Joy Hsu

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EDUCATION & CERTIFICATION

Columbia University, Mailman School of Public Health **2018 – 2020**
M.S. Biostatistics, Pharmaceutical Statistics Track

University of California, Davis **2009 – 2013**
B.S. Biological Sciences, Emphasis in Neurobiology, Physiology & Behavior

CCRP Certification, Society of Clinical Research Associates (SOCRA) **2016**

EXPERTISE

- Statistical Analysis and Programming in R
- Methodology for Drug Phase II-III Clinical Trials and Medical Device Studies.
- Application of ICH-GCP, US Code of Federal Regulations, HIPAA, and PIPEDA for clinical studies in US and Canada
- Knowledge of Medical Device IDE Submission, 510k and Premarket Application [PMA] pathways

EXPERIENCE

Clinical Research Associate II **June 2017 – Aug 2018**
Grifols Diagnostic Solutions **San Diego, CA**

- Responsible for implementation of diagnostic device studies for blood donor screening of infectious agents, across 4 major US laboratories sites. Oversight include staff training, regulatory submissions, supply logistics.
- Develop methods for data cleaning and verification of protocol compliance, to ensure clinical study was conducted in a manner that supports the planned statistical analysis.
- Investigate integrity of data processing workflow and introduce mitigation steps for high impact risks.
- Collaborate with engineering team for instrument performance root cause analyses.
- Collate datasets on case profiles for FDA infectious disease surveillance.
- Perform QC review and source data verification for Clinical Study Report submissions.
- Work with vendors on builds for electronic database, CRF design, and perform UAT Testing.

Clinical Monitoring Associate **Jan 2016 – June 2017**
PAREXEL International **San Diego, CA**

- Site monitor for Phase II-III clinical trials, therapeutic indications in Oncology, Cardiovascular, and CNS trials.
- Regular data verification to identify queries, track study progress and adherence to protocol.
- Oversight include subject visits, adverse event reporting, recruitment targets, IRB submissions, ICF negotiations, staff training.
- Conduct feasibility and site selection assessments, collating data for site usability reviews.

Clinical Trials Associate (contracted partner of AMGEN) **July 2014 – Jan 2016**
QuintilesIMS (IQVIA) **San Diego, CA**

- Feasibility, site selection, study start-up, and close-out responsibilities for Phase II-III clinical trials.
- Systems integration of enrolling study for new drug acquisition. Strategize with outgoing CRO and outgoing sponsor to transfer responsibilities, migrate study data and documentation.
- Collaborate with IRB & Biosafety Committee to compile regulatory submissions for oncolytic virus study.
- Leadership - Lead CTA across 4 studies for Sponsor deliverables. Develop training material for new hires.

Research Assistant, Pathogen Detection Laboratory **Aug 2012 – Dec 2013**
California National Primate Research Center **Davis, CA**

- Research project on the development of a confirmatory test for the diagnosis of Herpes B Virus infection in Rhesus Macaques. Coupled carboxylated microspheres and viral lysate to design a flow cytometry immunoassay based on the Luminex xMAP system. Optimized immunoassay conjugation and reagent consumption for integration into a multiplex assay. Validation of immunoassay demonstrated improved specificity and sensitivity, as compared to current diagnostic standards using surrogate glycoprotein markers. Evaluate Western Blots for serodiagnosis of B Virus infections and cross-reactivity.

Patient Case Manager, Connected Clinic **April 2013 – Dec 2013**
UC Davis Medical Center **Sacramento, CA**

- Supported clinic's activities to provide prenatal and postnatal care to women with psychiatric disorders.
- Conducted patient follow-ups, relayed patient communications to the psychiatrist, delivered Edinburgh Postnatal Depression Scale paper questionnaires, and participated in debriefing meetings with clinic staff.

Intern, Cardiac Rehabilitation Program **Sept 2013 – Dec 2013**
UC Davis Medical Center **Sacramento, CA**

- Collect biometric measurements during patient rehabilitation sessions. Support clinic physiologist with assessments during Exercise Tolerance Tests.

Analytical Laboratory Assistant **Oct 2010 – Feb 2011**
Arcadia Biosciences **Davis, CA**

- Conduct experiments and collected data for developmental trials for GLA Safflower Oil and Nitrogen Use Efficient Crops projects. Perform oil oxidation analysis to assess product stability.