcomes research (HEOR) analysis, publications, clinical evidence generation, and other business needs
  + Leading program level strategy, road map, budget, resource planning, and timelines to ensure alignment with business, patient, and physician needs
  + Identifying and managing key project and program level milestones, dependencies, risks and risk mitigations
  + Managing escalated study/project issues and reviewing monitoring reports
  + Established study and data analysis planning and progress tracking tools and dashboards to share progress with cross functional teams
  + Providing regular updates and projections to senior managements
  + Identifying and leading continuous improvements to increase efficiency and to decrease cost
  + Managing direct and dotted-line reports to assign responsibilities, providing feedback on performance, and to aid career growth
  + Identifying and creating recommendations for new opportunities to improve study design, and to reduce submission cost and timeline
  + Overseeing the design, creation, testing and continuous improvement of the data capture tools
  + Conducting data analytics to support internal and external studies and analysis projects
  + Established three study protocols, study reports, monitoring plans, seven case report forms (including database and ePRO) and CRF completion guidelines, seven informed consent forms, and other study documents per local regulations
  + Established 40 policies/SOPs and work instructions to ensure compliance and alignment with US and international clinical study regulations
  + Managing vendor selection strategy, RFP, study and vendor budget, conduct, deliverables, and performance monitoring, including but not limited to CROs, consultants, data and statistical analysis vendors
  + Leading the operational aspects of the studies throughout all stages, including the country selection, site selection, contract negotiation, site start-up, rate of recruitment scenario modeling, close-out and enrollment activities across the portfolio of studies
  + Established and managing steering committees, KOL and investigator engagements meetings
  + Collaborate closely with cross functional departments including quality, legal, safety, marketing, health economics, data management, and regulatory affairs to incorporate business needs into study design

**ICON Remote, United States**

**Clinical Scientist**, on Assignment with **Merck**, **Oncology** Feb 2021 – Aug 2021

* + Managed two large phase II&III clinical study’s primary endpoint data while providing support for three additional studies’ endpoint data management
  + Led the medical monitoring team in performing medical Monitoring activities across sites in all continents (US, EU, APAC, Canada, SA)
  + Served as a clinical and a scientific point of contact for external vendors, PIs, site personals, and cross-functional clinical trial team
  + Mentored and training other clinical trial members to boost efficiency and effectiveness for achieving high quality study data
  + Managed vendor data and providing guidelines on study and sponsor needs
  + Monitored endpoints, AEs/SAEs, protocol deviations, and other internal as well as external key study data that requiring clinical input
  + Shared study and safety related data at investigator meetings and to senior management
  + Facilitated/coordinated data review, database lock (interim and final data analysis) planning and activities, study enrollment and progress tracking, study close-out activities, protocol amendments, medical monitoring plan amendments and other study specific documents

**Abbott Twin Cities, MN**

**Clinical Scientist II**, Structural Heart May 2020 – Feb 2021

* + Managed and designed four international clinical studies and a registry (including endpoints, duration, IC/EC criteria and size) to fulfill pre- and post-market regulations for class I-III devices
  + Constructed clinical investigation plans and amendments, financial memo, study timeline, medical monitoring plans, study reports, DSMB report, PMA report, and other study related documents (e.g. ICF, IB, etc.) as well as study progress related updates to management and sites
  + Collaborated with marketing, regulatory, and engineering to ensure study design and endpoint data meet diverse needs
  + Collaborated with biostatisticians on sample size estimation, data analysis, periodic report generation and final submission data organization.
  + Managed and monitored AE and SAE reports, endpoints data, core lab reports, database lock and snap shot activities, data discrepancies, protocol deviations, all-cause mortalities
  + Served as scientist lead and authoring communication letters to external regulatory bodies and competent authorities (NMPA, FDA, BSI, EC, IRB etc.), sites, PIs, and internal stakeholders
  + Managed and supported adjudication committees, DMC, KOL, EC, DSMB, CER generation, IFU generation, and publication planning
  + Provided scientific input and review to study related documents, such as CRFs, IC, and DRP

**Medtronic Twin Cities, MN**

**Senior Scientist**, Neuromodulation July 2018 – May 2020

**Study Design and Execution**

* Designed and managed four clinical and weekly preclinical feasibility studies to improve, generate and refine novel design concepts and to conduct device performance evaluation
* Provided training and generated training material to sites, PIs, and FCEs
* Managed steering committee meetings and incorporated feedback into study design, device design, and publication plan
* Trained field engineers on the usage of new device and the programming process
* Managed site activation timeline, enrollment rate, data analysis timeline, and study budget
* Managed and aided study start-up, site evaluation, site selection, and site activation
* Generated three clinical study proposals, protocols, protocol amendments, Informed consent forms, case report forms and quarterly study reports
* Managed clinical data collection plan, external imaging data, data collection, database lock, safety events, and protocol deviations
* Generated quarterly reports and newsletter to report on study progress, SAE, and learning
* Served as scientist point of contact for PI, KOL and regulatory communications
* Constructed study related materials to support conference, publication, and marketing needs
* Led quality study design and essential clinical evidence collection by collaborating with cross functional teams (Sale, Marketing, Systems Eng., Firmware, Software, biometric, Regulatory)
* Led clinical, preclinical and bench data collection activities by identifying design refinement needs, premarket clinical study needs, and global regulatory submission strategy needs
* Designed and tested visualization software applications to support efficient review of collected clinical evidence (saved 2 to 4 hours per patient depending on application)
* Provided strategic directions by translating learnings from bench and preclinical experiments into novel clinical evidence collection strategy to validate learnings and to improve design

**Strategic Roadmap**

* Identified and evaluating new technologies, design needs and knowledge gaps, and planning preclinical studies, clinical feasibility studies and bench experiments to address them
* Routinely disclosed ideas (>5 per quarter), filing patent applications and refining novel design concept ideas to improve future device functionality and to ensure competitive advantage
* Assessed competitive landscape and keeping up with recent breakthroughs by conducting weekly scientific literature searches and by attending scientific conferences
* Proactively provided strategic recommendations and transferring knowledge of competitive scientific landscape to peers, senior management, development teams, and business units

**Therapy and Technical Expertise**

* Serving as scientific lead to share technical learnings, to identify technical risks and to advise on strategic planning for future commercial products through cross functional team meetings, reports, presentations, and conference publications
* Providing strategic and technical input to aid clinical evidence strategy and clinical trial design, risk analysis and claim generation
* Serving as therapy expert to educate physicians, primary investigators (PI) and senior leadership on next-generation design concepts
* Collaborating with key opinion leaders (KOLs) and with field advisory board, generated conference publication and white papers
* Mentored two individuals on physiological modeling projects, and trained 7 individuals on electrophysiological data collection

**Medtronic Twin Cities, MN**

**Scientist**, Neuromodulation May 2017 - July 2018

**Study Design and Execution**

* + Authored and led a cross-site cross-functional algorithm feasibility study to completion
  + Proposed new concepts and design improvements, and led the planning effort for two Insilco modeling research projects as a technical lead

**Product Development and Technical Expertise**

* + Invented, improved and facilitated patent application for two novel designs used as differentiable feature for next generation Class II and Class III devices
  + Led technology and knowledge transfer activities for three differentiable Class II and Class III device design features, and guided formal software, model and equipment verification and validation activity to enable commercialization within 16 months
  + Constructed two physiological models to enable novel MRI testing and reduce testing burden
  + Conducted statistical analysis to improve MRI testing strategy for unintended stimulation by utilizing data from clinical data registry

**Regulatory Submission**

* + Led scientific argument for a class III device’s global regulatory submission strategy with a non-clinical trial strategy
  + Served as subject matter expert and provided modeling evidence to support substantial equivalence argument without a clinical study for a class III device’s global pre-submission

**Medtronic Twin Cities, MN**

**Systems Engineer**, Neuromodulation January 2016 - May 2017

* Led cross-functional teams (HW, FW, Software, Marketing, Clinical, Regulatory, Risk and Reliability, Medical Safety) to finalize design decisions, to refine scope, and to resolve issues
* Constructed and improved computational models to better define design space, to decrease design cost, to increase design efficiency, and to translate design input information into system and product level requirements for the next generation DBS products
* Conducted product evaluation and root cause analysis to resolve issues and evaluate trade offs
* Constructed over 50 system requirements and design rationales for four development projects
* Conducted Pugh matrix analyses, Monte Carlo analyses, literature searches, statistical patient and clinical surveillance data registry analyses, FMEA, bench and animal testing, and Activity diagramming to guide the design decision process, to efficiently down select design concepts, and to generate meaningful innovative designs

**Boston Scientific Twin Cities, MN**

**R&D Intern**, NeuromodulationMay 2015 - August 2015

* Designed and conducted five exploratory preclinical experiments using IPGs and PowerLab
* Provided insights into design requirements by analyzing 60GB of physiological signal
* Communicated results and findings through multiple presentations to more than 50 colleagues and senior management within the Neuromodulation and Cardiac Rhythm management division
* Coached another intern regarding conduction of exploratory stimulation study

# LEADERSHIP AND VOLUNTEER EXPERIENCE

**Medtronic** April 2017 – May 2020

Women in Science and Engineering (WISE) Site Leader

Asian Impact at Medtronic (AIM) Talent Pillar Co-chair

* Launched Onboarding Program and recruited transition partners to aid new hires’ transition
* Organized and supported six volunteering, lunch and learn, and outreach events
* Hosting biweekly planning meetings to assess progress, challenges and to brainstorm ideas

**Duke University** September 2014 - May 2015

Peer Engagement Chair, International Involvement Co-chair

* Organized events to encourage communication and networking among engineering professionals
* Provided opportunities for MEng students to increase cultural awareness and cultural sharing

# PATENTS & PUBLICATIONS & CERTIFICATIONS

* Publication: Using a Computational Model for the Auditory Midbrain to Explore the Neural Representation of Vowels, Laural H. Carney, Jiashu Li, Tianhao Li, and Joyce McDonough, June 2013
* Publication: SOX9 is an Astrocyte-Specific Nuclear Marker, Wei Sun, Adam Cornwell, Jiashu Li, M. Joana Osorio, Dadia Aalling, Su Wang, Abdellatif Benraiss, Nanhong Lou, Steven Goldman, and Maiken Nedergaard, Journal of Neuroscience, 2017
* Abstract: Volume of Neural Activation Modeling Utilized to Evaluate Clinically Relevant DBS Unintended Stimulation Induced by MRI Interaction, Jiashu Li, Riki Banerjee, Neuromodulation: The Science, 2018
* Patent: Stimulation Lead with Electrodes Configured for Sensing and Stimulation over a partial Circumference, US16/862,732, Issued Nov 4, 2021
* Patent: Identification of Orientation of Implanted Lead, EP20719284.0, Issued Mar 19, 2020
* Implantable Lead Migration Monitoring Using ECAP, US16/988,144, Filed Feb11,2022
* Certification: NLP with Python for Machine Learning Essential Training, Certification Number: ARJ-KFM3VV5R8Nl1tgu1vmm2rn1X
* Certification: Change Management: Roadmap to Planning, Certification Number: AS8XHaS9yG5swY\_BJYjZF2ljy4bD